PhD degree in "Foundations and Ethics of the Life Sciences"

European School of Molecular Medicine (SEMM) and University of Milan

Faculty of Medicine

Settore disciplinare: M-FIL/02

PROPERTY *REDUX*. OWNERSHIP OF HUMAN TISSUE AND THE GOVERNANCE OF POST-GENOMIC RESEARCH BIOBANKS

Bettina Schmietow

IFOM-IEO Campus, Milan

Matricola n. R08920

Supervisor: Dr. Matteo Mameli

IFOM-IEO Campus, Milan

Anno accademico 2012-2013

Abstract

Biobank-based genomic research is considered instrumental to realize Personalised Medicine and considerable benefits for diagnosis and therapy of many common complex diseases. It raises manifold ethical and regulatory challenges which are discussed extensively, the main focus being on adaptations of Informed Consent to the emerging research context. This study highlights challenges to the strongly individualistic focus of classical research ethics in confrontation with biobank development. The debate on adequate protections for individual donor-participants tends towards deflationary accounts of participant rights, in which in particular the dimension of potential property in human tissue and genomic information is undervalued. Criticizing the common bioethical and legal stance that there can and should be no property in the human body and its parts, the close conceptual connections between privacy, property and consent underlying the protection of a more substantive version of participant integrity are emphasized. While ultimately the framework of traditional, in particular individual property rights is ill-suited to safeguard participant and public interests in research, property discourse is fundamental to advance discussion on the direction biobank ethics and governance should take by 1) taking serious the reordering of individual, group and societal interests in biobank research, 2) clarifying strength and limits of claims to “autonomy” and 3) refocusing to public or common goods biobank research should provide. These foundational insights are applied to an emerging normative model beneath biobank governance in which implications for the future role of consent and participant involvement in large-scale digitalized research projects are outlined.

Acknowledgements

I would like to thank everyone who makes the FOLSATEC PhD Programme possible, and the IFOM-IEO research campus in Milan such an enjoyable and inspiring place to work on an everyday-basis, especially Giovanni Boniolo, Matteo Mameli, Giuseppe Testa, and, of course, all my great fellow students.

For external advice I am indebted to Christian Lenk in Ulm, as well as to Jane Kaye and her colleagues at the Centre for Health, Law and Emerging Technologies in Oxford, where I spent most of last spring and summer, for the opportunity to advance some of the ideas in this thesis, and their hospitality.

Last but not least, thanks to my family and friends, for their continued support, love, and understanding.

Contents

Introduction

This thesis focuses on a major development in recent biomedicine and its ethical implications, the spreading of biobanks for genomic research, which is considered a key enabling factor in the movement to Personalised Medicine. While collections of human tissue for research purposes have existed for centuries, these new biobanks have particular features both in the way they are organized and in the ethical and regulatory issues raised by the involvement of large populations of donors that provide tissue samples.

In many ways, biobanks are a crossroad of developments in biomedicine and more general technological and social developments towards research on massive digitalized datasets, ever-faster sequencing and better technologies to map and understand the interaction of genetic and non-genetic factors in the constitution of health and disease of individuals.

Not the least, biobanks, as the term suggests, have drawn a lot of attention in academic, in particular bioethical discourse because they have particular institutional and organizational characteristics which show indeed similarities to corporate entities in terms of banks and accounts, and include intricate governance structures. Biobanks are emblematic of the bioeconomy, and the results – a better understanding of the factors that contribute to common complex diseases – are anticipated to be necessary to maintain public health in times of shrinking resources of publicly maintained healthcare systems.

Indeed a main peculiarity of biobanks from the ethical point of view is their hybrid nature between often publicly initiated and supported public health research resources and the envisioned networking with the databases of public health care systems, new data collections established in the course of research, as well private actors and pharmaceutical companies. While the biobanks I will focus on in this study do not in the traditional sense

deal in human tissue and genomic data, it is within the philosophy underpinning biobank research that they are neither a clear-cut public healthcare intervention or project. At the same time, promises of public benefits in terms of better diagnostic tools and therapies in the future are very important as part of the public promotion of this new form of research.

The ethical discussion has taken up this politically informed stance on the matter for the most part only indirectly, and an important thread in the literature has advocated a new age of bioethics that would be particularly exemplified in genomics, and by extension within biobanks and genetic databases: the age of *genetic solidarity and new forms of altruism* and *benefit-sharing* that would overcome a presumed overemphasis on individual and merely private interests of tissue donors and research participants – in particular the strong bioethical focus on respect for individual autonomy in all matters healthcare and research, which should prevail over the interests of science and society.

Differently from many authors in this debate, I disagree that there can be an easy transition to a new age of genetic solidarity and altruism with the implementation of large-scale genomic research projects. Indeed this thesis is designed to contribute towards the elucidation of some of the theoretical issues that are intersecting here: from the focus on individual rights of moral integrity and autonomy to private *interests*, sustained by indirect social pressures suggesting that in particular *rights to genetic privacy* might have to be limited to reach the high-staked aims of the new public health.

Genomics covers a vast part of traditional topics of bioethics and its key concepts, and so some selection has to ensue. In the mainstream debate, there are two contrasting positions in the quest to deal with biobank research. On the one hand, donation of bodily material and participation in research is conceptualized around *Informed Consent*. However, as will be analyzed in more detail below, the concept of consent and the context for which it was designed fits rather poorly with the large-scale, data-intensive research we are facing

today, and can be anticipated to be facing in the future. This has many reasons, the main ones centring around the supra-individualistic nature of genetic/ genomic information vs. the concepts of classical health research ethics centring on individuals, and the structural and institutional features of this research which do not allow for a simple picture of research benefitting 'the public'. Indeed the ethics of biobanks is closely tied to the general incorporation of governance approaches into bioethical matters. By governance I will mean multi-faceted and often informal approaches to conceptualize, order and influence human behavior that differ in their complexity from regulation and law. Instead, they encompass soft law, guidelines, the expertise of advisory boards and policy fora, of professional values and trends in general culture. This development is closely related to the fragmentation of science policy as top-down state imposed in an effort to enable research in an international and global context (cf. European Commission 2012[1]). The move to governance is fraught with ambiguities that I hope will also become apparent in what follows, since it introduces a political element into bioethical discourse, and at the same time denotes a technocracy, in which ethical issues and decision-making are distanced from the public and devolved to experts (cf. Gottweis and Lauss 2010).

For the present study, this should imply clearly that neither individualistic ethics – as more appropriate for the clinical contexts and traditional clinical trials – nor public health ethics – being traditionally concerned with issues such as epidemic control – provide straightforwardly the conceptual resources to deal with the limitations of making ethical choices in the face of genomic research. Instead, I propose here a piece-meal transformation of part of this debate using sources that have been largely disregarded in bioethical discourse. In particular, I argue that the debate on donor recruitment and research participation has not only prematurely moved to an over-individualistic approach

[1] European Commission. EUR 25302. 2012. Biobanks for Europe: A Challenge for Governance. Report of the Expert Group on Dealing with Ethical and Regulatory Challenges of International Biobank Research.

– and therefore actually shows paternalistic features within the sheepskin of enhancing 'autonomy'– but thereby has more or less explicitly turned the classic order of priority of research ethics on its head, without, however, adequate consultation of the public itself. At the same time, social dimensions and long-term effects of implementing new research agendas tend to be neglected by downplaying the dis-analogies between traditional clinical context research and globalized genomics. The result is that though there is extensive debate on ethics in terms of consent, not much of its ethical force seems to be left, while controversial aspects are transferred to a technocracy-oriented reasoning in terms of governance. In this approach, the language of rights to autonomy, privacy and – perhaps – property in tissue for research is devalued, and instead less stringent moral *interests*[2] are "balanced" and efficiency of research trumps more communally oriented decision-making about future technology scenarios and its impact on healthcare.

If, then, biobank research represents an innovative form of research, i.e. it simultaneously represents a new kind of 'ethical subject' and social institution in the making (cf. Cordell 2011), and the transformation of public *and* private sector research is crucial to this development, it would seem to follow that the ownership of the resources involved is the central issue of controversy. Indeed Knoppers and Sallée have stated explicitly that the ultimate issue of contention is the ownership *of DNA*, in particular in an increasingly commercialized environment (cf. Bauer et al. 2004). Yet, most guidelines as well as the bioethical debate avoid mentioning and discussing the problem in more detail (cf. Kaye et al. 2004). Nonetheless, new forms of informal property conceptualizations and arrangements are proposed, focusing in particular on shared, 'public' goods, the genome as a 'common heritage of mankind' and appeals to 'benefit-sharing' of the results of genomics (Kaye et al. 2004; Knoppers and Sallée 2005; Ossorio 2007).

[2] This development has been documented in the analysis of recent ethical guidelines for genomic research by Elger 2010.

The transition to Personalised Medicine presupposes that ideally, most sections of the population, at least in the wealthy and technologically advanced states, provide a 'piece of themselves', the information that it contains, and preferably some additional health-related information to such a research project. Before there will be Personalised Medicine, we have to be altruistic, and participate in research for the common good. According to some, we seem indeed to have a stringent moral duty to lay open our 'body bank account'[3].

Or do we? Do I 'own' the minute snippets of my body that are required here, and what does that mean? Who, if anybody, has the ultimate control over these parts and the information they contain, which has now risen to new importance – from waste to, at least potentially, a 'future diary'[4] (Annas 1993) and, sometimes, a valuable market asset?

Although the topic of ownership of DNA and genetic information has public appeal –or at least, some aspects of it, such as the 'patenting of life' and concerns about the 'commodification' of embryonic tissue for instance in stem cell research – its ethical relevance and implications remain opaque. Here, my aim is to bring the issue of the *moral* importance of claims over human tissue for research that fall squarely within the conceptual domain of property and ownership into closer connection with the mainstream of bioethics. I argue that this is necessary in the interest of an ethics that reflects factual developments situated in real social and political contexts, and because of the conceptual and ethical importance of the issue. Property is important, because in biobank ethics control and decision powers over bodily material and its informational content is a primary and deeply normatively charged problem. This is the larger thesis I try to ground and plausibilize. The issue of informed consent to 'authorize' research will remain vital, but an

[3] In 2009, biobanks were named as one of '10 ideas changing the world right now', using the metaphor I reframe here (TIME 2009).

exclusive focus on it has led to distortions and misrepresentations which are not defensible, if not for a narrow idea of donor-participant welfare and the risks involved in genomics.

As the domain of property is vast, I cannot hope to answer the question in its fullness. Instead, I will concentrate on the individuals that donate or participate in a project and that in the following will be sometimes called the 'supply side' to emphasis the transactional and economic character the phenomenon studied here expresses. I argue that very plausibly, the requirement of consent, and the priority of the person and her subjectivity in research ethics, requires the acknowledgement of a moral 'ownership' of bodily material that remains connections to this subjectivity, and this is the case with DNA samples and tissues used for genomic biobanking. The transfer of tissues into a vaguely defined sphere of 'common property' and 'public good', on the other hand, is ambivalent and weak, specifically in combination with a focus on consent which, by necessity, would seem to imply a moral primacy of individual human rights. This latter claim is analytically independent from, for example, problems of intellectual property and patents on genetic sequences and research products involving larger issues in innovation policies which cannot be dealt with here in detail. I emphasize, however, that the issue of moral property in human tissue cannot strictly separate claims on tissue as *material* from claims on *information and data*, because the morally legitimate claims span both spheres.

I also call, as a consequence, for a recovering of the material basis of genomics, and that means the basis of research in the parts of human *persons and their bodies*. There is a tendency to consider the moral interests of participants merely in informational terms, as what might be termed 'data persons'. Data persons or data resources, indeed, have limited moral interests in research, and risks of research can be technologically managed. Perhaps these risks are actually so low as to appear negligible, and therefore consent or other ethical safeguards are not necessary. This is a view that I criticize as morally unstable. It is

not well grounded, because the requirement of consent is based on a more comprehensive picture of rights and interests than many authors in recent biobank ethics suggest.

Having recovered firmer ground of the requirement of consent by an analysis in terms of property, autonomy and control, we must ask how a moral ownership of tissue might fit within the traditional requirements of research ethics and the practical limitations of research in large-scale digitalized environments. Indeed one reason for the disregard of property seems to be that it is not easily translatable into the conceptual categories of law. Moral ownership 'rights', however, do not need to include alienability and therefore commodifiability of tissue. I argue that this line of reasoning, compatible with the human rights and liberal foundations of the traditional account and also the new research context, suggests that we should rather foster possibilities of donors to become engaged research participants in the sense of a co-ownership of genomic resources. Importantly, individuals *should* be engaged in genomics in a coherent picture of Personalised Medicine as a not merely technocratic imposition, in which the promise of future health care benefits must foreclose the privacy and moral property rights of current and middle-term publics. New forms of 'dynamicizing' consent and patient engagement could be a remedy to this effect if they reach populations in a more commensurate form to the research undertaken.

The proposed argument proceeds as follows.

Chapter 1 provides background on the sociological, political and scientific framing in which biobanks have become a focus for ethical debates. I introduce a working definition for the type of research that shall be investigated, outline some features of the movement of Personalised Medicine and how biobanks are promoted as instrumental towards the fulfillment of its promises, and draw attention to some peculiar features that likely will become even more important in the future. Notwithstanding these, some of which plainly are ethically worrisome, I suggest that the response of policy has been insufficient in

realizing the scope and depth of challenges involved, and produced conflicting and unconcerted guidance.

In *Chapter 2*, I aim at analyzing in more detail the sources of this incomplete and partly inadequate response, and for this purpose move to the level of the moral concepts and principles that traditionally guide reflection in research ethics. I propose to approach the issue from three main conceptual pillars of this framework: the universal requirement of informed consent in healthcare and biomedical research, the protection of confidentiality and privacy of the individual, and an overarching ideal of non-commercialization and altruistic donation of human bodily material for therapy and research. As concerns consent, it can be shown that there have been many attempts to fit the traditional doctrine into the biobank context. I argue that many of these are primarily pragmatically oriented and inspired by utilitarian ethics, and that they misrepresent the requirements of autonomy one-dimensionally and skewed towards a liberistic choice-model.

Though I suggest that this is morally inadequate, I do not advocate stricter consent requirements, but instead emphasize that framing all the moral issues in terms of providing information to participants is misleading and unhelpful, in particular in contexts in which epistemic insecurity is by definition high. Following the diagnosis that the meaning and value of individual autonomy in a general and traditional form is of very limited use taking account of the context of genomics, I sketch some of the challenges to the protection of privacy for research participants and donors, which intersect with the protection of autonomy *and* moral integrity via consent. The last section of the chapter focuses on the relevance of the appeals to altruism and non-commercialization, originating from transplantation medicine, but that nonetheless exert an ambivalent influence in the ethics of biobanks with the advent of increasingly commercialized research environments.

Chapter 3 is the heart of the contribution this work aims to achieve. I propose to extend and complement the assessment of the limitations to the traditional approach with a discussion of participant interests and rights in terms of property and ownership. To this end, I provide a preliminary cartography of the place of the issue in the conceptual domain of property in the *human body*, which is an intricate and persisting problem in both law and philosophy. Answering the question of ownership in the body requires some theory of what property is, and while I do not defend a fully developed theory here, it is suggested that property rights are not 'natural' and stable, the moral implications of which are often not recognized in both legal and philosophical debate. Or rather, legal theorists are sympathetic to constructivist approaches to property rights, but tend to undervalue the moral claims that attach to these rights, or what kinds of moral interests they should actually express. Bioethicists, instead, have settled on an over-general 'no-property rule' – or alternatively a presumed evidence of 'self-ownership' – that both tend to associate property rights exclusively with the topos of commodification and market valorization of an object of property rights.

Again, the *moral* dimension of potential property rights is underexplored. I also show that the philosophical justifications for anti-commercialization policies to human tissue for research are not straightforwardly supported by Kantian considerations of anti-*commodification* of tissue. Kantian concerns, that also feature in the substantive interpretation of the justification for informed consent I defend in Chapter 2, are instead addressed to the moral standing of persons. This is compatible with a gradual model of commercialization – or rather, propertization[5] – and a constructivist approach to property rights. Property rights in tissue and DNA accordingly *could* be designed to serve particular purposes, as some authors such as Donna Dickenson and Graeme Laurie have proposed for

[5] By 'propertization' I will mean the use of notions, metaphors and moral claims associated with 'property' and 'ownership'.

the context of genomics and protection of participant rights. Though it would be theoretically possible to conceptually construct in particular 'control rights' for individuals that confer greater powers to them than the negative ones of consent as authorization and privacy, there are limitations in making these approaches effective. Notwithstanding these complications, the ownership-like interests in tissue are thereby not reducible to mere symbolism, and this implies in conjunction with the weakness of consent and privacy that they have to be accounted for in innovative ways.

Some steps towards such an implementation for biobank governance are discussed in *Chapter 4*. I present the model of a 'tissue trust' that might provide a conceptual space between marketization and strict-anticommercialization approaches in the sense of stewardship. This model is *prima facie* morally neutralizing, while ownership-like rights should help to safeguard possibilities of control, transparency and democratic accountability, in short, moral agency in a liberal and democratic research governance system. The recent approach of a participant-centrism for genomics and tissue research might be employed to this end. Finally, I discuss some criticism of this approach that recalls the ambivalent policies of simultaneously fostering 'autonomy' and detachment of research subjects and tissue donors from larger aims of biomedical inquiry, and consider some possibilities for the future role of informed consent in this context.

A Note on Methodology

This is a thesis in applied, normative philosophy. Its subject is an emerging biomedical and biotechnological development that seems to embody larger transformations in research organization and the ethics of science in democratic societies, and it is because of this transitional nature of the research subject, the biobank, that the study does not easily qualify as bioethics as it has been carved out from the 1960s onwards. In a more traditional

picture of bioethics, principled moral theories can be applied to moral controversy, in particular to issues in clinical medicine and research, particularly clinical trials. Bioethics is therefore indeed infused with the definition and safeguarding of *individual* rights in the face of powerful societal and state agendas.

This picture has changed rather dramatically with genomics, and in the course of the stabilization of a newer field of bioethical inquiry, *public health ethics*. The latter deals with what has typically been public health policies of individual nation states, regarding the organization and responsibilities of these systems towards individuals and the duties of individuals to promote public health in turn.

In my view, a stark opposition between principles that would apply either to the clinical context or the public context – autonomy vs. solidarity, for example – is indefensible with regard to genomics and leads to the academic consolidation of blind spots in ethics and an artificial separation of phenomena. Biobanks as part of international networks and as public-private partnerships do not fit this categorization, and also the interests and rights of participants are not plausibly only individualistic or altruistic.

Property, moreover, is a topic that spans the fields of moral, legal and political theory, and all these fields are relevant for biobank ethics and governance. This is a contention that I hope to convey in this work as of importance even in case the more imminent emphasis is on moral issues. The idea is, while focusing on moral theory and the clarification of theoretical concepts and argumentation, not to lose sight of the real-world constraints of these considerations and the prospects of normative claims to be transformed into policy. The ambition is, in short, the rational clarification, ordering and enlightening of an emerging scientific and social phenomenon, as a philosophical task of moral importance in itself, and also to potentially inform public debate. As for the latter, while biobanking

ethics has from the beginning been cast in terms of governance, this political stance is not reflected in the bioethical debate, which seems often detached from political reality.

To approach the objective of elucidating the conceptual and moral importance of ownership and property claims with respect to biobanks, I have to make use of many resources that fall within the academic scope of law and legal theory, as well as political theory. As concerns law, in the form of in particular soft law and legal commentary, it will be used for mainly illustrative purposes, and not aim to be in any way exhaustive. Though case examples from different jurisdictions are used, the focus is largely on developments of ethics and governance in a European context. By making use of these different resources and in emphasizing scientific and social constraints, I hope that this work, to some extent, can count as an interdisciplinary effort, inspired by the holistic approach of the PhD programme in "Foundations and Ethics of the Life Sciences" in the ambit of which it has been conceptualized.

1. The Promise of Personalised Medicine and the Role of Biobank-Based Research

1.1 The Proliferation of Genomic Biobanks

At least since the completion of the Human Genome project, a new form of genomic research has emerged all around the world. This form of research, the so-called 'banking' of human tissue, is, in a first approximation, the systematic collection of human tissue and associated data to study the interactions of genetic and environmental factors in the aetiology and prevalence of common disease such as cardiovascular disease, cancer, and diabetes.

The sequence of the human genome, the draft of which was completed in 2000, provided the background map, which is combined with a long-term oriented approach of establishing physical and digitalized libraries in which, so the expectation goes, one day we will be able to read the natural history of disease and, in some cases, observe their progression in real-time. This development is closely related to the emergence of the philosophy of *Personalised Medicine* that will be introduced in the next section.

It has been established by now that

> responsible biobanking is desirable as a means to make – actually, a prerequisite for making – medical sense out of the map of the human genome.
>
> (Malinowski 2005: 54)

Though there have been collections of tissue or tissue 'banks' for a long time, currently an unprecedented proliferation can be observed. Traditionally, pathology sections of hospitals kept specimen of various tissues, an approach that has been developed more systematically and more recently in multi-tissue banks serving both research and therapeutic needs,

including for example bone, brain, and eye banks, as well as tumor tissue banks. An important trend is also the private and public banking of cord blood and stem cells, for example for the treatment of leukaemias and anaemias. There are also various biobanks that study particular diseases.

Overall, biobanks can be differentiated with reference to a number of parameters, such as number of samples retained, type of sample, disease-specific vs. general or 'exploratory', prospective or archival, according to population studied, the identifiability of samples, and various organizational factors such as scope of use in research and context including clinical, research and forensic context and status of organizers in charge, such as a public university or a commercial enterprise.

These are all in a sense biobanks, but they will not be at the centre of attention here, even though clearly many aspects of their regulation and ethics are overlapping. Here, I will focus on a generic type of biobank as a collection of tissue and associated personal data in particular for the prospective and exploratory study of various diseases. This approach of biobanks has first been established following the development of sequencing technologies and improved bioinformatics analysis around the turn of the century and in national contexts or across larger populations in which measurable effects of heritability in particular sectors of a study population can be expected. Population biobanks are defined within the European context as follows:

> Article 17
>
> A population biobank is a collection of biological materials that has the following characteristics:
>
> i. The collection has a population basis;
> ii. It is established, or has been converted, to supply biological materials or data derived therefrom for multiple future research projects;

iii. It contains biological materials and associated personal data, which may include or be linked to genealogical, medical and lifestyle data and which may be regularly updated;

iv. It receives and supplies materials in an organized manner.[6]

The biobank as an object of study here is, however, not necessarily a national project, and it will become clear in what follows why a narrow focus on a particular type of biobank is not useful in the extremely dynamic field of genomics. Nonetheless, particular features of genomic biobanks in relation to traditional pre-genomic research abound. To study complex common diseases it is anticipated that research must connect biomaterials, in particular blood samples, provided increasingly by as of yet healthy participants with extensive health and lifestyle information provided by participants themselves and by medical registries and health system databases. These encompass clinical, genotype or sequence and phenotype data.

The idea of research behind genomic biobanking has a number of characteristics that seem to justify referring to it as a new level in terms of both quantity and quality, indeed, as a paradigm shift in medical research. But first, let us take a look at some of these projects. While initially nationally planned, these projects are also increasingly linked with various networking structures, and they exist on all continents.[7]

The first large-scale national biobank was the 1996 deCODE-associated Icelandic biobank in cooperation with the Pharmagene company. In 2002, the Estonian Genome Project followed, in 2003 UK Biobank, in 2007 the Norwegian HUNT Biobank,[8] and in 2008, the BBMRI (Biobanking and Biomolecular Ressources Research Infrastructure), a network of biobanks and biobank services, was established. Other biobanks of larger dimensions can

[6] Recommendation on Research on Biological Materials of Human Origin. Rec(2006)4.
[7] For a recent overview of major international biobank projects cf. Scott et al. 2012.
[8] Cf. in particular Steinsbekk et al. 2009.

be found in France, Sweden, Austria and other European countries (cf. European Commission 2012[9]; Hewitt 2011; Scott et al. 2012).

While the landscape of biobanking even within Europe is very heterogeneous, the two biobanks that are most often referred to in the literature concerning governance and ethical aspects are the Icelandic and British Project, which will also be used here for illustrative purposes. Their set up has indeed interesting, contrasting features for thinking about the regulatory issues involved. The early Icelandic project[10] directed by the private company deCode Genetics involved the first national project of this kind. The project was to connect a genealogy database, a health database and a DNA database, aimed at comprising samples from approximately 270.000 individuals. The endeavour soon made headlines not only because of its novelty in scientific terms, but because deCODE held exclusive rights over the database.

The Icelandic Act on Biobanks in 2000 was opposed by public initiatives for controversies surrounding presumed consent of donor-participants to tissue and data provision and issues relating to their commercialization. This spurred a heated and long-term debate still influencing the bioethical framing and in particular the question which form of consent such a project should employ. In the Icelandic case, insecurities and concerns over transparency eventually led more than 20.000 people to opt out, and the law on Biobanks was changed (Santosuosso 2002; Cambon-Thomsen 2004; Rose 2006).

The UK Biobank[11] instead is a not-for-profit charity, the central objective of which is to create a major research resource containing biospecimen and associated information as described above from around 500.000 people in the UK, aged between 40 and 69. With the aim of supporting research, both in the UK and abroad, UK Biobank hopes to contribute to

[9] European Commission. EUR 25302. 2012. Biobanks for Europe: A Challenge for Governance. Report of the Expert Group on Dealing with Ethical and Regulatory Challenges of International Biobank Research.
[10] www.decode.com.
[11] www.ukbiobank.ac.uk.

better health outcomes for the generations to come. Partly in reaction to the Icelandic experience, particular attention was given to an appropriate ethics and governance framework which could incorporate issues of consent, privacy, as well as questions relating to cooperation with commercial partners. An independent Ethics and Governance Council was established to this effect.

The projects to be looked at here will all share features with these two examples, in particular, biosamples will often be taken in a non-therapeutic context, i.e. tissue donors or research participants will have to be specifically recruited for cohort studies or population biobanks and they will be asked to consent to a linkage of these with health databases and other databases to be established.

Biobanks for epidemiological, genomic research are not only a novelty in terms of institutional structure, by pooling samples and data from various sources that can then be analyzed and connected for various and future research uses. Behind the proliferation of genomic biobanks is a significant turn to preventive medicine that it is useful to outline to understand the ethical and regulatory complexities involved. While biobanks and sample collections, for the time being, extend to large and varied populations, the final aim is one of a highly individualized, indeed personally tailored future of healthcare and therapy.

1.2 A Tool for Personalised Medicine

One crucial aim of biobank-based research employing –omics technologies is the elucidation of the interactions between lower-penetrance gene variants and environmental and modifiable lifestyle factors which contribute to elevate disease risk. Statistically relevant varieties, SNPs, copy number variants (CNVs) and haplotypes on population level can be systematically investigated using massive and long-term oriented databases.

Research of this kind can identify and characterize heritable components of disease, contribute to understanding of molecular mechanisms and lead to improved diagnostic tools and new therapies. To this end, the genomes of hundreds and thousands of individuals are anticipated to be the key to these applications, in particular as the relevant technologies become more affordable.

Biobank-based research is expected to improve on the biases inherent in traditional-case control studies, by advancing statistical power, diminishing false positives and helping to systematize new stratification efforts in a given population. It is also anticipated that this will lead to a better and more accurate representation of minority disease populations (O'Brien 2009: 195).

Genotype-informed medical treatments are the scientific vision implied in Personalised Medicine, i.e. custom-made diagnostics and treatment to a particular genotype that helps to predict efficacy and risk of pharmaceutical compounds (pharmacogenomics) (cf. Laberge 2003).

Advances in bioinformatics have enabled countries or regions, in particular the ones with existing archived health information from public healthcare systems such as in the UK, Iceland and Estonia, to literally mine these data and link them with one another and emerging research projects.

The link between this scientific and healthcare-service oriented vision and the expected impact on population or public health as well as the larger bio-economy surrounding it is the movement and philosophy of *Personalised Medicine* which acts as a motor and advertiser also of biobank endeavours, including in the ethical and regulatory discourse. Personalised Medicine more generally can be defined as the use of genomic and other biotechnologies to derive data about an individual that could be used to inform types of health interventions that would best suit that individual, predict disease development, and

could influence and help adapt decisions about choice of lifestyle, or to tailor medical treatment options for a particular individual (cf. Savard 2013). Genetic testing is therefore crucial to Personalised Medicine and includes the increasing use of these tests through health care providers or direct-to-consumer services.

Personalised Medicine is also part of a larger healthcare and research strategy implemented by the European institutions and a restructuring – some would argue dismantling – of the traditional, now seen as too ineffective, public health care systems. Clearly, research results and products derived from this research are strategically envisioned to strengthen Europe as part of the leading global players in the bioeconomy. Biobanks in their various shapes are considered "essential elements of particular European strength that may ensure a continued leading role for Europe in the area of Personalised Medicine" (European Science Foundation 2011: 2). Indeed the priorities of the new funding framework "Horizon 2020" prominently include health and the bioeconomy (European Commission 2011[12]; cf. Editorial Nature Genetics 2013). Biobank initiatives are therefore also created in response to a perceived commercial potential of such resources (cf. Einsiedel and Sheremeta 2005).

The persistence of data, their widespread sharing and analysis should help to advise ordinary people on risk factors, help to advance healthy behavior and make people participate more actively in healthcare – and perhaps research. There is a strong emphasis on prevention and prediction in the movement to Personalised Medicine, which has also been called "asymptomatic medicine". The individual is seen as a 'future patient' who should therefore take increasing responsibility for his physical and mental condition. Before personalised therapies, however, there have to be data for personalisation derived from biobanks, which has been expressed in the 'Paradox of Personalised Medicine':

[12] European Commission. Horizon 2020 – The Framework Programme for Research and Innovation. COM(2011) 808 final.

> personalised medicine requires the involvement of many. This in turn raises important questions about public participation in science and the goals of health care and equity. For if Personalised Medicine relies upon populations contributing data and bio-specimens, then it would seem appropriate that the public should expect to benefit from the insights of personalised medicine and that the "goods" of Personalised Medicine should be accessible and should be distributed justly and fairly.
>
> (Savard 2013: 201)

'Justly and fairly' refers also to the risks that people volunteering now might face in terms of privacy and property concerning their 'donations', but also to the incremental changes on research and research ethics culture that can be expected with an eye on the current development.

1.3 Trends, Hopes, and the Lack of Directed Governance

A number of developments can be envisioned to be of particular relevance in regard to the future of biobank-based genomics and its effect on the way the participation of individuals is to be guided by ethical reflection and overarching governance. Some particular trends seem worth highlighting:

(1) Informatization/Digitalization: increasing use of web based-computing and 'cyberbanks', escalation in number and power of associated databases (Majumder 2005; Sensen 2005; Thorisson et al. 2009).

(2) Networking: formation of consortia in international and global contexts; merging of research projects and infrastructures, leading to the biobank as a platform and resource including 'biolibraries' for research; linking of larger and smaller biobanks, including within the context of clinical trials; encouragement of regulatory harmonization (Yuille et al. 2007; Riegman et al. 2008; Elger and Biller-Andorno 2011; Austin, Hair and Fullerton 2012).

The Public Population Project in Genomics (P^3G),[13] for example, is an international, non-profit consortium to promote collaboration between different projects and all the stakeholders involved, mainly focusing on the sharing of expertise including guidelines and operational procedures. The aim of the European flagship project BBMRI[14] is "the construction of a pan-European infrastructure for biomedical and biological research in Europe and worldwide, building on existing infrastructures, resources, and technologies, specifically complemented with innovative components and properly embedded into European ethical, legal and societal frameworks" (European Commission 2012: 21[15]).

(3) Data-Sharing Policies and Involvement of Increasing Numbers of Stakeholders:

In June 2013, *Global Alliance* was launched, connecting 69 institutions in 13 countries to develop a data-sharing policy and encourage DNA sequence and clinical information sharing and also technical cooperation through cloud computing and similar developments (Hayden 2013).

(4) Public-Private Partnerships:

Gottweis and Lauss distinguish three broad models with reference to financing: an entrepreneurial model , i.e. a public-private partnership between a commercially oriented entity and different state institutions; a 'biosocial' model which is supported by patient advocacy groups; and a public biobank model in which biobank networks are financed primarily with money of taxpayers and through support of not-for-profit funding organizations (Gottweis and Lauss 2012). In an increasingly commercialized research environment strict distinctions between 'public' and 'private' biobanks do, however, not seem to map reality adequately (Einsiedel and Sheremeta 2005; Steinsbekk et al. 2009),

[13] www.p3g.org.
[14] www.bbmri.eu.
[15] European Commission. EUR 25302. 2012. Biobanks for Europe: A Challenge for Governance. Report of the Expert Group on Dealing with Ethical and Regulatory Challenges of International Biobank Research.

and there is a clear political move to foster in particular the first model, testified for instance in a recent European Union science policy report (European Commission 2013),[16] which underscores the importance of ownership issues for the ethical assessment of governance approaches in this field.

Hopes and investments in biobank-based genomics and Personalised Medicine are evidently very high (Scott et al. 2012). Some authors, nonetheless, express doubt concerning the pervasiveness with which biobank-structures are implemented without more in-depth consideration of alternative and complementary approaches to future healthcare. This critique is spelled out for instance in terms of an overly reductionist, in particular molecular reductionist philosophy of medicine, and a partly socially and commercially created need for Personalised Medicine, which are seen to be related (cf. Schneider 2003; Williams 2005; Savard 2013).

The first kind of skepticism revolves around an overemphasis on genetic factors in understanding and promoting health or even, in a wider sense, the promotion of a genetic conception of the human self for all kinds of diseases, including the ones that are in actual fact known to be strongly influenced by other factors such as the so-called social determinants of health. Williams criticizes that a consistent approach to mapping the complexity of common disease would have to take into account more than is the case environmental, non-genetic conditions, and involve monitoring of the 'future patients' from childhood onwards (Williams 2005). This involves a concern that 'technological' and pharmaceutical solutions to population health are envisioned as primary, relying on benefits from commercialization of the body and genetic knowledge.

Overall, Personalised Medicine, to which research biobanking and genomics are instrumental, are considered to represent a tremendous challenge in biomedicine and

[16] European Commission. Public-Private Partnerships in Horizon 2020: A Powerful Tool to Deliver on Innovation and Growth in Europe. COM(2013) 494 final.

healthcare, the ethical implications of which are to be carefully evaluated (Rothstein 2005; Gottweis and Laus 2010; Karlsen et al. 2011).

In some respects, it is evident that biobank-based research is *sui generis*, in that it does not qualify straightforwardly as human subjects research, even though identifiable bodily material retains its human dimension (cf. Harmon 2009). Judith Kissell has instead coined the term "human non-subject research" which she characterizes in the following way:

> Emerging biotechnology is producing a genre of cases that, while not quite "human-subject research" – not about *subjects* – clearly engages the human, evoking considerations of embodiment, rights, privacy, dignity, personhood, physical integrity and respect. […] Human non-subject research encompasses any experimentation or procedure that deals with human material – nucleic acid, sequences, genes, cells, organs, etc., that does not, however, affect the personal-physiological functioning of its donor-source. […] some ambiguous continuity exists between personhood and human material, however indeterminate this connection, and even though *personhood* seems in these cases to be distinguished from *subjectivity*.
>
> (Kissell 1998: 279/280)

Human non-subject research is not easy to place within existing law and ethics for biomedical research. Indeed an overarching international binding law does not yet exist and the ethics underpinning the many guidelines, recommendations and soft-law instruments tries to adapt norms from other fields, mainly traditional research on human subjects in clinical contexts as well as research on anonymous biomaterial. The result, however, has been mosaic-like and piecemeal, leaving many details unresolved (cf. Kaye et al. 2004; Rynning 2009; Wagstaff 2011; European Commission 2012[17]; Sándor et al. 2012).[18]

[17] European Commission. EUR 25302. 2012. Biobanks for Europe: A Challenge for Governance. Report of the Expert Group on Dealing with Ethical and Regulatory Challenges of International Biobank Research.

[18] For an overview listing the various forms of consent promoted in different national and international contexts cf. Scott et al. 2012.

2. Applying Traditional Research Ethics to Biobank Recruitment and Research Use

2.1 The "Ethical Centre of Gravity": Informed Consent[19]

2.1.1 Key Elements of the Received View

Descriptively, there is no doubt that the requirement of what has become known as the doctrine of informed consent is the main pillar of research ethics around which questions pertaining to the treatment of competent human beings in relation to health care and research revolve. The doctrine in fact has been enshrined in all the important declarations, guidelines and policy documents in the area in the second half of the 20th century, following in particular the abuses of human beings in medical experiments during the Nazi regime (cf. Beauchamp and Childress 2012: 120).

Here, we can make reference only to some, which are also a primary point of orientation in the application to biobank research. The Declaration of Helsinki proclaims

> 6. In medical research involving human subjects, the well-being of the individual research subject must take precedence over all other interests.
>
> 24. In medical research involving competent human subjects, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail, and any other relevant aspects of the study. The potential subject must be informed of the right to refuse to participate in the study or to withdraw consent to participate at any time without reprisal. Special attention should be given to the specific information needs of individual potential subjects as well as to the methods used to deliver the information. After ensuring that the potential subject has understood the

[19] Adapted from Brekke and Sirnes 2006. Cf. Høyer 2008 and Budimir et al. 2011 for more on the socio-political background and empirical data.

information, the physician or another appropriately qualified individual must then seek the potential subject's freely-given informed consent, preferably in writing. If the consent cannot be expressed in writing, the non-written consent must be formally documented and witnessed.

25. For medical research using identifiable human material or data, physicians must normally seek consent for the collection, analysis, storage and/or reuse. There may be situations where consent would be impossible or impractical to obtain for such research or would pose a threat to the validity of the research. In such situations the research may be done only after consideration and approval of a research ethics committee.[20]

The Convention on Human Rights and Biomedicine (also known as Oviedo Convention) reads:

Article 5 – General rule

An intervention in the health field may only be carried out after the person concerned has given freeand informed consent to it.
This person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks.
The person concerned may freely withdraw consent at any time.

Chapter V – Scientific research

Article 16 – Protection of persons undergoing research

v. the necessary consent as provided for under Article 5 has been given expressly, specifically and is documented. Such consent may be freely withdrawn at any time.[21]

The Guidelines of the Council for International Organizations of Medical Sciences (CIOMS) and the World Health Organization (WHO) consider consent generally and biospecimen research, but not the peculiarities of biobank research as described here:

[20] World Medical Association. 2013 [1964]. Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects.
[21] Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine [Oviedo Convention].

Guideline 4: Individual informed consent

> For all biomedical research involving humans the investigator must obtain the voluntary informed consent of the prospective subject or, in the case of an individual who is not capable of giving informed consent, the permission of a legally authorized representative in accordance with applicable law. Waiver of informed consent is to be regarded as uncommon and exceptional, and must in all cases be approved by an ethical review committee.
>
> *Use of medical records and biological specimens*. Medical records and biological specimens taken in the course of clinical care may be used for research without the consent of the patients/subjects only if an ethical review committee has determined that the research poses minimal risk, that the rights or interests of the patients will not be violated, that their privacy and confidentiality or anonymity are assured, and that the research is designed to answer an important question and would be impracticable if the requirement for informed consent were to be imposed. Patients have a right to know that their records or specimens may be used for research. Refusal or reluctance of individuals to agree to participate would not be evidence of impracticability sufficient to warrant waiving informed consent. Records and specimens of individuals who have specifically rejected such uses in the past may be used only in the case of public health emergencies.
>
> (CIOMS 2002)

Finally, the United Nations Educational, Scientific and Cultural Organization's (UNESCO) Declaration on Bioethics and Human Rights confirms under article 3, point 2: "The interests and welfare of the individual should have priority over the sole interest of science or society" and also the requirement of prior, free, express and informed consent for all scientific research (Article 6, UNESCO 2005).

In their highly influential *Principles of Biomedical Ethics*, Beauchamp and Childress refer to general "building blocks of a definition of *informed consent*: A person gives an informed consent to an intervention if (and perhaps only if) he or she is competent to act, receives a thorough disclosure, comprehends the disclosure, acts voluntarily, and consents to the intervention" (Beauchamp and Childress 2012: 124).

According to Beauchamp and Childress, informed consent is a process encompassing the following elements:

I. Threshold elements (preconditions)

1. Competence (to understand and decide)
2. Voluntariness (in deciding)

II. Information elements

3. Disclosure (of material information)
4. Recommendation (of a plan)
5. Understanding (of 3 and 4)

III. Consent element

6. Decision (in favor of a plan)
7. Authorization (of the chosen plan)

(Beauchamp and Childress 2012: 124)[22]

Many commentators consider the legal and moral right to informed consent a very strong right, perhaps inalienable (McConnell 2000), so that allowing and justifying waivers – intentionally and voluntarily relinquishing a right – is considered problematic (e.g. Beauchamp and Childress 2012: 137).[23] Waiver of consent is not an infringement of autonomy according to another influential account by Dworkin (Dworkin 1988), but then, as we will see, 'autonomy' does not seem to be the sole justification for the requirement of consent. Apart from this fundamental debate, and the related issue of waiving consent due

[22] The authors specify that their model allows for the possibility of an 'informed refusal' and that element 4. – recommendation of a plan – should not apply to potential participants in research. Beauchamp and Childress 2012: 124.

[23] Strikingly though, Manson and O'Neill (2007), for example, interpret the primary function of consenting as waiving of rights. Beauchamp and Childress comment that "Although this interpretation is not incorrect, it is often more illuminating to describe informed consent as an exercise of rights rather than a waiver of rights." Beauchamp and Childress 2012: 148.

to therapeutic privilege, exceptions to requiring consent would be emergency situations and clear cases of incompetence.

Consent and its potential waiving are a matter of individual rights, decidedly constructed as an application of human rights for the context of healthcare and clinical trials. As Caulfield and Brownsword highlight,

> The requirement to obtain consent is one of the most fundamental in health law and bioethics. It flows directly, although not exclusively, from a rights-based concept of human dignity, such as that typified by the Universal Declaration of Human Rights.
>
> (Caulfield and Brownsword 2006: 73)

There is, however, a wide spectrum of moral and practical considerations and ideals underlying the requirement of informed consent and the correlative duties of disclosure of healthcare providers – dignity, non-instrumentalization, protection of life, health and against risks, the right to self-determination, respect for personal integrity and agency (cf. Bobbert 2007: 239/240) – and the relationship between autonomy and consent therefore more nuanced and complex than often asserted (cf. McLean 2010: 3).

Nonetheless, in terms of moral justification, in the history of informed consent regimes, there has been a shift from the assumption of a more protective function of consent as minimization of harm towards the protection or fostering of autonomy (Faden and Beauchamp 1986; Manson and O'Neill 2007: Chapter 1; McLean 2010: Chapter 1; Beauchamp and Childress 2012: 121).

The philosophically oriented debate of academic bioethics has, indeed, focused on the value and meaning of 'autonomy'. In particular the work of Beauchamp and Childress has lend support to the prominent place of the so-called "principle of respect for autonomy" in bioethical scholarship, even though the authors clarify in reaction to criticism that this

principle does not always have priority over other moral considerations (Beauchamp and Childress 2012: 101).

Beauchamp and Childress explicitly focus on autonomous choice in non-ideal conditions rather than general conditions of self-governance – the literal meaning of 'autonomy' – and yet, the principle of respect for autonomy is also described as encompassing both negative and positive obligations, freedom from external influence and enhancement of autonomy:

> The principle of respect for autonomy consists of respecting an agents' right to hold views, to make choices, and to take actions based on their values and beliefs. Such respect involves respectful action, not merely a respectful attitude. It also requires more than noninterference in others' personal affairs. It includes, in some contexts, building up or maintaining others' capacities for autonomous choice while helping to allay fears and other conditions that destroy or disrupt autonomous action. Respect, so understood, involves acknowledging the value and decision-making rights of autonomous persons and enabling them to act autonomously, whereas disrespect for autonomy involves attitudes and actions that ignore, insult, demean, or are inattentive to others' rights of autonomous action.
>
> (Beauchamp and Childress 2012: 106/107)

Their theory depicts autonomy in terms of the three basic conditions of intentionality, understanding, and non-control, while simultaneously stressing that context will be crucial to specify the appropriate criteria for substantial autonomy (ibid.: 104/105).

The specific normative commitments of this view continue to be discussed, and are sometimes criticized as shallow (O'Neill 2004a; cf. also Wilson 2007), sometimes described as a middle or standard position (cf. Bobbert 2007). It is probably fair to say that Beauchamp and Childress' model is based on a bundle of normative and practical considerations that should make it both conceptually resistant and also applicable as a practical reference in bioethical matters across the spectrum of healthcare and research.

Given that their account would be the standard, deviations can be categorized in the more minimalistic form as 'informed choice' with focus on liberty as independence from external control, and a more demanding account of e.g. substantive or 'relational' autonomy, which is then correlated to what is the final moral aspiration in the requirement of consent.

Though the overarching importance of autonomy as a value in itself and the Beauchampian principle of respect for autonomy have long been hailed as a triumph over traditional medical paternalism and the societal authority of science, recently there has been a reconsideration of this quasi-dogmatic status in which respect for autonomy as the main guiding principle is questioned (Caplan 2009; 2012). Some commentators have even referred to a "bioethical paternalism of autonomy" (Stirrat and Gill 2005; cf. Hofmann 2004). This phenomenon has also a certain importance for the issue of biobanking ethics as part of the rise of new forms of public health initiatives which challenge the traditionally strong concern with clinical ethics, and I will try to explicate in the following which parts of this critique of the general doctrine of personal autonomy are to be taken seriously.

Another influential account by Onora O'Neill and Manson and O'Neill claims that the relation between autonomy and informed consent in the preceding decades has largely been misconstrued, concluding that "standard accounts of informed consent, standard arguments for requiring consent in clinical and research practice and standard ways of implementing consent requirements lead to intractable problems" (Manson and O'Neill 2007: viii). They propose a less demanding theory in which informed consent serves mainly to avoid coercion and deception.[24] While O'Neill's and Mansons' critique concerning the justification of consent is not shared here, another feature of their analysis is relevant to the application of informed consent in the bioethical debate on involvement

[24] From which Beauchamp and Childress distance themselves while adding that the respect for autonomy requires moreover "an attempt to instill relevant understanding, to avoid forms of manipulation, and to respect persons' rights." Beauchamp and Childress 2012: 121.

of participants in genomics and 'donating' parts of their bodies. They rightly point out that the so-called 'Conduit-container model' in which information provision has a pivotal role applied to all kinds of health care and research contexts is unhelpful, and even dangerous since

> they encourage us to think of information in abstraction from human activity, and specifically in abstraction from the normative framework that governs successful communicative transactions between people.
>
> (Manson and O'Neill 2007: ix)

As a result, there is often too much focus on consent, and the disclosing of information and processing of data. This in turn leads to what Manson and O'Neill term "drift from agency", a phenomenon I claim can also be discerned in the ethical discussion surrounding biobank initiatives (cf. Brekke and Sirnes 2006).

As Paula Boddington points out in her recent book "Ethical Challenges in Genomics Research", another problem to be addressed as part of this critique, particularly if we think of new information technologies, is that the domain of autonomy and therefore control over it is dazzlingly large, covering selfhood, the body, as well as life in biological and life in informational constitution (cf. Boddington 2012: 112). This is obviously also related to the question of human *identity* and how we conceive of it with reference to the conceptualization of control over parts of the body, in particular if personal information is tied to it: is autonomy important to the self mainly insofar it concerns the bodily sphere, and where are the moral and practical limits of this conception of the self?

Just as with autonomy, however, one should avoid an idealization of a general concept of informed consent as a panacea, since it apparently has never been the ultimate solution to the philosophical puzzle of 'true' autonomy, and in any case is to be pragmatically adapted to context (cf. Ursin 2010b; cf. Beauchamp 2011). This implies that a contextualized discussion of what kind of form and content of consent is required will be necessary. In

addition, two further assumptions will undergird the ensuing discussion of adapting consent to biobank research: First, even though the specific deontological sources can a be a matter of debate, the requirement of consent is here conceived of as having both a protective *and* a liberating – or perhaps, 'empowering' – function, which stem from the origin of the doctrine of informed consent in the tradition of human rights thinking (cf. Beyleveld and Brownsword 2001; Brownsword 2003).

As a result, what is often referred to as a generic standard account of the requirement of informed consent to 'protect' autonomy is, in actual fact, even *prima facie* rather demanding, since it includes not only the process of direct and final authorization by a patient and/or research participant, but a procedure of surrounding considerations, such as a risk-benefit assessment of health care professionals and/or a research ethics committee, guided by the duty to protect against harm and the expectation that the invention or research will be beneficial, plus an overall embeddedness in a relation of trust, enabling all in all a meaningful implementation of respect for the person. Moreover, often understanding of provided information as well as situated and contextualized competences of decision-making are specifically emphasized (Bobbert 2007) as well as the weighing with competing principles and values (Beauchamp and Childress 2012).

Concerning research that is not of benefit to the donor or participant, only research aims that qualify as good and just are justified if risk is minimal. Informed consent by itself, therefore, legitimizes only the invasion of the private sphere of an individual in a broad sense, but – being about individual rights – cannot 'legitimize' the quality or particular contribution of a research project or societal research agenda to some common good.

This problem of the reach and meaning of consent is a key issue in the bioethical debate about the rights and interests of biobank participants. Brownsword and Caulfield observe that

> most of the policy reforms that have been suggested to address this consent issue involve a departure and, in some cases, an erosion of traditional consent norms — such as the use of a blanket consent or, as in Iceland, the creation of a system of presumed consent.
>
> (Caulfield and Brownsword 2006: 73)

Hence, the issue of a potential 'dilution' of consent will be the entry point into the present debate on the rights and interests at stake for persons who are asked and motivated to transfer bodily material and/or DNA to a research project.

Second, it is important to stress that with the universal requirement of consent comes the idea of the primacy of the individual human being or respectively, the non-instrumentalization of the person as a guiding ideal in biomedicine. This idea is central to the whole endeavour of research ethics (cf. Jonas 1969), however – with the implementation of large-scale public health research projects in digital environments, largely lacking close interaction with donors, patients and the public – it has come under some strain.[25]

2.1.2 Outlining the Challenges

This section examines limitations in the application of consent doctrines and their various justifications to biobank ethics. In particular, I aim at clarifying some implicit or hidden *normative* assumptions in a systemic way, which is not usually done within the scope of the main bioethical articles pertaining to the subject. This task is of particular importance since also the many regulatory guidelines make appeal to principles and values without further discussion. The focus will be on the question if there are any significant ethical

[25] Sometimes, this 'primacy-principle' is now considered outright wrong or too vague to be of any ethical guidance, cf. Helgesson and Eriksson 2008; 2011 who claim it should be abolished, and the critique by Parker 2010.

costs with reference to the new application and how the underlying rights change or have to be adapted.

In general, challenges in adapting informed consent to the context of biobanks concern issues deriving from two overlapping sources, the genetic/ genomic nature of the research as well as the unique organizational structure of biobanks (cf. Kegley 2004; Harmon 2009). Firstly, the concept of a well-informed consent as required by e.g. UNESCO's International Declaration on Human Genetic Data stating that "clear, balanced, adequate and appropriate information shall be provided to the person whose prior, free, informed and express consent is sought" raises questions in both medical practice and research on tissue and health information. As high-throughput sequencing is used increasingly, a wealth of potentially relevant information for researchers and patients is accumulated. The complexity of genetic information complicates the process of establishing the causal influence in determining disease or susceptibility to disease.

If a threshold of clinical relevance can be established, it must be considered that this information will be potentially relevant beyond the individual level. The information that a person carries the BRCA1/ BRCA2 mutation, for instance, will be important for family members and in some cases, reproductive decision-making, which raises the question if there is a duty to inform patients and/or return genetic/ genomic results, and how its demands can be specified. Informed consent to genetic tests and research, in any case, applies only to an individual. Although presently this is an issue mainly for what concerns the provision of tests in the clinical context, it might very soon also concern participants in so far *prima facie* only-research contexts. While most larger-scale genomic studies are likely still at the stage of exploration rather than confirmation concerning gene-disease and gene-environment interaction, the disclosure of relevant research results and so-called

incidental findings to participants will be a key challenge (cf. Beskow et al. 2001; Berg et al. 2011).

Under which conditions disclosure is appropriate, however, is contentious. Fundamental problems include the epistemological and statistical conditions of assessing disease susceptibility as well as a potentially necessary independent confirmation of the result. Even if a result is valid, duties of disclosure might hinge on circumstances, such as the availability of treatments. And what is the role of the researchers who so far have no recognized duties to act in the best interest of study participants as doctors have towards patients (Beskow et al. 2001: 2320)? While there seems greater consensus on researchers' duties in this regard, the demandingness and concrete implementation as an enforceable positive duty remain a matter of debate (Wolf et al. 2012; Bledsoe et al. 2012; Clayton and McGuire 2012; Ossorio 2012; Zawati and Knoppers 2012; Biesecker 2013). In larger, public health contexts (as facilitated by biobanks) rather than the clinical setting, some authors stress that returning results should be strictly limited (Stjernschantz Forsberg et al. 2009; Berg et al. 2011): "Only clearly deleterious mutations in genes known to cause a high risk for preventable disease should be routinely reported. This differs from the public health pursuit of newborn screening, for example, in which sensitivity is maximized at the expense of specificity" (Berg et al. 2011: 500).

Early on in the debate on the provision of genetic information to participants in research, non-individual forms of consent and consultation have been proposed, in particular group or 'community consent' as a result of the ethical quandaries in particular with research on ethnic or cultural minorities (cf. Foster et al. 1998; Dickenson 2004; Widdows 2009; Widdows and Cordell 2011b).

Concerning the particular structural and organizational features of biobank research, the application of traditional consent forms is limited by the impact of informational insecurity

or openness that is, at the same time, the rationale and aim of the whole endeavour (Greely 2007; Mascalzoni et al. 2008; Beier 2010). Biobanks, as Shawn Harmon pointedly remarks,

> are an exercise in the unknown; they are future-oriented and optimistic; although we believe they will contribute to high-powered future research, new understandings, and the discovery and generation of new therapeutic products and processes, we really do not know what their ultimate value or their social risks/consequences might be.
>
> (Harmon 2009: 31)

The platform character of biobank means that we must conceive of biobanks as research *resources* rather than a research project. It is, in many cases, envisioned that samples will be networked and shared with other research institutions and databanks. As a consequence, new potential uses of the resource material, i.e. the tissue and data, seriously limit the possibility to define research protocols and inform participants, but even ethics review boards at the time consent is sought. This is further complicated by the fact that possibilities of data storing and the technological tools for analysis improve rapidly (Mascalzoni et al. 2008).

Since these research infrastructures are projected for future, continuous and repeated use, unknown or uncertain factors abound. At the time of collection, when consent is required, it is not possible to anticipate the identity and/or location of all the (potential) users; the specific ends to which the research will be put; the eventual (but presumably therapeutic) outputs, if therapeutic or of other kind, the governance structures of the particular location or locations where the materials are to be used and the lifespan or security of the biobank (Harmon 2009: 31). The 'scope' of information stored and perpetuated clearly is also a matter of technical development (e.g. data-mining, cloud computing, whole genome methods) and consequently informational risks are underspecified at the time of consent (Kaye et al. 2010). This can have an effect on the validity of the consent insofar the

protection of confidentiality should be covered through it, which in turn raises the question if participants should know details about access to data and security measures (cf. Tavani 2004; Mascalzoni et al. 2008). As Greely (2007; 2010) discusses, tying up the demands and scope of consent almost exclusively with the protection of privacy interests, as has been explicitly the case in the United States, is therefore both ethically and pragmatically highly problematic.

Generally, it can be concluded that it will be difficult to secure transparency concerning the exact research in relation to evolving projects. Under which circumstances then should donors or participants re-consent and must be updated? Some authors assume that it is in the interest of participants to be re-informed only of what researchers or ethics review boards would consider substantive changes to the research agenda and governance structure (Steinsbekk and Solberg 2011; Stjernschantz Forsberg et al. 2011). Steinsbekk and Solberg (2011) specifically discuss whole-genome sequencing, data sharing and commercial utilization as the currently most likely cases in the international biobank research scene that will demand careful consideration of re-consenting to research (within a model of 'broad consent' to be explicated below).

In some cases, participants may want to make use of the right to withdraw from research which traditionally is a correlative of the requirement of informed consent. Due to the increase and networking of data generated from tissue research it is, however, not clear that this right can be respected in the original form as applied to clinical research (cf. Widdows and Cordell 2011a; Holm 2011). This seemingly very strong right is justified by appeal to autonomy and bodily integrity, but in its absoluteness and unconditionality also by the power difference between researchers and participants. In the traditional form, it has five key components: it is absolute, unconditional (requires no explanation or justification), is immediate, complete and non-tradeable or inalienable. These features do not

straightforwardly translate to the context of large-scale biobank studies (Holm 2011: 271). Holm argues that unconditionality can be qualified for the biobank context since there are no imminent risks and the power situation is different. One potential consequence is that researchers could be allowed to give general information about the implications of withdrawal, which would be wrong according to the traditional scenario in clinical research. The completeness condition of withdrawal can and should also be qualified, alternative options being e.g. the anonymization of tissue samples with or without additional generation of data from the existing samples, consenting to specific research projects, or more demanding options such as the formation of a "donor committee" that represents its interests in the relevant research ethics committee (ibid.: 278). In any case, the concrete meaning of withdrawal and how realistic the possibility of withdrawal is should be specified.[26]

Moreover, it is not possible to stop data being used in subsequent studies which build on the results of previous research done based on biobank samples and information. To offer this as a realistic possibility in the process of a one-time consent will be difficult and is certainly scientifically undesirable as the value of stored samples increases over time due to additional generation of data. Data may also be kept by sponsors or oversight bodies for verification and have entered aggregation and data pools already published or to be used for further research. Even if different forms of withdrawal are specified, a complete stop of data flow may therefore simply be impossible (cf. Mascalzoni et al. 2008; Widdows and Cordell 2011a; Kosseim and Jospe 2011).

If the potential non-adherence to completeness of withdrawal that seems to follow from the configuration of biobank research is indeed ethically problematic is, however, a matter of

[26] UK Biobank, for instance, communicates the options of 'no further contact', 'no further access' and 'no further use', the latter being qualified as destruction of samples where possible in entirety, though data are kept for archival purpose, and from data analyses already undertaken (UK Biobank Ethics and Governance Framework 2007).

debate. Søren Holm suggests that changes to the strict requirements of the right to withdraw from research in the clinical research context in larger-scale genomic research can be justified by comparing the desire to withdraw with other situations in life that are similarly low-risk, but where the continued existence of the overall project might have very important social goals: "Participants can effectively break off any future engagement with the biobank. This seems analogous to many other kinds of social cooperation where participants can stop future engagement without having a right to retrieve their past contributions" (Holm 2011: 280). Eriksson and Helgesson have argued for the stronger position that withdrawal must be conditional and should only be allowed in case there is "a sufficient argument for doing so, out of consideration of fairness and a duty to contribute to the continuous development of public health resources" (Eriksson and Helgesson 2005: 1076).

A further issue which has become questioned in applying the traditional informed consent to biobanks is how commercialization and potential profit from donated biological material and data should be communicated and dealt with in a research ethics model that relies primarily on the tool of consent. This does not only concern the question if commercial use of tissue or commercial collaborations of the biobank must be disclosed. As will be discussed in more detail below, it also engages more conceptual questions that seem to have a large impact on how the ethical sub-structure of biobank governance is thought of and organized. In fact, what does consenting to future and likely broader, unspecified research use imply concerning potential property interests of donors? Is informed consent the mechanism of a – complete? – property transfer, or are donors rather participants with morally justifiable continuing interests in 'their' material? (cf. Høyer 2008; Widdows and Cordell 2011a; Ursin 2010b).

2.1.3 New Functions for Informed Consent

2.1.3.1 From Presumed Consent to Informed Authorization

Biobank research on the one hand might be considered to complicate the recruitment of donors under the circumstances of uncertainty, while indeed the very nature of research organization raises the appeal of a blanket, broad or presumed consent. This has raised concern and sometimes heated debate. Should we accept what converges on "carte blanche" as functional and justified, or at least a good enough proxy to 'true informed consent'? But then, what would be 'true informed consent'? (cf. Malinowski 2005).

These kind of questions are indeed what caused the first wave of bioethical discussion, the controversy that arose following the presumed consent of the Icelandic population to the project of deCODE that became a model for reflection on "how not to develop a biobank" (cf. Rose 2001; Rose 2006; Winickoff 2003; Pálsson 2007).

The Icelandic population in this case presumably was willing to participate in deCODE's studies, meaning that they would have their tissue and data available in the health sector database, which then gives access to deCODE, including its commercial partners, unless there is an explicit request for exemption. Following intense public and academic debate, the applicability of informed consent in large-scale research databases and the internationally developing biobank projects became investigated, that should later centre around the idea that a classic consent does not fit here, since it is not informed anymore (Kaye and Martin 2000; Greely 2007; Hofmann 2009). In a similar vein, Harmon concluded that "the "informedness" which underlies proper, ethical consent cannot be fulfilled, making any claim to having obtained consent as we wish and need it to mean in the clinical and research setting a fallacy" (Harmon 2009: 32).

In fact, some commentators in particular in reaction to the Icelandic case argued that the concept of informed consent cannot be stretched to accommodate genetic research based on large-scale tissue and data collection and should be substituted with a different format – a so-called 'informed authorization.' The concept denotes "an explicit written *authorisation* for participation in database research based on general knowledge about the database and the research purposes and practices" (Árnason 2004: 44). This proposal of a middle way between standard and presumed consent derives from the recognition that the use of informed consent for research participation which is not specified is misleading, and the distinct and open question "whether it is wise to require informed consent for all secondary research purposes" (Árnason 2004: 42). The second question, I take it, refers to practicality in terms of temporal and financial resources as well as limitations due to the organizational structure of tissue and database-based research.

Authorization would imply the provision and understanding of "at least" the following:

- which information about her/him will be placed into the Health Sector Database;
- how privacy will be secured (without going into technical details);
- how the information will be connected to other data;
- who will have access to the information;
- in what context the information will be used and for what purposes;
- how consent for genetic research will be obtained;
- what are the foreseeable risks and benefits of participation;
- how research on the data will be regulated; and
- that the individual has the right to withdraw the healthcare data at any time.

As in the traditional scenario, these last right of withdrawal remains the most important part of respecting and protecting research participants (Árnason 2004: 45/46). Árnason assumes that though different from informed consent, this model remains faithful to its original spirit. However, as the above list of the minimum (!) of information provided and understood shows, it is not clear how authorization is indeed an adaption to the new context rather than merely more linguistically appropriate because openness and indeterminacy of research seem less concealed (cf. Beier 2010: 59).

Timothy Caulfield et al. also suggest a type of authorization model which should help to overcome the difficult policy choice of abandoning the prospect of biobank-based genomic research versus abandoning informed consent. More concretely than Árnason, they stress that a more appropriate model should not only not conflict with the ethical principles and rights underlying what so far has been considered legally valid, but to find ways to accommodate continuing interests of control in their donation, especially since large-scale genetic research has different characteristics than more traditional clinical research. Accordingly, we must find ways to take into account these continuing interests (e.g. in specific research uses and if commercial use of tissue and data is accepted). This authorization model thus anticipates the transformation of informed consent into an "ongoing consent process" (Caulfield et al. 2003: 2). After an initial, still largely traditional informed consent for the collection of genetic material and health information, a "pre-authorization" could be instituted through which it is possible to pre-specify uses which will or will not be acceptable in the future. Moreover, different levels of choice could be offered, including 'blanket consent' (ibid.: 3). Clinging to consent in applying a fiction precludes not only being really informed, but also the possibility to exercise at least a basic

interest in controlling what happens to tissue and data as part of the traditional model (Caulfield 2002; Kegley 2004).[27]

Hofmann concludes that although understanding risks, benefits and circumstances of research as part of informed consent can be seriously impeded in biobank research, "consent has become an ethical device for making research morally acceptable", and this presumably without any adequate justification. While the concept of an 'authorization to research' forces us at least to face the challenges of biobank research head-on, the insistence on consent suggests legitimacy of research that might actually be contentious as concerns its subject and organization and therefore rather mask these challenges (cf. Hofmann 2009: 128).

2.1.3.2 Broad, Broader, Open Consent?

In particular the assumption that the amount and specificity of information are central to enable respect for what is taken to be the main justification for the requirement of consent – safeguarding individual autonomy – is denied by a number of commentators. They advocate what has become known as "broad consent" to biobank research (Clayton 2005; Wendler 2006; Hansson 2009, 2010, 2011; Hansson et al. 2006, 2013; Otlowski 2009; Sheehan 2011; Stjernschantz Forsberg et al. 2009; 2011; Steinsbekk et al. 2013a).

At first sight, broad consent means that potential donors could be asked not to participate in specific research projects, but to take part in as yet unspecifiable usages of 'their' biological material. The emphasis here is on the unknowns, while some authors specify that the notion of a "broad consent" designates a wide spectrum of providing information

[27] In a later article, Caulfield states explicitly "In the realm of biobanks, autonomy is largely about the maintenance of control over something that implicates personal integrity. It implies that the research participant should retain a right of control over their genetic and personal information" Caulfield 2007: 223. Neither Caulfield not Kegley specify why or in which sense these continuing interests are part of the traditional model, but see Chapter 3, *infra*.

on research from rather specific to very generic, sometimes referred to as 'blanket consent' (Hansson et al. 2006: 268; Broström and Johansson 2011: 240). In the more specified case, commentators at times highlight the ethical justifiability of a variety of consent regimes according to context.[28] Others assume more generally or in addition that offering less information can be justified by reference to participant expectations and wishes concerning their 'informational involvement' with a particular biobank and/or the potential practical difficulties and costs that e.g. re-contacting and updating participants would cause (Hanson et al. 2006; Wendler 2006).

Indeed, it has been urged that the scope of consent must be broadened to "permit the creation of robust biobanks, which will facilitate the type of research needed to reap the fruits of genomics" (Clayton 2005: 20), while the "strict interpretation of consent requirements is lowering the scientific value of studies, limiting their capacity to provide new medical knowledge that would be beneficial for patients" (Hansson 2010: 1172). This, in conjunction with the assertion that regulations for patient consent do not allow for effective international collaboration in biobank research, leads Hansson to advocate a "minimal ethical framework for biobanking" (Hansson 2011). He contends that

> there is no need for a top-down superstructure of detailed rules and guidelines to be imposed on biobank researchers. […] Taking into consideration the low risks for sample donors associated with biobank research, something most participants in the discussion seem to agree on, the current efforts to create long and complex lists of "principles" and "best practices" looks like trying to kill a mosquito with a baseball bat.
>
> (Hansson 2011: 40)

In this perspective, although there are some risks involved in taking part in biobank research, these are all risks that can be handled mainly through adequate information and security management, or so it seems. Presupposing that it remains possible to withdraw

[28] Hansson insists that there is a well-established and approved practice to select different information and consent procedures for different research protocols and refers to the example of national cancer registries which would not require individual consent (Hansson 2009).

from research, and an ethics committee approves new directions of research and changes in legal or ethical authority in the overall governance framework, Hansson et al. argue that forms of broad consent are hence "ethically valid" (Hansson et al. 2006: 266). Against criticism of Árnason's and Caulfield's type Hansson et al. insist that appropriate information as underlying the validity of informed consent is simply information covering "all aspects relevant for a person's choice" (Hansson 2009: 10). The ethical 'validity' of this appropriateness is explained as to be witnessed by the factual appearance of large-scale biobanks in several countries.

It remains unconvincing though that the fact that "it is possible to inform about the importance of these research platforms with only general purposes describable" can be traded off against presumably perfectly stable and inconspicuous risks and clear benefits such that "general information on these studies may be sufficient for the donor of the sample to make an informed decision" (Hansson 2009: 10). It may be, but it may also not – and in any case a general appropriateness of this thinner concept of informed consent as a *fait accompli* in biobank-research conflates what is the case with what might be morally desirable. Beier appropriately designates this as a 'strategy of evasion' if not begging the question in the face of the particular characteristics of biobank research. In this light, Hansson and others take as safe premises exactly what seems particularly doubtful in this context: data security, adequate safeguarding of individual rights, and exceptionally low risk (Beier 2010: 54, cf. also Caulfield 2007 and Hofmann 2008; 2009).

Hansson claims, however, that balancing the specificity of consent with risks and scientific value and benefit is a matter of an "expanded view of autonomy" necessary for epidemiological research. In fact, "acceptance of broad consent and future consent implies a greater concern for autonomy than if such consents are prohibited" and generally "less

restriction on the types of consent allowed implies increased respect for autonomy" (Hansson 2006: 267/268).

If the requirements of consent are too strict so that they might not be realized in practice this might lead to an inhibition or even stop of research projects (cf. Hansson et al. 2006). Ethics review should ensure that their work is not turned into a contradiction in terms in the sense that patients and research participants could be harmed by not having the possibility to do their part for the advancement of these projects. Asking for consent then "undermines the possibility of participating in the development of medical science, and if this is one interest at stake the participant is more likely to experience a lack of respect from being asked" (Hansson 2010: 1173).

Although a certain amount of 'balancing' might be unavoidable in transferring the traditional concept of consent to the newer, larger-scale, and in particular genomic research contexts, it should be stressed that Hansson is simultaneously advocating a much stronger reform of the consent regime. He and other authors are implicitly redefining participant interests in autonomy as interests primarily, uncontroversially and/or rationally to be expected interests in the advancement of science (cf. also Hansson et al. 2006: 267; Helgesson et al. 2007: 974). This line of thought eventually yields – at least as part of the rhetoric – the unethicalness of even asking for consent *tout court*, a result of a rather different magnitude than the mere balancing of individual with scientific and public interests. Hansson's position derives from the conviction that there is actually nothing significantly new or challenging in biobank research as an endeavour of public health, and therefore the concept of informed consent can be stretched quite far or even abandoned.

The most extreme form of consent – if this term still applies – that has been proposed in reaction to the impracticalities and data insecurity in biobanks is "open consent". Defenders of this kind of reconceptualization start from the premise that confidentiality

and the right to privacy are key to the question which forms of consent to research are ethically acceptable. The main point then is that since there simply can be no promise of anonymity, confidentiality or 'privacy' in the emerging research contexts anymore, radical openness towards participants about this circumstance is the appropriate answer. This implies that the common emphasis on autonomy is qualified as being primarily a matter of 'veracity'. Similar to Hansson and colleagues, the more or less implicit justification of potentially curtailing the protection of individual rights is an appeal to everybody's interest in the benefits of genomic research (Lunshof et al. 2008; Lunshof, Chadwick and Church 2008).

Another indirect way of relaxing the protection of individual rights including privacy and eschewing a substantially informed consent is Arthur Caplan's support of the proposal (by the US Office for Human Research Protection in 2004) to enlarge the definition of "non-identifiability" of specimens or information: In Caplan's words, this would mean essentially that "if researchers are required to hand all data to trusted third parties that, following international standards, can encrypt, anonymize, and link them, then biobanking can be put on a firm, universal, and practical ethical foundation. Researchers must agree that they will not have access to the codes used to anonymize data. Third party organizations can maintain identifiable links to specific persons. But researchers themselves will only receive coded, anonymized information unless the trusted third party entity agrees that there is a reason so powerful as to break the code (i.e., discovery of a drug that can benefit those with a certain genotype)" (Caplan 2009: 30/31; cf. Elger and Biller-Andorno 2011). Overall then,

> This proposal provides a way to protect those in biobanks without creating the illusion that consent can do so. […] This is because there is no way harm or wrong can be done to individuals. It is of course still necessary to obtain general consent in order to gain access to tissues or DNA samples simply to respect each person's right to privacy but if the information garnered from the acquisition of biological materials will remain unidentifiable to those doing

> the biobanking research then no further consent ought be required since there is no prospect of harming someone by the release, intentional or inadvertent, of sensitive medical information about them.
>
> (Caplan 2009: 30)

In line with the title of his contribution, Caplan simply assumes "what no one knows cannot hurt you." The final result is similar to Hansson's and Lunshof et al.'s argumentation: " If high standards of anonymization can be created and strictly enforced in the biobanking community then the need to invoke informed consent for either retrospective or prospective biobanking can be eliminated" (Caplan 2009: 30; cf. Stjernschantz Forsberg et al. 2013).[29]

Alternative consent models of this type remain, however, contentious. Even though some commentators have been asserting confidently that there is a consensus emerging and recommendable (Knoppers 2005a; Hansson 2009; Cambon-Thomsen et al. 2007) on the need for broader forms of consent, others remain skeptical (Maschke 2006; Casado da Rocha and Seoane 2008; Caulfield and Kaye 2009; Hofmann 2009; Widdows and Cordell 2011a).

In the traditional legal and governance framework of research ethics that forms the conceptual backbone of the discussion of consent also for biobanks, circumventing specific informed consent is accepted under certain conditions, but this does not imply that alternative consent such as 'broad', 'open' or 'collective' are legally recognized (cf. Hansson 2006: 267; Sándor et al. 2012),[30] certainly not for biobank governance as a still emerging new field of application. As yet, as Sándor et al. point out, a general moral

[29] Surprisingly, in an earlier article co-authored with Bernice Elger, the enlargement of the notion of "non-identifiablity" is discussed with more precaution, and results as only second-best to adopting a standard policy of 'general' consent, the right to opt out and IRB approval, also because "one might question the sense of a solution whose main goal is to escape existing regulations so that most biobank research can take place without further surveillance" Elger and Caplan 2006: 665.

[30] An exception is the Estonian Human Genes Research Act.

acceptability of broader consent and the legal compatibility with the old framework should be "considered more as the researchers' wishes projected into the realm of ethics" (Sándor et al. 2012: 349).

2.1.3.3 Recovering the Foundations

Karlsen et al. 2011 note that remarkably little has been achieved conceptually in a two decades spanning debate that produced "a mudslide of research papers, policies, and guidelines" (572) which advocate consent models seemingly based on diametrically opposed underlying moral concerns vis-à-vis the interests of individual and societal interests in biobank research. Commentators overall seem to accept a continuity of biobank issues with medical research and the transplantation medicine model. A neglect to ground the debate in the complex scientific and societal advances that make genomics possible, and the reordering of the normative order for individuals, institutions and societies supports a curious conflation of contexts. In combination with a rhetoric of autonomous choice of technological progress, it has been suggested rather emphatically that biobank research exemplifies a new age of public health in the common interest, the final chance to overcome the age of medical paternalism:

> Could it be that we are finally moving away from the privatization of the sample, from persons as owners of the "property" of every cell, to citizens participating for public health, for the public good with no immediate personal benefit? Or, will paternalistic ethics committees "protect" participants from consenting "broadly?" Isn't such consent with authorization for future unknown uses an expression of their personal values and autonomy; that is, improved research outcomes?
>
> (Knoppers 2005a: 12)

Here, I will argue that this is part of a likewise paternalistic tendency deriving from an insufficient appreciation of the larger scientific and social project that biobanking expresses. Moreover, concerning the conceptual and normative debate, there is relatively sparse attention to the clarification and redefinition of potential harms, risks and benefits which would be commensurate to the long-term orientation of the relevant research projects and infrastructures.

In a nutshell, and contra Knoppers, initially it might therefore equally seem that "the interests of research biobank donors tend to be debated *as if* they were identical to the interests of research subjects and patients in a medical context" and thus that

> the fundamental interests of so-called donors are too readily being defined *for* them in order to facilitate scientific and technological progress, often by bioethicists and legal experts kept on a leash by their own fantasies of biomedical utopia.
>
> (Karlsen et al. 2011: 572/573)[31]

While there is a spectrum of risk perception and assessment (Hofmann 2008; Trinidad et al. 2011)[32] also the more precautionary commentators tend to remain within a conceptual horizon in which informed consent is not only the keystone of ethical approval, but also the exclusive centre of normative gravity. On this background though, the graver distortions are caused by linking consent to some direct way of respecting, protecting or enhancing "autonomy".

Indeed consent has come to dominate contemporary debates with respect to the donation of human material, albeit without any shared or unifying vision what would constitute 'consent', and the respective interests it is designed to protect (cf. Høyer 2008).

In the field of research on human beings and human tissue more generally, this can probably be explained by the fact that consent was established as a reaction to the

[31] Cf. Hofmann 2004.
[32] For some problems of conceptualizing and assessing risk in this context cf. Hoppe 2011.

instrumentalization of persons and their bodily material for research purposes, and incidents of the kind continue to appear and sometimes stir public controversy.[33] Not asking then remains the crucial disrespect, but the specific content and function of consent and the role of information still have to be elucidated for biobank research.

On the one hand, authors focus on the protective function of consent and advocate precaution, also with reference to historical precedence:

> biobanks depend on scores of individual donors who are generally unlikely to be direct beneficiaries of the commons created. In light of the commercial and research interests involved and the fact that laudable objectives for biobanking may be twisted into rationalizations for questionable practices, donor participants in biobanking must be protected. This need to protect is underscored in an era where an individual sample will generate voluminous information – surely more than we can appreciate presently. As is true with biomedical research in general, where the potential collective gains are treatments and perhaps even cures for now fatal and otherwise life-debilitating diseases, there is immense temptation to sacrifice individuals to achieve them. History cautions that this temptation must be checked through the enforcement of reliable safeguards to protect human subjects.
>
> (Malinowski 2005: 59)

On the other hand, traditional informed consent as default plus assumption of beneficial use (Gillett 2007)[34] leads to a more or less implicit undermining of the moral foundations of informed consent. Defenders of the hypothesis of a priority of research are then lead to rhetoric moves of the following kind:

> (1) How much can the ethical and legal requirement of informed consent be expanded and strengthened before the *socially beneficial research* done by geneticists, pathologists, epidemiologists, and other investigators is seriously impeded?
>
> (Weir and Olick 2004: 49/50, emphasis in original)

[33] Cf. for instance the recent upheaval concerning the publication of the HeLa cell line genome (Hudson and Collins 2013).

[34] Gillett explicitly states that respecting donor rights seems to impede research. We should move to a presumed consent system, justified by what he calls the 'common clinical endeavor' - argument involving the immorality of disallowing one's tissue to be used, and a 'presumption for beneficial use'- argument. Cf. also *infra* 3.2.6.

Many bioethical commentators, suspicious of the idea of stretching concepts to cover new contexts, have then asked:

(2) Can broad consent be informed consent?

As I will argue below, they focus on the abstract conceptual features of informed consent rather than the potential dis-analogies of context. The next step might be the question

(3) What is the relation between the general concepts of 'informed consent' and the value of autonomy?

Both are obviously perceived as central in research ethics across fields of application and as an underlying justification for the requirement of consent. Eventually, following this reconstruction of the debate, one might ask:

(4) What does this mean more concretely for the context of biobanks (given we can abstract?)

An analysis of the debate, however, suggests there was rather an implicit assumption that consent quite generally, if it does not promote "autonomy", is nonetheless somehow 'in accordance' with it. Broström and Johansson, for example, enlarge the perspective by asking "whether so called broad consent, where the individual authorizes research usages that are specified only in rather broad terms, may morally legitimize the relevant research." Their analysis results still in only negative assessments, presumably caused by the assumption of a continuity with an older model and its moral power which leads to the previous impasse: "And if it can, will it be able to legitimize research in the same way, and to the same extent, as traditional informed consent?" (Broström and Johansson 2011: 237/238).

The debate, in brief, is in an impasse, oscillating between informed consent as the ultimate means of protecting and legitimizing participants' and societies' moral rights and interests and hence the relative dispensability of consent (and other safeguards?) in the interest of general societal benefits.

In what follows, I first recapitulate some answers that have been given to question (2). Answering this pivotal question in the affirmative opens the possibility of acknowledging a wider spectrum of consent as *prima facie* legitimate. I do not wish to deny this as a general idea – on the contrary, it is important to be clear about why this must the case *in abstracto*. The reconstruction requires to shed some light on the epistemological and morally relevant relation between consenting, the value of autonomy and the role of provision and understanding of information (question (3)). Secondly, and more importantly in terms of the larger picture of governance, where should we move from there in a more contextualized ethical perspective? (question (4)). 'Anything goes', after all, does not seem to be the solution for the disrupted field of biobank ethics and governance. This will lead us back to reflect on the overall importance of the concept of autonomy and the primacy of consent.

Mark Sheehan, in preparing to answer his initial question if broad consent can be informed consent, defines 'broad consent' as "giving permission for someone else, usually in the form of the governing body of the biobank, to decide how to use that sample or data" in future research (Sheehan 2011: 227). This covers consent to a general framework of governance, including potentially some specific institutional values, and to a general research programme or research goals. According to Sheehan, deciding to consent broadly to participate in biobank research is perfectly analogous to many other situations in life where we autonomously refrain from making particular choices with 'full' information about the consequences, delegate decisions or even accept that a choice might lead to

future restrictions of 'liberty'. Examples of these situations reach from deciding for a dish in a restaurant, delegating the choice to someone else, or deciding to give up some autonomy for a long-term commitment such as marrying or deciding to buy a house. If these cases are all encompassed by broad consent, then they also all do seem to raise quite different scenarios, with different implications in comparison with consenting to research participation.

The first case is the most straightforward one, indeed its epistemic conditions seem to be universal: in any given context of choice, if a certain piece of information is available, it will be either relevant for me and a potential autonomous choice (that is, it must then be integrated with further requirements of autonomous choice, my values and convictions etc.); or else it is irrelevant, and will not change anything concerning my choice. Thus, having more information is always in a loose sense better than less, but nothing more can be said in general terms about how consent relates to autonomy without adding contextual considerations. Specific information, in other words, must not be 'operative' in the justification or motivation for what conceptually and intuitively qualifies as 'informed consent' (cf. Cohen 2011).

This simple observation is in line with Sheehan's *prima facie* conclusion from his assumption of analogous situations of choice in everyday life and research participation:

> On the face of it then, there is nothing in the justification of the requirement to obtain informed consent that implies that the nature of the choice must be limited or restricted. There is certainly nothing that requires only specific consent – indeed, the idea that it could require such a thing looks unintelligible.
>
> (Sheehan 2011: 229)

In fact, apart from the epistemic puzzle, i.e. – what would be truly informed consent – the limits of the paradigm of providing information as the primary enabling condition for respecting or even enhancing the consenting person's autonomy have been critically

discussed in various real-world medicine and research contexts for some time (e.g. O'Neill 2003; Corrigan 2003; Manson and O'Neill 2007; Felt et al. 2009).

Ulrik Kihlbom, for instance, argues that in many medical contexts, we should actually more correctly speak of a "negatively informed consent", and that this is also absolutely compatible – or even better – as concerns respect for autonomy (Kihlbom 2008). According to Kihlbom, in the traditional model advocated by Beauchamp and Childress, the requirement of informed consent as being in line with the exercise of respect for autonomy means that a patient is entertaining "positive belief in the methods, means and risks concerned, and that they concern what the, for example, methods amount to." Accordingly, an informed consent has been given when the patient:

> a. is competent, and
>
> b. has the capability of understanding the information
>
> c. has received information of:
>
> 1. purpose of the treatment
>
> 2. period of time
>
> 3. methods and means
>
> 4. all the significant difficulties and risks that are likely to occur
>
> 5. that the treatment is voluntary
>
> 6. that the consent can be withdrawn at any time, and
>
> d. on the basis of this information gives his/her voluntary and explicit consent to undergo the treatment.
>
> (Kihlbom 2008: 147)

Kihlbom believes that there is a general overemphasis on positive beliefs in the medical context, and that to exercise autonomy it is not necessary to "to know *how* your ends are realized, given that you have good grounds to believe that they will be realized. You might,

instead, have a number of well-founded negative beliefs, beliefs about what will *not* happen to you. The corresponding negatively informed consent has been given when the following conditions are fulfilled:

> the patient:
>
> a. is competent, and
>
> b. has the capability of understanding the information
>
> c. has received information of:
>
> 1. Purpose of the treatment
> 2. That it is possible to receive more information if wanted
> 3. That the treatment is voluntary
> 4. That the consent can be withdrawn at any time
>
> d. has well founded beliefs that the physician will choose the treatment that best promote his/her values
>
> e. has well founded beliefs that the physician will choose the treatment, the risks of which are in accordance with his/her attitudes towards different kinds of risks.
>
> f. on the basis of this gives his/her voluntary and explicit consent to undergo the treatment and express his/her voluntary and explicit wish not to have more information.
>
> (Kihlbom 2008: 147)

Instead of having been provided with knowledge and the possibility of understanding of all the likely risks and difficulties, there are the new conditions (d)-(f). If this is true and can be applied to research, we can see that a certain 'broadening' of consent, as it has been proposed for biobanks, is acceptable only when there are also adequate *relationships* that enable confidence in delegating decision-making (d). Interestingly, reformulating condition (e), we might notice some limitations in stretching the analogy between medical context and large-scale research too far: researchers will not choose research that is in accordance with his/her attitudes towards different kinds of risk, rather, the whole spectrum of different risks larger study populations might have *and* might develop as research goes on

is a limiting condition of the research undertaken. As Caulfield formulates: "We ought to use a research participant-centered approach to determine what counts as minimal risk in this context […] The question is not whether a REB[35] or a researcher believes that biobank and cohort research is minimal risk, but whether a research participant is likely to see it that way" (Caulfield and Weijer 2009: 55).

What I try to suggest here goes beyond that in that it is not only desirable – a favor, so to say – to empathize with participants and their differing risk perception, but a matter of respecting their right to a comprehensive idea of personal integrity. This means that although it can be useful to assess people's attitudes and concerns about genomic research of this kind, the results cannot justify relaxing the legal and moral standards of research protection *rights* – unless, and as I will suggest in later parts, everybody involved and that will be affected have decided this as an expression of their common will. Moreover, a positive commitment to public rather than individual and private interests– in conjunction with the negative commitment not to jeopardize individual rights – seems to entail that research decisions must be derived from a much broader basis of stakeholders and a representation of their interests.

Going back to Sheehan's analogy, the second case – the delegation of decision-making – given that there are some risks, minimally requires that my fundamental interests will be represented by somebody I can trust. However, the acceptance of 'broader consent' or some form of 'negatively informed consent', as Kihlbom's considerations show clearly, require additional circumstances to be in place, namely a "substantive patient-doctor relationship of confidence or trust" (Kihlbom 2008: 148/149). In addition, and as the author anticipates, negatively informed consent should not be misused as an easy way to withhold information. This objection is rejected on the grounds that the point is not a

[35] REB= Research Ethics Board.

concealment of information. Instead, all the relevant information must be there if wanted. As I have emphasized, this is another kind of limiting condition in the application to future-oriented research that is made possible by long-term storage of human biomaterials and related information. Equally, the ethical acceptability of condition (f) – withdrawal – in Kihlbom's scheme hinges on the *de facto* availability of information.

Generally, we can conclude that the epistemic problems in combination with the fact that a relationship of trust and confidence between participant and researcher cannot be taken for granted as the norm can undermine the ethical acceptability of at least some forms of broader consent. We should instead, such as in a Rawlsian 'original position',[36] expect reasonable disagreements about risks, harms and the benefits we envision. Yet, insofar the process of consent remains to be applied on an individual level by definition, reconsidering the potentially changing normative role of respecting autonomy in this new context is an additional step. 'Respect for autonomy', given an analogy with the clinical context, is threatened or potentially undermined, and cannot be traded off with other competing interests unless we abandon the framework of informed consent.

Nonetheless it seems intuitively clear that for the most part, an appeal to a more substantive account of autonomous agency in e.g. Kihlbom's or Caulfield's sense will play less of a role in participating in larger-scale research projects, or at least its content will probably be contentious. Is an experiment done using my donation of tissue and DNA years afterwards in the relevant sense part of an 'aspect of my life' or 'has anchoring in the person?' (cf. Law 2011: 264). But this is relevantly different from undermining the content of consent implicitly by trading off the provision and/ or availability of information with

[36] In the Rawlsian scenario, an agreement about the essential interests of free and equal citizens in a fair society must be reached by individual parties behind a 'veil of ignorance', in which every individual is unaware of their social position, endorsement of a religious, philosophical or moral doctrine, and information such as race, gender and natural endowments. Cf. Rawls 1993.

even a minimalistic and generic notion of respect for autonomy, and autonomy with risks as if they could be measured and compared in neutral, non-question-begging ways.

Let us consider again the last case Sheehan discusses as part of his analogy. While I might autonomously decide to buy a house, which will restrict my freedom of movement, the analogy to biobanking, given that there is a risk of violating the right to privacy and other important interests, shows that the analogy is dangerously flawed. Broad consent then seems to cover open consent, and the envisioned acceptable forms of consent are at least on the verge of a contradiction in terms: should it be possible to consent to a possible violation of my fundamental interests and rights if respect for and protection of my fundamental interests is made contingent on the possibility and willingness of maintaining confidentiality?

Although lack of information is endemic to situations of choice, we simply cannot conclude from a generic situation of not being perfectly informed or not being omniscient when making decisions that a very wide range of broad consent will be acceptable in the context of biobank research. In the case of marriage, the idea of consent presupposes that the terms and conditions are reasonably clear, in particular what would violate my fundamental interests in sustaining the overall endeavour, and the ensuing consequences. A case of known adultery will in various cultures be considered to at least lead to a necessary re-negotiation (cf. Steinsbekk and Solberg 2011: 238).

The case of research with tissues tied to sensitive data, however, and unforeseen research developments, is different: It will be rather unclear and maybe impossible under these conditions to determine and anticipate what would violate participants' interests, with very different interests and sensitivities. The concept of informed consent makes only sense with reference to a reasonable amount of information – subject to context – which will enable all the consenting parties to make informed decisions in line with their potentially

wide scope of reasonable interests. The contextual factors render the determination of reasonableness not only a matter of two or few people involved, and therefore, of their individual autonomy, but a matter of hundreds or thousands of people, and even future persons. For all these reasons, it is important to stress that

- generally, how consenting to any interaction relates to individual autonomy is strongly dependent on the relevant definition of autonomy and the context
- the requirement of informed consent, as conceived for the context of medical interventions with bodily risk in a situation of general epistemological confidence and/ or a trustworthy relationship between an individual patient and the medical expert, can only be applied in the research context with careful attention to the differences from the medical model; and, insofar individual autonomy is still of special relevance, to the conditions that are key to respecting it.

We should thus be careful to promote uncritically the idea that a general concept of autonomy can be considered justificatory for informed consent and also the main ethical reference in the context of research biobanks. The ethical demands that flow directly from respect for 'consensus autonomy' (that is, neglecting the contestedness of the concept and contextual conditions) are limited, though not negligible: providing participants with a reasonable amount of information, and not coercing them into donation/ participation.

A more substantive invocation of autonomy in the sense of self-determination in biobanking is not straightforward, except for turning the reference to autonomy into a dubious justification for broadening or rather 'diluting' consent requirements while narrowing down participant interests (cf. Steinmann 2009b; Karlsen et al. 2011).

As Iain Law makes clear, this 'weakness of autonomy' should not be as surprising and worrying as the debate in relation to biobanks suggests, because there are other ways apart from disrespecting 'autonomy' in which we might not live up to treating the people involved well and rightfully. Not respecting autonomy is not, at least not in any obvious

way, the only true form of all wrongdoing, in biobanking or elsewhere. If, for instance, the development of a genetic test based on donated genetic material reveals that a certain part of the donor population has an increased disease risk or risk to be affected by a particular medical condition, the putative duty to inform is not necessarily based on respect for autonomy if this was not part of the initial agreement, but could be based on a duty of avoiding harm or perhaps even a duty of gratitude (Law 2011: 267).

Which other concepts are of ethical importance then? Sheehan argues that the relevant ultimate justification for consent in the research context is not the protection from harm, rather, "informed consent most clearly functions precisely to enable individual participants to choose to take on certain risks for the sake of the possible benefits and according to their own plan of the course of their lives. Thus in research, the requirement to obtain informed consent is not primarily justified by the need for protection from harm or risk of harm, but by the requirement that we respect autonomy" (Sheehan 2011: 228). If we would really be concerned about harm, Sheehan maintains, we often would not ask people about their preferences precisely because their behavior, in particular their health-related behavior (diet, smoking, alcohol consumption, etc.), is often harmful.

These considerations, as I have tried to outline, are misleadingly reductionist, because they presuppose an analogy to general decision-making and/ or medical context individual decision-making in the interest of a substantive form of 'autonomy' which is dubious because unacknowledged and secondly suggests that there is some kind of trade-off between protection from harm (and thus, the safeguarding of fundamental rights and interests) and an empowerment of patients or research participants through this medical-context 'respect for autonomy'. Asking for consent also in biobanking would then tend to be either paternalistic or else lead to a kind of automatic empowerment through free choice.

Although it seems correct to assert that consent *functions* in the research context as a signifier of potentially free choice, this says little about the relevant moral justification in this context, and less about a function that one might deem ethically satisfactory. There is indeed a danger that this reference to 'autonomy' becomes instead assimilated only to an undefined 'free' choice, and – in case very little information is available and required for acceptable consent – to the technical possibility and willingness of researchers or managers of the institution to safeguard privacy and perhaps other participant interests.[37] This condition is only exacerbated by the fact that research is reaching out into the future. A narrow concern with free choice (or else 'respect for autonomy' uncritically adapted from the medical context) is also evident in the definition of consenting as 'giving permission of use to somebody else', which does not take into account the possibility of continuing autonomous agency that we can reasonably expect at least some people will value.

A more plausible primary justification for the requirement of a reasonably informed consent in this broader, social and dynamic context of research seems to be the following. Asking for consent is neither only a direct protection from harm nor respect for various forms of decision-making or substantive autonomy, but a general commitment to respect not only the bodily, but rather the (sphere of) personal or moral integrity of the individuals who are participating.[38] Only then, the requirement to ask for consent can enable and protect choice, including different varieties of 'informed' or 'autonomous' choice (cf. Wilson 2007).

[37] As Árnason pointed out in a critical discussion of the Icelandic database project, coding samples and asking for consent cancel each other out, leading to what seems indeed a contradiction in terms: Presumed consent. The mistake is the assumption that coding and consent can be traded off: "technical secrecy must not be confused with, and hence cannot replace, the requirement of consent. While technical secrecy protects important interests of individuals, obtaining consent shows respect for their moral status" Árnason 2004: 37.

[38] I am not attempting here to outline an ultimate justification for the requirement of informed consent or indeed the moral primacy of the value of integrity/ dignity, which might well require referring back to (Kantian) autonomy, cf. e.g. Kristinsson 2007.

We can make this point clearer by referring back to the way in which the traditional account of informed consent and the standard reference to its justification of respect for autonomy in Beauchamp's and Childress' sense continues, and in which way the genomic research perspective might have to reach beyond it. Interestingly, concentrating only on autonomy as a moral reference for biobanking can lead to radically opposed outcomes if we draw some attention to the sources of the Beauchampian model, Kantian and Millian ethics.

For a Kantian, the moral duty to act autonomously is based on the potential for rational agency residing within every human being. A truly autonomous action is one which can be equally accepted by every rational being. If the only reason for asking consent were respect for Kantian autonomy, then the requirement to obtain an actual, well-informed consent hinges on the condition of the *de facto* rationality of the consenting party. Therefore, in theory, if it could be shown that people's decisions are irrational, we might be justified in replacing standard consent with some relaxed form of hypothetical or presumed consent (Häyry and Takala 2007: 24; 26/27; cf. Häyry 2005: 646). While for a Kantian, autonomy is primarily the metaphysical aim of all human endeavour and therefore remains abstract (cf. Gracia 2012), applications of the Kantian notion are not atomistic or excessively individualistic as they would seem to presuppose agreement of the relevant standards. Even Hansson, who insists in a series of articles on the practical necessity and ethical justifiability of broad consent, has stressed the important social dimension of Kantian autonomy for the ethics of biobanks:

> Respect for people's autonomy entails […] a respect for their capacity to participate in the formulation of the moral principles that every human being would wish to endorse. Making autonomous decisions […] thus involves taking into account of the well-being of others through a judgment of how one's own decisions affect other people's ability to act in a morally responsible way and to attain their own goals […] with the implication that the working out of legal protections for self-determination and privacy in association with biobank research must

> simultaneously do justice to both the research subject's independence and to this individuals' dependence on others for fulfilling mutual interests such as new biomedical knowledge and new treatment opportunities. As a consequence, several information and consent procedures may be available, which all are legitimate. […] From the perspective of the Kantian view on moral autonomy where the individual is called upon to take also other individual's interests into consideration (for example, future members of society), it may be sufficient if there is a democratic instrument available that ensures the individual citizen insight into how the biobank is organised and that principles for balancing of interests at the ethical review boards take all relevant interests into account.
>
> (Hansson 2009: 9)

As will be argued in more detail below, these latter reflections are indeed key – rather than "sufficient" – to what should be concluded from rethinking the invocation of autonomy for an 'ethical' governance of large-scale biobanks. The conceptual and practical consequences of this, however, have not been unpacked in the bioethical debate. There is instead a significant tendency to interpret autonomy one-sidedly and without closer scrutiny for the pursuit of general social goals of 'public health benefit', and also Hansson, in my view, relies too much on technological and social 'self-organization' in this respect. Moreover, the Kantian potential to autonomous action crucially confers to subjects the status of 'end in themselves' that appears in the ethical debate as dignity and, less often, as (moral) integrity. The intertwinement of autonomy and dignity, which will resurface in the discussion concerning ownership of human tissue, might then not give rise to action-guiding prescriptions and still be of non-negligible ethical importance.

In a Millian perspective, the actual, uncoerced individual consent of people who give their tissue and genetic information to a biobank would be of overarching relevance. The stress here is more on *de facto* freedom of choice rather than on a metaphysical or actual and substantive realization of autonomy through rational action. Individuals must nonetheless be free to exercise 'autonomy' under the condition that innocent third parties do not suffer

any harm – the famous harm principle (Mill 2009). Consequently, the Millian choice must not necessarily be accepted by anybody else (cf. Häyry and Takala 2007: 24; 26/27).

2.1.3.4 The Frailty of Autonomy

The difference between these approaches is that while Millian-inspired autonomy-as-liberty is concerned with the negative but concrete function of defense against unconsented intrusion into the private sphere, Kantian-inspired autonomy has a positive and double moral function: It concerns both the proximal potential for individual rational agency as well as the distal aim of implementing self-determination as abiding by the metaphysical construct of the moral law.

We can now appreciate better why Sheehan, for example, encourages a liberist overinterpretation of 'autonomy'[39] while simultaneously downplaying the strict non-negotiability of individual, in particular minority interests in the face of external authority that Mill stresses. In contrast, I am trying to show here that according to the underlying justification and rationale of consent in the tradition of human rights, autonomy and liberty are mutually reinforcing. We should not expect that people will want to take risks in some 'common' or 'public' interest in line with their 'autonomy' ("informed consent most clearly functions precisely to enable individual participants to choose to take on certain risks for the sake of the possible benefits and according to their own plan of the course of their lives"), we must instead as default respect their will, however risk-averse, morally sensitive for various personal or cultural reasons and ignorant to vague 'possible benefits' he or she may be (cf. Steinmann 2009b: 288; Rehbock 2011: 526).

[39] In a related vein, Hofmann – in reply to Helgesson – criticizes the latters' "fallacy of confusing autonomy and liberty" (Hofmann 2008: 979).

I consequently suggest that actually the Millian consideration has a certain ('phenomenological', not necessarily moral, recalling the importance of both aspects) primacy in biobanking in comparison to a less directly social and political decision-making context affecting an individual or a small number of individuals. Also, a general reference to autonomy based on, for example, invoking the Beauchampian 'central dogma of bioethics' does not provide for more specific direction concerning the scope of consent, or other relevant ethical 'tools.' In any case though, an overemphasis on autonomy in that model could be tempered by balancing with the other principles of beneficence, non-maleficence and justice.

Overall, this reexamined reference to autonomy considers it a higher-level, and yet not secondary moral category in relation to respecting the integrity and dignity of research participants. We have, with the latter, identified a limiting condition of research uses by which one can avoid the temptation of a 'trade-off' between information provision and risk-benefit assessment deriving from the idea that autonomous choice is often less than 'perfectly' informed. While this latter informational opacity is indeed the rule rather than the exception in a wide spectrum of decision-making contexts, it does not justify disregarding or circumventing a baseline of respect in the face of donors' and research participants' values and aims, i.e. their moral integrity. This is the more basic consideration, focusing on 'negative autonomy' and liberty in the combined Kantian/ Millian model.

The higher-level and more complex consideration is that even though from this re-instated human rights perspective[40] individual interests and the protection against harm must remain crucial, at the same time, the interests of larger entities, from families, new biosocial entities such as disease communities, to ethnic and cultural groups, become

[40] Strangely enough, it is seldom explicitly appealed to in the bioethical literature on consent. See, however, the more legally and politically informed debate in Andorno 2007; Brownsword 2003, 2007a, 2007b, 2009, 2013; Harmon 2009, and Meslin and Garba 2011.

important in genomic research. Part of respect for participants' dignity and a pre-condition for enacting autonomous agency is attendance to potential *moral* harms (which we might call wrongs) which certain kinds of research, methods or collaborations could inflict on research participants (cf. Beskow 2001; Andrews 2005; Eriksson and Helgesson 2005; Malinowski 2005; Rothstein 2005; Elger 2010; Sterckx and Van Assche 2011).

This has been shown compellingly for instance by the case of the Havasupai Indian tribe, which concerns the question of the scope of consent for future, and possibly unrelated use given initial considerations and possible ethnic discrimination. Researchers of the University of Arizona used the Indians' blood samples and their findings were in disaccord with what the tribe had believed to be the main disorder to be studied – diabetes. The samples were indeed also used to study schizophrenia and inbreeding, which raised severe concern of possible stigmatization.[41] Nonetheless, moral harm is frequently neglected or even downplayed by a majority of commentators, in particular in favor of 'informational' risks.

In short: "The potential donor must have the opportunity of ascertaining whether the proposed use of the material for research is contrary to her moral values" (Sterckx and Van Assche 2011: 255).[42] Groups can be wronged if 'used' for research due to being in a position of weakness or limitations in being able to show disapproval and also, as Eriksson and Helgesson remind, "when treated *unjustly*, if they are systematically excluded from the benefits of research" (Eriksson and Helgesson 2005: 1073).

Clearly, the traditional ethical horizon around informed consent instead focuses on 'visible' risks, harms and benefits to identifiable individual research participants. But even

[41] In addition, research uncovered facts concerning the origin of the tribe contradicting their traditional ancestral story. Revelations about these unanticipated uses lead to a $50 million law suit, settled partly successful for the tribe members in 2010 (Havasupai Tribe v. Arizona 2004; Mello and Wolf 2010; Beauchamp 2011).

[42] Sterckx and Van Assche also propose a coding system allowing for stratified research use, e.g. for inclusion/ denial of commercial use (Sterckx and Van Assche 2011).

though non-physical, in particular informational harms such as misuse of data and/ or psychological and economic harm due to genetic discrimination or stigmatization are discussed, however, less so the important larger social consequences this could incur. For example, genomic research tends to be organized around perceived susceptibility to particular conditions. This can lead to a reinforcement of stereotypes and stigmatization or discrimination even when disease risks for a particular individual turn out to be very low (cf. Beskow et al. 2001: 2318). While this is a point that concerns genetic and genomic research generally, I want to stress how the organization of long-term research resources is proceeding without sufficient attention to both individual *and* group interests.

Again, we face a large degree of uncertainty and also what could be termed 'invisibility' of the risks, harms and benefits in biobank research which seem to point beyond relying solely or primarily on informed consent. I have argued that rather than trying to unravel these challenges towards a more conclusive normative proposal, a significant part of the bioethical discussion is more or less directly reducing participant rights and interests via reference to 'autonomy' to a vague idea of choice for an almost equally vague research benefit in the public interest. Before discussing how research participation could include also possibilities of the more positive autonomy that should remain at the core of ethical research governance, we will have to understand better how the concept and requirement of consent interacts with the idea of protecting confidentiality and privacy in healthcare and research, and how this relates to the large conceptual domain of potential ownership interests and rights in tissue, genetic/ genomic information and research data. Thereafter, I will revisit the issue of appeals to public goods and interests as a justification for curtailing individual rights and interests. This, in turn, will make it possible to clarify how the observable deflation of consent is to be evaluated and might, perhaps, be overcome.

2.2 Confidentiality and Privacy

2.2.1 The Peculiarities of 'Genetic Privacy'

As part of the respect for persons protected by the requirement of informed consent, information about the research participant or tissue donor is to be kept confidential and 'private' unless the source of the information consents to its divulgence. Via consent, a donor or participant should be enabled to choose if he or she wants to accept the risks to privacy that might be entailed.

While in general personal data may be processed for research purposes according to the EU Data Protection Directive (if the processing is technically secure and will be limited to a specific purpose), the processing of personal health data requires a person's specific consent (Data Protection Directive 1995; Bovenberg 2006). This requirement, however, is subject to important qualifications, in that processing for research in the public interest or an undue burden on part of the researchers exempt from asking for consent. Nonetheless, if consent is required in the standard scenario, one would expect that the data subject is provided with sufficient information to understand what kind of data will be passed, to whom, as well as the purpose for which data will be processed (cf. Shickle 2006).

How the application of the various legal and conceptual categories of privacy, confidentiality and personal data anonymization and coding applies to biobank research with its specific scientific needs is an intricate matter. Though there is large spectrum of terminology applied to the various forms of coding and anonymization of data and samples, it seems that the existing legal categories do not map the complexity of genetic/genomic information, or rather, the demands of confidentiality and privacy as well as scientific needs (Bovenberg 2006; Elger and Caplan 2006; Beyleveld 2007; Elger 2010).

A DNA sample is always potentially identifying, depending on access to other samples or information from other repositories (Lowrance and Collins 2007). In most cases, there will be some form of coding or reversible anonymization. This, however, leaves open if the data-sample thereby should become 'personal' and if the term 'anonymization' can still be used in a coherent way, i.e. such that it would represent the technical and institutional facts, as what is 'anonymous' depends on who has legitimate access to a code and/or dataset.

Thus, while there is a strong tradition in most countries of medical confidentiality and the more general right to privacy considered an unquestionable achievement of democratic and liberal societies,[43] genetic information – as sample and/or data – still sits rather uncomfortably between the traditional categories of confidential information in the small-scale medical context and the technical possibilities that genomics makes use of in the name of public health. Condensed:

> Paradoxically […] it is the development of a public interest in the welfare of individuals that has proved to be one of the greatest threats to individual privacy in the last century. […] The provision of health care is of primary importance among these; […] Hence, while individual interests are given more importance in democratic communities, public interests are, at the same time, afforded greater weight.
>
> (Laurie 2004: 9/10)

The extent to which genetic information indeed should be considered *sui generis* has been discussed extensively. The thesis of a so-called "genetic exceptionalism" has by now lost appeal for most commentators, but it would still seem reasonable to insist on the

[43] "ARTICLE 8. Right to respect for private and family life: 1. Everyone has the right to respect for his private and family life, his home and his correspondence. 2. There shall be no interference by a public authority with the exercise of this right except such as is in accordance with the law and is necessary in a democratic society in the interests of national security, public safety or the economic well-being of the country, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others" (European Convention for the Protection of Human Rights and Fundamental Freedoms).

peculiarity of genetic information due to a number of factors combining genomics and technology: From minute samples large quantities of stable, predictive information of potentially supra-individualistic relevance can be derived, and the location and uses or misuses can be exceptionally hard to pinpoint in digitalized contexts (cf. Manson and O'Neill 2007; Casado da Rocha and Seohane 2008; Krajewska 2009).

In addition, the specifications of the confidentiality and privacy envisioned by traditional policy and law are rather vague and notoriously heterogeneous. Graeme Laurie summarizes that the traditional duty of medical confidentiality is inapplicable to the contemporary health care and research contexts. The duty is "amorphous and ill-defined" and "compromised by its twin roles of protecting both the confidential relationship and the confidential information which arises from that relationship. Moreover, to the extent that the duty of confidentiality is solely concerned with keeping confidential information out of the public sphere, it says nothing about the duties that might be owed within the confidential relationship towards the subjects of the information so as to ensure, inter alia, that the personal interests of these individuals are not treated with a lack of respect by unwarranted uses of information with regard to the subjects themselves" (Laurie 2004: 3).

There is also little agreement on the notion of "privacy" that would allow for straightforward guidance in relation to biotechnologies. Laurie distinguishes at least two senses of privacy, the more commonsensical idea of 'spatial privacy' as a "state of non-access to the individual's physical or psychological self" and 'informational privacy', as a "state in which personal information about an individual is in a state of non-access from others" (Laurie 2004: 6). Manson and O'Neill, within their theory of rethinking informed consent in bioethics, advocate a diverging interpretation of informational privacy as "requirements on communicative transactions, rather than as requirements that certain types of information be kept inaccessible" (Manson and O'Neill 2007: x; Chapter 5).

Alongside informational privacy and local privacy we might consider a third basic category of 'decisional privacy' – concerning all 'private' actions and decisions e.g. choice of lifestyle (Rössler 2001). Since privacy is determined by cultural and social context and sensitivity of genomic information is relative, it must be decided within a particular context what exactly is of only private interest, which in turn can have implications for the specificity of the requirement of consent (cf. Ursin 2010a; 2010b).

Which forms of 'confidentiality' and 'privacy' are at stake for a subject participating in a biobank project, even disregarding the issue of as how sensitive genetic information should be classified? Data protection legislation concerns mainly the technical and institutional security of information and therefore *prima facie* informational privacy. Yet, it is not obvious that not also 'spatial' or 'decisional' privacy are of moral importance in this context. While subject to exceptions of public interest or, respectively, public health (e.g. in the case of an epidemic), the human right to privacy as applied to healthcare and science is much wider than the concept of confidentiality, involving clearly spatial privacy to protect the whole of 'private life'. Undoubtedly then, anonymization and confidentiality cannot protect this wider-dimension privacy (cf. Laurie 2004: 243).

At the same time, the right to privacy remains elusive and under-specified in regard to use of samples in biomedical research. This leads to a curious situation in which there is, as some authors suggest, somehow both too little and too much 'privacy'. Despite the fact that data protection legislation is very strict, it might not be appropriately equipped to face the moral and technical challenges of protecting personal interests in genomics, because it merely distinguishes between 'anonymous' data and sensitive personal data, so that the actual research use in which there is an overlap of sensitive and 'normal' data and which requires linking and sharing of personal data is not envisaged (cf. Laurie 2004: 296; Bovenberg 2006; Sándor et al. 2012; Santosuosso 2013).

To overcome the problem of overprotection vs. no or merely 'formal' protection, these conditions need to be appreciated. Accordingly,

> the systemic post-genomic approach suggests that the reason for protecting subjects donating samples for research is not that their DNA is a 'future diary', […] but that, in order for samples to be meaningful, the data extracted from them must be linked with other sources of information. […] the need for ethical safeguards, so that the confidentiality and integrity of this information can be respected, remains as high as ever, and so does the concern with social stigmatization or discrimination by employers or health-insurance companies […].
>
> (Casado da Rocha and Seoane 2008:443)

A more useful concept to connect technical with deontological aspects might be "informational self-determination", which hints to a parallel or overlap between the sphere of 'privacy' and that of 'autonomy' (cf. McLean 2010; Taupitz and Weigel 2012).[44]

As a consequence of this overlap, the application of general confidentiality and data protection frameworks to govern biobanks to some extent mirrors the one regarding the requirement of informed consent. Beneath the surface, even the general concepts are strongly contested, and it remains uncertain if the practice of research and the advancement of technology is not stretching the concepts to its limits. Again, this is true in terms of the potential long-time effects of research participation and the seemingly diminishing role of individual rights and interests, as genetic information is not only relevant for an individual source. On the other hand, the protection of the private sphere of autonomy of a tissue donor or study participant is the indisputable priority according to the human rights-based fundamentals of traditional research ethics.

[44] Informational self-determination is part of the personality rights protected by the German constitution. Ingrid Schneider mentions recent efforts to spell out this concept as a right to 'bio-informational and bio-material self-determination'. Cf. Schneider 2008.

2.2.2 Exceeding the Private?

The challenges to accepted wisdom concerning confidentiality and privacy in the evolving biobank infrastructures can perhaps best be illustrated by the parallel trend of personal genomics companies, genealogical databases and ancestry tracing which have been flourishing in the last years. These developments have an impact on trends in research, though it is unclear if it will be favorable (cf. Kaye et al. 2010). People are providing voluntarily personal information to this services, to an extent that it has been anticipated that future healthcare will come to rely on these 'health information altruists' (Kohane and Altman 2005).

In both areas – 'public' research and direct-to-consumer services – larger and larger amounts of fine-grained, digitally stored individual-specific information is generated with the costs of sequencing falling and increasing use of whole genome methods (Kaye et al. 2010; Kaye 2011; 2012; Presidential Commission for Bioethical Issues 2012). These 'big data' cannot be assumed to remain within narrow areas of use and within national borders, which has created concern that privacy governance frameworks will be unable to keep pace with the developments of disappearing boundaries in cloud computing and the phenomenon of 'converging technologies', as parts of the traditional public health registries are digitized and linked to biobanks, including emerging platforms of e-health which can provide a wealth of potential sources to be mined (Tavani 2004; Majumder 2005; Mandl and Kohane 2008; Schadt 2012).

It is also becoming easier to draw conclusions about the origin of de-identified samples, a topic that has drawn considerable attention by the public and appeals for action by prominent scientists (McGuire and Gibbs 2006; Lowrance and Collins 2007; Homer et al. 2008; Gymrek et al. 2013; Rodriguez et al. 2013; Bohannon 2013; Brenner 2013). As

absolute anonymity is illusory, some commentators have also insisted on the need to think about potential misuse of data by people "with scurrilous motives" (O'Brien 2009: 201).

A related concern that has been observed critically, e.g. in the UK, is the expansion of forensic DNA databases (cf. Brownsword 2007b; Campbell 2007; 2009). What would happen if research databases were to merge with databases initially established for other ends is not a science fiction or merely scholastic scenario, since there have already been instances of using data obtained in a research context to convict suspects. For example, in the 2003 case of the murder of the Swedish Minister of Foreign Affairs, Anna Lindh, a research biobank provided the police with information to identify the culprit (Campbell 2007: 238; Wendel 2007: 115).

Sharing of data in voluntary form, in any case, is a crucial part of the philosophy of Personalised Medicine, and increasingly encouraged by funders. One can speak of an emerging norm that data are to be shared to enable data-driven medicine (Kaye et al. 2010; Knoppers 2010; Fortin et al. 2011; Friend and Norman 2013; Larson 2013).

Yet, it remains unclear if and to what extent different kinds of coding, especially in case there will be a rise in interoperable and interconnected systems with uses beyond direct-research or treatment contexts, will prove reliable and can be effectively harmonized internationally. It has already been proposed to eliminate the terms "anonymized", "anomymous" and "non-identifiable" altogether in particular from policy documents to avoid misleading the public about the viability of these differentiations and the possibilities of sustaining perfect anonymity (Schmidt and Callier 2012).

Governance reactions to these developments in relation to consumer-oriented genomics focus on self-management rather than top-down regulation limiting the willingness of "health information altruists" to share and which also biobanks might have to rely on (cf. Kohane and Altman 2005; Editorial Nature Genetics 2013). As a consequence, the

implementation of 'open data', it has been claimed, must be coupled to open consent. The initial consideration towards this turn is the abandonment of traditional views on confidentiality and privacy:

> Transporting the traditional idea of confidentiality into the protocols of large-scale genomics research and biobanks, is misleading. The accessibility of data in a databank will become the endpoint of a chain of unsustainable promises of privacy and confidentiality that once started with the Hippocratic ideal in mind, in a doctor's office.
>
> (Lunshof, Chadwick and Church 2008: 2)

The concept and promise of absolute anonymization should be dropped since it cannot be guaranteed and also for moral reasons, as it precludes re-contact of research participants for potentially significant future personal medical discoveries which might benefit them. Consent forms, in view of that, should explain that confidentiality will be sincerely attempted but cannot be guaranteed (O'Brien 2009: 205).

As we have seen, some authors anticipate that this state of affairs has mainly positive effects, relying on technical possibilities, the regulation of third party access, as well as the belief that dangers of data misuse should not be exaggerated. In this vision, the post-genomic approach to privacy can, in contrast, help to demystify genes and their supposed deterministic relation to the prevalence of common disease (Knoppers 2010; MacLeoad, quoted in Ursin 2010a). Changing to open consent would be momentous, but then again it seems to be implied in biobank research almost by definition given that it must violate the traditional idea in data protection of trying to avoid data accumulation (cf. Data Protection Directive 1995).[45]

Overall, there is an evolving pressure in the ethics and governance fields to reassess the pre-eminence which had been accorded to privacy and personal autonomy, in particular as

[45] This principle is also known as "data reduction" or "data minimization", cf. Beier 2010.

smaller and larger-scale genomic research and genetic testing can be assumed to be converging to some extent. This has first been articulated in the area of small-scale family genetic testing and in relation to emerging 'duties' of information sharing and the ensuing discussions on the 'right to know' vs. the 'right not to know'. On this background, community-oriented or 'communitarian' notions challenging individual privacy have first been reintroduced (cf. Sommerville and English 1999; Callahan 2003; Laurie 2004).

The ethical demand – besides the acknowledgement of the both individualistic and supra-individualistic interests touched upon – seems to be a functional conceptualization of the *aim* of privacy protection in research. While guidelines applied to biobanking make reference only to general coding and information policies, bioethicists and legal scholars are refocusing their normative accounts. A corollary of the community-orientation applied to these issues is the relativization of privacy advocated for example by Helen Nissenbaum as 'contextual integrity', guided by norms for different areas of life – one of the problems, however, seem to be a converging of contexts of use to which data subjects might not have the chance to transparently agree on (Nissenbaum 2010).

There is also a more general renewed attention to the factors sustaining the relationships and forms of communication that protect a sphere of privacy rather than the other way round, by conceptualizing 'the private' as a technically manageable, abstract object (Manson and O'Neill 2007; Ursin 2010a). This latter view leads to a thin notion of 'privacy' as mere data protection. In contrast to the enthusiasm of some authors with respect to a future of 'health data altruism' in a social network style, legal commentary has been wary of these developments as they might imply reducing the persons involved to 'pure information' or what might be called 'data persons' (cf. Laurie 2004; Tallacchini 2005; Simon and Robienski 2010; Macilotti 2013).

This ‘informational human being’ or in Personalised Medicine perhaps primarily ‘statistical’ human being is in stark contrast to the respect for *persons* underlying the traditional consent norm, which would seem to entail a form of decisional privacy, or so I will argue. Nonetheless, the challenge for research on tissue is how to spell out what might be needed for a more substantive version of privacy than what is achievable through technical fixes, without leading back to traditional or even stricter forms of consent. The latter, as I have suggested, do simply not capture scientific and technological reality, and neither are adaptable to individual and supra-individual rights of research participants as potential future patients with the need to access genomic information.

Graeme Laurie’s position – to which we will return in due course – is that a paradigm shift might be initiated by exposing the weaknesses of the medical context notions of confidentiality and privacy, and strengthen them with aspects of the rights that ownership and property confer. This view, however, is not the most obvious route to follow, also owing to a strong tradition of altruistic donation of human bodily materials the main tenets of which will be introduced in the next section.

2.3 Ideals of Altruism and Non-Commercialization

2.3.1 The ‘Gift of Life’ and the Tissue Economy

The transfer of bodily material in the medical area has traditionally been surrounded by a strong normative discourse of gift giving, personal altruism and social solidarity. This is most spelled out in the so-called ‘transplantation model’, meaning that in particular solid organs should be isolated from any associations with market commercialization, while the

voluntary, uncompensated 'gift' of an organ to a stranger is valued as a virtuous act (cf. Marshall et al. 1996; Tutton 2004). This idea is – in general terms – codified in the law of many countries, in that human body parts, as a matter of human rights, shall not be traded, and in particular not be sold in their natural form:

> Chapter VII – Prohibition of financial gain and disposal of a part of the human body
>
> Article 21 – Prohibition of financial gain
>
> The human body and its parts shall not, as such, give rise to financial gain. [46]

A similar formulation can be found under Chapter 1, relating to the protection of human dignity, in the Charter of Fundamental Rights of the European Union:

> Article 3
>
> Right to the integrity of the person
>
> 1. Everyone has the right to respect for his or her physical and mental integrity.
> 2. In the fields of medicine and biology, the following must be respected in particular:
>   - the free and informed consent of the person concerned, according to the procedures laid down by law,
>   - the prohibition of eugenic practices, in particular those aiming at the selection of persons,
>   - the prohibition on making the human body and its parts as such a source of financial gain,
>   - the prohibition of the reproductive cloning of human beings.[47]

The model of the gift for life and, related to this, altruistic participation in research, is inspired by a long tradition of separating the commercial from the morally pure – for instance in Christian thought – and has been adhered to in modern healthcare systems, in particular the European ones which are largely sustained by public money. This framework

[46] Convention on Human Rights and Biomedicine [Oviedo Convention]. The second article in this chapter of the Convention is dedicated to consent. The interesting conceptual relations between these two articles are investigated in section 3.3.3, *infra*.
[47] Charter of Fundamental Rights of the European Union.

is bound to particular norms and societal expectations, as Steinmann recalls, as "we do not give our organs or our blood to just anyone, but only to those in need, and we presuppose that those who receive our gift are really those who need it most. Altruism is a moral concept that entails a certain obligation we feel towards others" (Steinmann 2009a: 1). While an expression of free, uncoerced and virtuous agency, there is an unspoken expectation that the well-intentioned gift will be reciprocated with respect, at least as much as physical risks are excluded, and the will and wishes of the donors are taken into account (cf. Steinmann 2009a).

A common reference undergirding this discourse that is also brought up commonly in relation to the more recent development of burgeoning tissue banks and genomics is Richard Titmuss' influential 1970 study "The Gift Relationship: From Human Blood to Social Policy". Titmuss, starting from concerns about the impact of increasing 'marketization' of health care systems, compared different aspects of two blood 'donation' schemes: the British system, based on voluntariness and altruism, and the US American, which involved commercial aspects. His aim was not only a socio-political study, but also to draw more general conclusions concerning the concept and function of altruism in healthcare as well as the overall societal effects of different 'donation' schemes. Both the moral and practical implications of a market approach to the provision of blood for healthcare purposes are devastating in Titmuss' analysis. The influence of financial compensation and market thinking devalues the altruistic gift, which is also an important factor of social cohesion. Moreover, the altruistic system also results as superior in terms of blood quality, and under considerations of safety, efficiency, and cost (Titmuss 1997).

According to a recent discussion by Peter Sýkora, however, it has been shown empirically that both a commercial and a non-commercial approach of blood provision can result in misadministration, contamination and inefficiency (Sýkora 2009: 21). He also points out

that although Titmuss is referred to as the main proponent of an altruistic tissue and transplantation system, what he seems to have actually intended is charity, independent from the reciprocity of whatever indirect or implicit kind that is attached to gifts and donations (Sýkora 2009: 38).[48]

Notwithstanding these ambivalences, general non-commercialization and pro-altruism policies exert a strong appeal in policy and public debate, as witnessed for instance in the Nuffield Council report "Human Tissue. Ethical and legal issues" of 1995 and the recent Nuffield Council-commissioned report on the concept of solidarity in bioethics (Nuffield Council 1995; cf. Indech 2000; Prainsack and Buyx 2011). While defenders of quasi-unlimited accounts of personal rights of autonomy and liberty have always considered these policies on the verge of a paradox if not immoral – in particular as the scarcity of donor organs is increasing[49] – there are clearly strong deontological and consequentialist considerations in support of these policies. Besides safeguarding the dignity and autonomy of the person, rewards or incentives for tissue donation or research participation were generally outlawed in order to ensure that no coercion or pressure was put on the volunteers. This could undermine the quality and validity of consent by way of, for example, concealment of health risks, a consequence that might disproportionately affect poor and disadvantages sections of the population, which in turn could skew the population of donors considerably (cf. Schneider 2010: 168/169).

Evidently though, the last decades have seen an expanding process of market mechanisms entering more and more sectors of life (cf. Sandel 2012), and in science and research there is a steep increase of corporate forms of research and merging of public university sector research and private enterprises (Nelkin and Andrews 1998; Rothstein 2005; Waldby and Mitchell 2006). This is particular apparent in the United States, with, however, 'spill-over'-

[48] Indeed reciprocating the 'gift' of an organ such as, for example, a kidney, seems impossible to fulfill. Cf. Marshall et al. 1996.
[49] Cf. for example Taylor 2005, who argues for a market in human organs.

effects in Europe (Geuna and Nesta 2006). The boom of biotechnology industry from the 1970s onwards lead to some keystones in policy which enabled and incentivized universities to seek commercialization and protection for their research through patents. There has been a large extension of entities considered patentable including genetic sequences[50] and even whole organisms since the case of *Diamond v. Chakrabarty* – concerning the patent on an engineered micro-organism, leading to the proclamation that 'anything under the sun made by man' is patentable subject matter – decided by the US Supreme Court in 1980 and the *Bayh-Dole Act* of the same year, which allowed patents on federally funded research (cf. Malinowski 2005; Sampat 2006; Williams-Jones and Ozdemir 2007). As for genomics, the Human Genome Project preceding the establishment of systematic biobanking efforts is indeed a case in point, as a public and a private enterprise were competing fiercely for the sequencing and patenting of the research involved (Sulston and Ferry 2002).

More generally, the hunger for tissue that has been observed (cf. Anderlik 2003; Womack and Gray 2009) finds a sociological counterpart in descriptions of the life science industry as "tissue economies" and "biovalue" (Waldby 2000; Waldby and Mitchell 2006), and even the constitution of post-genomic life in its entirety as "biocapital" (Sunder Rajan 2006).

Waldby's and Mitchell's tissue economy "is a system for maximizing this productivity, through strategies of circulation, leverage, diversification, and recuperation" of tissues donated for the benefit of the health of others which where once "biological substrate of the self, the condition of viable human life" (Waldby and Mitchell 2006: 31). A particular characteristic of the tissue economy as a systematic pursuit is that it is infused with manifold, overlapping and morally charged connotations and valuations, such as a 'use

[50] The pervasiveness of sequence patents of the human genome – though not the overall effect on innovation – is well documented, cf. Rosenfeld and Mason 2013 and Graff et al. 2013.

value', relating to health purposes and saving lives, social values such as the creation of trust, inclusion, and equity, but also the commodity value of objects with a market price (ibid.).

Sunder Rajan's 'biocapital' similarly refers to "circulations of new and particular forms of currency, such as biological material and information" (Sunder Rajan 2006: 17). 'Tissue economies' in particular in the form of genomic research epitomize features of the bioeconomy and informational economy in that they aim to not only represent, but to *conceive* of life in informational terms according to Sunder Rajan. On the one hand, this occurs through a paradoxical "materialization of information, and its decoupling from its material biological source (such as tissue or cell line)" (ibid.) and on the other hand through a valuation of the "felt possibility of *future* productivity or profit" due to the generation of large amounts of data that could all potentially be very valuable in terms of both therapy and profit. These phenomenon also explains the overarching importance of intellectual property and the desire of strong patent protection as part of the philosophy of Personalised Medicine (Sunder Rajan 2006: 16/17; 42/43).

While increasing need of patentability and the potential for profitability of life science research have generally been accepted as an inevitable standard form of innovation policy, at the margins there has been moral upheaval that sometimes engaged the wider public. The patentability or non-patentability of basic research (tools) such as sequences, whole organisms (the *Oncomouse* case) and applications for diagnostics (*Myriad*), for example, have led to long-term lawsuits, in particular in the US (cf. Nwabueze 2007; Graff et al. 2013). In Europe, which allows for moral or 'public order' considerations to preclude patentability, there is an ongoing controversy surrounding stem cell patents and their potential immorality (cf. Caulfield and Ogbogu 2012).

Tissue banking and indeed the 'tissue industry' came into renewed focus in the UK in 1999 with incidents of unconsented removal and storage of deceased children's organs at the Alder Hey Royal Liverpool Children's Hospital and the Royal Infirmary in Bristol (Mason and Laurie 2001; Parry and Gere 2006; Nuffield Council 2011).

While these cases *prima facie* engage rather with the issue of consent and the moral interests and rights of donors, patients and research participants, questions connected to 'appropriate' research uses including patentability of potential research products and use for commercial research are closely related. A famous case engaging all these themes is also the one of the HeLa cell line (Holm 2006; Skloot 2010; Feldman 2011; Hudson and Collins 2013). The indignation raised by these known mistreatments and moral controversies testify a multiplicity of values attached to human tissues between scientific-clinical and personal cultural views (cf. Schweda and Schicktanz 2009), and some authors state a general crisis of public trust in relation to bioscience as a consequence of these developments and incidents (Nelkin and Andrews 1998; Laurie 2004; Parry and Gere 2006).

The US have also seen a number of lawsuits touching upon the issue under which circumstances potential property rights in tissues derived from the public and 'donated' should be considered to be given up. The paradigmatic case concerning a potential exploitation of 'sources' remains *Moore vs. Regents of the University of California*, in which property figures both as a form of innovation policy, but also brought again attention again to the question if individuals can *de jure* own 'their' bodily material and which legal and philosophical concepts should guide these decisions. The plaintiff John Moore was a patient diagnosed with hairy-cell leukemia. During the long course of his treatment, researchers observed peculiarities in cells derived from his spleen, from which they developed a cell line. Moore, however, was not aware of these developments. When it

turned out that the cell line was to be patented and seemed a very promising investment, while Moore was asked to relinquish any further interest in his tissue via consent, he became suspicious and brought suit against the researchers for conversion[51] to protect possessory interest in what he claimed his personal property.

However, Moore was eventually not granted a property right in the tissues which had been used in the research. He could, for one thing, not share in the researchers' profits. It was reasoned that giving rights of this kind to Moore would be inconsistent with the patent. Moreover, the court stated that recognizing a property right in excised cells was not elementary to protect a patient's privacy interests. It was recognized, nonetheless, that the researchers were guilty of breach of fiduciary duty and improper procedure of informed consent models, which would have required full disclosure of the economic interests of the researcher and all facts that could be in conflict with their professional responsibilities.

Interestingly, it was indeed recognized that the case made by Moore for a property right in his biological material engaged more fundamental matters and so was better suited to legislative than to judicial resolution. But even so, many commentators have argued that research subjects should not be compensated in cases of this kind, because the researchers, through their work only, create a marketable product, while Moore had not invested these efforts leading to improvement (that in particular intellectual property requires) and that any property would depend on the investment of creative labor of this kind. One might contend, yet, that Moore had had a property right *before* the cell line was developed, and that consequently he should have been compensated for his contribution to the development of the specialized cell line by indeed providing its basic ingredient (cf. Boyle 2002; Sethe 2004).

[51] "Conversion" in common law refers to wrongful acts towards things deemed to be inconsistent with the ownership rights of the person holding title to it.

The line of reasoning sustaining the abandonment of tissue by donation and the creation of property interests by scientific work prevailed. The overall effect of the decision in *Moore* has been a strong presumption that patients, when they voluntarily dispose of parts of their body, forfeit any further interests in these, even in case the purpose for which they are used is not or not adequately disclosed to them (cf. Moore v. Regents of the University of California 1990; Laurie 2004; Nwabueze 2007; Price 2010).

Other high-profile cases illustrating different aspects of property issues related to human tissue in material form and genetic information are *Greenberg* and *Catalona* that will be briefly reviewed. In *Greenberg vs. Miami Children's Hospital*, a group of families and non-profit institutions founded the Canavan disease (a neurodegenerative disorder) registry, recruited tissue donors and provided substantial funding for research into the genetic causes of the disease, entrusted to a particular researcher. The researcher indeed isolated a particular gene and filed for patent protection of the sequence and applications. His institution also began negotiating exclusive licensing agreements and charged high royalty fees, and thereby restricted the public accessibility of Canavan disease testing which the donors and funders had envisioned. The Greenbergs sued for conversion and unjust enrichment.

Again, no property interest for the body tissue and genetic information voluntarily transferred without, as was reasoned, expectations of return was considered. Yet, it was observed that in this case clearly the investment of time, work and financial resources applied equally to the patient group which seemed to entitle them to some compensation. In the end, a claim for unjust enrichment was indeed upheld, at least partly redressing the inequity between patient group and the researchers (cf. Greenberg v. Miami Children's Hospital Research Institute 2003; Weir and Olick 2004; Bovenberg 2005; Hoppe 2009).

In *Washington University vs. Catalona*, the U.S. District Court for Eastern Missouri decided against patients seeking control over tissues that they had donated to William Catalona, a urologist who was formerly at Washington University. Catalona had, through decades, accumulated a large tissue collection for research, including over 4000 prostate samples and 250.000 blood specimens from approximately 36.000 men. These specimens were collected under informed consent, and stated explicitly that "participation is voluntary and you may choose not to participate in this research or withdraw consent at any time."

When Catalona wanted to move to another institution, he informed the patients of his plans and requested permission to relocate the samples. Several thousand of Catalona's patients demanded the samples to be released from the university for transfer. Washington University, however, refused with the justification that the collection had been maintained with university funds. The subsequent lawsuit resulted as in *Moore* and *Greenberg*, by confirming that patients had relinquished their rights to the samples (cf. Andrews 2006; Schmidt 2006; Piccolo 2008; O'Brien 2009).

All these cases, limited though their function for guidance in other settings and jurisdictions may be, converge on the position that tissue, voluntarily transferred to a research project or institution, will become property "by mere reduction into the possession of a third party" (Price 2010: 253). The question if property for the sources existed before it 'emerged' in a research or clinical context, is not addressed in depth by the courts, in which policy arguments rather than moral or conceptual considerations seem to prevail.

A number of commentators criticize that the denial of property rights to 'donors' in these common law cases amounts to the application of a double standard, asking if it is fair that original tissue sources remain without compensation for the profits that could be reaped from 'their' tissues (Boyle 2002; Laurie 2004; Bovenberg 2005; Waldby and Mitchell 2006; Campbell 2009; Steinmann 2009a; Schneider 2010). Tissue donors, however, are not

only excluded from financial reward, but also of control about the body material and genetic information. There is a perceived conflict between sufficiently protecting donors' interests and the efficient running of the various services which depend on human material.

A more general notion for this phenomenon might be called the *asymmetry thesis*: there can be asymmetries in terms of reward or commercialization 'downstream' (cf. Schneider 2010), which are fostered by a moral double standard in terms of 'investment', but the perhaps more decisive asymmetry is one of control and power. For some, Titmuss' social equity programme of anti-commodification and anti-commercialization has accordingly turned into a rather dubious practice:

> Effectively, his strategy to make the human body a bulwark against the commodification of social life, a strategy now institutionalized in bioethical procedure, has simply rendered the body an open source of free biological material for commercial use.
>
> (Waldby and Mitchell 2006: 24)

Alastair Campbell asks if "this not a hypocritical appeal to an altruism which only one party to the transaction is expected to adopt?," realizing though that "Any answer to this question must deal with the central issue of whether, even if my body parts are – in some senses at least – my property, they are also correctly viewed as tradeable, that is, as commodities in a market" (Campbell 2009: 16). This ambivalence is hindering straightforward answers to the moral, legal and policy matters involved, specifically as concerns the material, original 'sources'.

2.3.2 Redrawing the Boundary

Reconsiderations of the altruistic expectation and a rhetoric of gift-giving start from emphasizing the profound changes medicine has undergone in the transition to

contemporary biomedicine. Though not all biomedicine is tied to 'big business', in particular pharmabusiness, it seems that "developments in genetics have brought this characteristic to the forefront, and gradually our hopes and dreams in medicine are linked up with the rather expensive promises of genetics" (Simm 2005: 34).

As will be explored below, in biobanking, the appeal to solidaric donation remains very strong, but there are also voices who have relativized the strict dichotomy that has traditionally been drawn between the commercial and non-commercial spheres. One striking example is the recent update of the Nuffield Council report on donation of human bodily material for medicine and research, which speaks of the "increasingly 'transactional' nature of dealings concerning the human bodily material" (Nuffield Council 2011: 64), including not only circulation of tissue for various therapeutic and research purposes worldwide, but complex layers of technical and institutional intermediaries.

Indeed the dis-analogies between transplantation contexts and modern bioeconomies and a crucial feature on which Titmuss' vision of solidarity relied do not apply in the latter: donation for a single, clearly defined purpose, helping or saving another person's life directly by virtue of the donated tissue.

Biobanks cannot respond to the moral commitment of donors because their purpose is scientific, not moral, and the recipients are not suffering individuals, or only in very indirect ways, but researchers. Perhaps, Steinmann reflects, 'gift' and 'donation' is just the wrong category to refer to in the case of genomics, because there is no serious sense in which one can "'donate' to something as impersonal as the general progress of science" (cf. Steinmann 2009a: 1/2).

The mentioned Nuffield Council Report now takes a much more reluctant position on the moral (or rather pragmatic?) necessity of keeping the spheres of altruism and solidarity apart from propertization and commercialization. The suggestion seems to be that the

importance of altruism and solidarity are somehow tied to *identifiable* benefit of particular persons:

> Donation for research purposes may differ in important ways from donation for treatment purposes. While both forms of donation seek to benefit others, the contribution that any one research donor or healthy volunteer makes to the health of any other identifiable person is exceptionally hard to pin down. A move away from a primarily altruistic model for research purposes may therefore pose a lesser challenge to solidarity and common values than such a move in connection with donation for treatment.
>
> (Nuffield Council 2011: 132)

In the previous report of 1995, the potential commodification of the human body was considered as clearly undesirable (cf. Tutton 2004: 22). This had two effects: On the one hand, the gift relationship was promoted as morally superior, and on the other hand, the gift did not come with 'strings', i.e. attached to particular conditions, so that, just as in *Moore* etc. the gift has been abandoned and freed from donor claims. Donors do not have "the slightest interest in making any claim to it once it is removed" (Nuffield Council 1995: 68; cf. Tutton 2004).

Contemplating not so much control, but rather compensation and/ or payment for the donation of tissues, the new report puts forward a conciliatory approach, in which "the concern for others implicit in altruism can co-exist with monetary reward. This in turn supports arguments to the effect that a contrast between altruism and payment is not the stark 'trade-off' of incommensurables it once seemed" (Nuffield Council 2011: 125). With particular view on Titmuss, 'genetic solidarity' and biobank research, there is support for a new pragmatism on commercialization, "rather than two mutually exclusive black and white alternatives, altruistic donation and commerce can be considered to be the opposite poles of a grey continuum, with various coexisting donation forms between them" (Sýkora

2009: 14). This is a significant relativization of a long-held practice of altruistic donation and research as proclaimed by policy.

It is not immediately clear what effect this will have for the supply-side. Is it in the interest of donors that the boundaries are becoming blurry – not only *de facto*, and politically sanctioned – but in terms of rights and duties vis-à-vis research, in particular in genomics?

Intricate conceptual relations involved preclude easy responses. Scholars sensitive to the issue have pointed out that the notion of gift-giving (also legally) presupposes underlying property rights or at least some particular interests in the subject matter constituting the gift (cf. Laurie 2003; 2004; Ursin 2010b). In fact, as Magnusson notes:

> To hold categorically that human tissue cannot be the subject of proprietary rights suggests that, in the absence of specific empowering legislation, such tissue could not be gifted, bought or sold, stolen or converted, bailed or patented. In a rapidly developing biotechnological age, a legal vacuum such as this would be very curious indeed.
>
> (Magnusson, quoted in Price 2010: 4)

On the other hand, it has been considered that *Moore* is an exceptional case and that there could be harmonious midway solutions between altruism and capitalism (Boyle 2002; Harrison 2002). While this assessment might be correct, it does not follow that there are no further ethical issues if consent has been voluntarily given, which is a question of general relevance in genomic research based on tissue collections. Can we just rely on other types of (human) rights, which protect privacy, dignity and the inviolability of an individual, as Campbell suggests? (Campbell 2009: 15). This question is closely related to the problem of the contested status of tissue between person and commodity (cf. Radin 1996). Shifting attention back to the protection of 'whole' persons, however, fails to take into account the boundary status of tissue and is likely to lead to the problems of category mistake and an

ineffective over-regulation of research projects which might indeed impede scientific work.

At the same time, it is submitted that "debates about key issues which affect the human body, such as the controversy over a potential market in human tissue and organs, still tend to be dominated by claims that it is irrational to treat the body with any special respect or to take any note of our intuitive repugnance at treating the body as an object of trade" (Campbell 2009: 4). Yet, this assessment fails to take note of the complexity outlined, and makes appeal to seemingly shared intuitions about the moral significance of the body and a shared understanding of property as a concept that is actually conspicuously absent, both in academic discourse as well as public debate. It is also known that research participants and citizens do have concerns about commercialization of the body and in genomics (cf. Haddow et al. 2007; Steinsbekk et al. 2013b).

On the face of it, the more morally suspicious trend hence seems to be one of a strict anti-propertization and -commercialization in ethics and policy: an often superficial dismissal of all things property for the supply side. Indeed Campbell, though lamenting insensitivity to the problem of tissue commodification, assumes that 'altruism' in relation to biobank research can easily be reestablished through something he calls "informational interconnectivity" (Campbell 2009: 61). Information and knowledge derived from tissue can be potentially beneficial for large groups of people, for instance if research leads to more tailored drug responses in a certain group of patients. He continues to point out that the new informational value leads to a shift in questions concerning the ownership of the biological material to issues concerning the information derived from the material, and "to what extent this information should be sequestered for private interests, as opposed to being put into the public domain for the benefit of all" (ibid.: 62).

However, it is not self-evident that *open data* should also imply *open consent*, in fact it would seem inconsistent to remain under this circumstances within a framework of fundamental individual rights. Another commentator, after asserting the lack of consensus on the ownership issue and related rights and responsibilities in genomics, notes that the denial of property rights to sources seems to contradict international bioethics principles, in particular the stipulation that the interests of science or society should never take precedence over the ones of research subjects (O'Brien 2009: 200). The article nonetheless finishes with the proposal of an 'ownership'- model in which the sharing of biomaterial and genomic information as well as scientific data has gained priority over a closer look at how individual rights might have to be reconceived:

> Four principles to guide ownership or custodianship of biospecimen repositories
>
> 1. Custodianship should encourage openness of scientific enquiry and should maximize biospecimen use and sharing so as to exploit the full potential to promote health.
> 2. The privacy of participants must be protected and informed consent must provide provisions for unanticipated biospecimen use.
> 3. The intellectual investment of investigators involved in the creation of a biorepository is often substantial and should be respected.
> 4. Sharing of specimens needs to protect proprietary information and to address the concerns of third-party funders.
>
> (O'Brien 2009: 196)

An alternative approach to these argumentative leaps faces a number of tasks, especially in relation to biobanks. The first is a (balanced) reestablishment of the individual person and the human body in relation to DNA, because often, contra Campbell, there is not even assumed to be any human dimension left in respect to a genetic sample, although the

doctrine of consent is applied in biobanking. An asymmetry of interests and entitlements persists in this case in a multitude of forms: disembodiment is taken to an extreme in the debate when the interests of science are at stake, and the repugnance at commercialization is applied asymmetrically to donors and users. Second, it must be clarified what would be the moral implications of a loser boundary between commercial and non-commercialized 'donation', which in turn requires a nuanced understanding of property rights and the moral problems associated with 'commodification'.

Overall, this will require a restructuring of the debate from issues of consent to issues of control over biomaterials and their uses. Here, we will mainly investigate the limits of the no-property approach for the supply-side and try to understand if property concepts can also have a positive function with an eye on the larger picture of governing biobanks. This is an important part of the bioethical task involved, as policy is moving to strategies that seemingly facilitate research, but perhaps at the price of jeopardizing the trust that participants place in it.

In the next chapter, I show that this framework should be extended in respect to larger-scale genomic research. While currently research regulations are seemingly built on a theory of autonomy that is independent of any property right in one's tissue (Alta Charo 2006), there are intimate connections between the pillars of consent, privacy and property although the latter have been treated by ethicists in a rather cursory manner. Clearly, personality rights are still at stake, but the issue of control looms large behind the sticking points that limit the application of the traditional framework: the fragility of appeals to autonomy, the de-materialization and/or over-individualization in the discourse on privacy and the asymmetries of entitlements in the context of altruism vs. commercialization identified. The moral sources of the traditional research ethics model are conceptually and morally robust as for the protection of individual rights, if properly interpreted. However,

the analysis of the debate on informed consent vs. various diluted versions shows that what we need is not so much more protection of the individual, but primarily that the differences between research contexts are starker than many authors seem to admit.[52] Elger, for example, provides the following résumé:

> Although the discussion about solidarity and altruism has been ongoing for 20 years, community values have not overruled the human rights framework of research ethics. This needs to be firmly recognized as deeply reassuring because it increases the trust in the present regulatory structures which were able to maintain the protection of research subjects as their priority and have so far not been overrun by the pressure of commercialization, commercial progress and the worldwide competitiveness of biotechnology research. In the era of modern bioethics and post Tuskegee,[53] the idea that the good of society could sometimes outweigh the rights of research subjects continues to be rejected in Europe and North America, so far.

A few lines below, however, it is acknowledged that

> Biobanks are a sort of trial and error: new ethical questions emerged and different biobanks created ethical governance frameworks that were tested in real-life scenarios. Countries and their populations responded by legislations and guidelines, and the different solutions continue to be tested in practice. In this somewhat Darwinian way, biobank frameworks were created and selected because only some 'passed' in the long run.
>
> (Elger 2010: 252)

To me, there is a clear discrepancy here between the supposed robustness of the individual human rights framework and the assumption that what materializes in social and scientific reality will necessarily yield the right kind of protection. If that were the case, one might doubt that there had ever 'evolved' the framework of human rights and human subject protection. This tension, in any case, opens the debate to explore some additional considerations, in particular the perspective of property which the "research model" with its focus on the human person as a single, physical entity tends to exclude or bury under

[52] Cf. Kanellopoulou 2004.

[53] The 'Tuskegee Syphilis study' involved, from 1932-1972, around 400 black males from Tuskegee, Alabama, suffering from syphilis who were told that they were treated for 'bad blood', while in fact the natural course of the disease was observed. At later stages, patients were systematically excluded from treatments that had become available. Cf. Faden and Beauchamp 1986.

the protection of ‘autonomy’ (cf. Glantz et al. 2008; 2010). But can and should we adopt a property model? What would that actually mean?

3. Conceptual and Normative Extensions

In this part, the common bioethical view of a no-property approach to the human body and its parts shall be challenged with a view to the application in biobank-based research and the deflationary account of informed consent which dominates the debate of participant rights and interests.

At closer inspection, Kantian considerations often used to this effect do not support strict anti-commercialization policies concerning human bodily material, but point to different concerns. Moreover, it can be shown that informed consent requirements in the related human rights view cover property-like interests, in particular a continuous form of control over bodily material if it remains related to its human source. While this property logic in terms of the *worth of human agency* underlying the requirement of consent would have the potential to strengthen the interests of donor-participants and trust in research, most commentators that have taken up the issue in relation to human body tissue at all focus instead on ownership as a form of desert, or a mere market tool. In contrast, it can be demonstrated how, without constructing ‘real’ property rights, considerations of ownership lie at the heart of a comprehensive picture of participant interests and rights. Moreover, reconstructing the debate from this perspective allows clarification concerning the key goods involved in genomic research.

3.1 A Preliminary Map

3.1.1 The Human Body and its Parts in Terms of Property

It might not be exaggerated to call the topos of the bounds of the human body and its susceptibility to propertization a central if not the most important idea of liberal Western thought: How far do the rights over our body extend? And how do they relate to the essence of personhood and the value of autonomy? Do property-like entitlements in our bodies justify the selling of the same into slavery or for prostitution, a right to abortion, or more or less regulated markets in non-replaceable human organs?

What can be ascertained is that the human body has often been a site of enormous tension in terms of what other individuals, powerful entities and the state can do to this perhaps 'last undiscovered country' (Stewart 2007; cf. Karlsen and Strand 2009). In the spectrum between the threat of commodification of persons and arguments in presumption of the greater good of medical research, the impression that there could or should be an interest or right in biological material and the information that can be derived from it – if this material has been voluntarily given to a research project – might at first blush seem rather marginal, even considering the profound changes that the research context has undergone. This is in fact what a large part of the bioethical literature seems to assume, but there are good reasons to be skeptical of this position. In particular legal scholars are very aware that there are important conceptual connections between the protection of 'privacy' and the rights that ownership confers, and also between the concept of consent and ownership.

The rationale of the following exploration will be what exactly is *of ethical importance* about these connections in the context of transferring bodily material from an individual

that contains potentially very valuable information to a research infrastructure such as a biobank.

I will argue that there is a significant tension between the more traditional approach of 'donation' and the doctrine of consent from the perspective of property theory. That we should apply property theory here, however, is far from clear. Bioethicists have been very reluctant in applying even the *language* of property to the human body. Language also inhibits transparency in this case, as property talk tends to be loose or merely technical, i.e. using legal terms of art. For starters, ordinarily, property is things, while law describes the rights and powers of exclusion property confers. Whereas it seems natural to speak of myself as 'owning my body', we are or inhabit our bodies, and the legal conception of ownership instead assumes property to be transferable and alienable (cf. Calabresi 1991).

Nonetheless, even the issue of property rights in *body parts* clearly detached from a person is contentious, as there is a spectrum of philosophies to what extent the body, dead or alive, and with reference to its parts represents a "substratum of personhood" or an entity of special, e.g. religious or cultural value and consideration (cf. Dickenson 2007; Lenk and Hoppe 2009; Schweda and Schicktanz 2009; Price 2010).

Before we can approach the issue in a more contextualized fashion, we need a preliminary idea of what 'property', 'property rights' and 'ownership' refer to. By "property" I will mean "a legal and social institution governing the use of most things and the allocation of some items of social wealth", an introductory definition by the legal scholar J.W. Harris (Harris 1996b: 56). Property institutions have at least two main functions, regulating use and distributing power: "It is one thing to say that a society ought to afford to an individual the use of some resource. It is another to say that the individual should be armed with power over others by virtue of a capacity to dictate the use of the resource" (ibid.: 57).

An *institution* of property consists of trespassory rules – defining the rights and duties attached and punishments for violation (trespass) as well as an 'ownership spectrum' – an aggregate of rights. "Ownership" is akin to a "range of open-ended relationships presupposed and protected" by the trespassory rules law enforces, and it is therefore the less technical and more morally charged term, in that it connotes the kind of social interactions that shall underpin the legally recognized rights of use of things and the concurrent powers of 'owners' and 'property holders'.

Ownership *in a normative sense* has an 'expansionist' connotation, in that full ownership of an entity is often considered "the best possible entitlement under the circumstances, relative to the nature of the *something* in question and the entitlements of others" (Hoppe 2009: 48). While, as also J. W. Harris points out, the content of ownership interests is "a function of cultural assumptions" (Harris 1996b: 59), there is a tendency in political theory to conceive of these entitlements as absolute (c.f. Singer 2000).

Analysis of ownership as employed by legal and bioethical scholarship is strongly influenced by the work of Anthony Honoré. In trying to systematize how 'mature' legal systems employ similar concepts of ownership he identified 11 incidents of 'full liberal ownership'. This conceptualization encompasses the right to possess, the right to use, the right to manage, the right to the income, the right to the capital,[54] the right to security, powers to transmit, devise or bequeath, the absence of a term to one's ownership rights,[55] responsibility for harmful use, liability to execution[56] and rules governing the reversion of lapsed ownership rights[57] (Honoré 1987). This list of incidents does not solve the problem of what property essentially *is*, and has been used both by theorists who defend an integral

[54] Meaning the power to alienate the thing, and the liberty to consume, waste, or destroy the whole or part of it (Honoré 1987).
[55] Absence of a future date or event that would cease ownership (ibid.).
[56] An owned thing can be taken away in case of debt or insolvency (ibid.)
[57] For theories which propose less incidents and modifications, and an application to human body parts cf. Björkman and Hansson 2006.

approach and a deflationary approach of a bundle theory, 'sticks' of which can be disaggregated and re-assembled. For example

> a person whose estate is subject to an entailment which requires it to descend in the male line unless there are no male heirs will still own the estate (it will still be his private property) but he will not have the right to bequeath it to whom he wishes. Similarly, a person might possess the right to the physical possession of his kidneys, the right to their use and management, the right to security in his possession of them, and the right to transmit them by gift or bequest, but *not* the right to transmit them to others by sale, or to secure any income from others' use of them.
>
> (Taylor 2010: 175)

This means that the objects of property and what Harris calls property institutions could be distinguished from the relations in terms of ownership to understand how rights define the relations not only between an object of property and property holders but also between property-holders and non-property holders. Also, it implies that the bundle can be disaggregated and reassembled giving rise to a complex of ownership in various potential relationships. In a constructivist view of property rights, for instance, entitlements to control can be conceptually split from the *prima facie* more morally contentious rights to income and commercial transfer (cf. Christman 1994) and the 'control rights' seem to have a certain overlap with the personality rights constructed around 'autonomy'.

Property rights are also characterized as prototypically *alienable* rights, meaning that they can be given up, waived or traded, differently from, for instance, the human right to life, liberty and security, and indeed according to some the right to informed consent in the context of healthcare and research (McConnell 2000).

Another significant characteristic of a general concept of property is that it, traditionally, concerns solely material items, not information or ideas. The exception are the different forms of intellectual property that are widely discussed in the life sciences, in fact because there did seem to be a trend of expanding and reifying intellectual property rights as if they

were rights over natural, material things, while in theory, patents are not exclusive rights over things, but rather time-limited privileges to exclude others from the use of inventions (cf. Nwabueze 2007). "Intellectual property" therefore is in a sense indeed a contradiction in terms. This is of interest as part of the asymmetry-thesis discussed above, as to some extent, one can probably say that as much as intellectual property is conceptualized in ethical and public debate as 'real' property, property in bodily material on the supply side is denied.

The traditional view of legal and political theory, in any case, is that property *rights* require physical entities and 'thingness'. In this view, the human body is not adequately distant – both physically and metaphysically – from the human subject to constitute 'thingness': "biological materials which remain part of the human body are not things because they lack the requirement of separability" (Hardcastle 2009: 14/15). The conceptual heart of 'property', indeed, seems to be the more normatively charged notion of 'alienability'.

What then is the normative status of *tissue*? Blood transferred to a biobank is a physical entity and a thing, but equally refers back to person as for the genetic information contained in it. In the context of a governance-oriented biobank ethics the crucial problem seems to be that we have to think about ownership and property claims in a holistic, temporally continuous and 'three-dimensional form' (Macilotti 2013), i.e. on a spectrum from human being to DNA, to sequence data, scientific output – perhaps even a potential scientific product such as a cell line to be patented.[58] While we are dealing with "non-human subjects-research", insofar information is implied, it will not be morally neutral information. In most cases, links to personal information and a potential for sensitivity of the material will remain. The main point therefore is that for a morally and practically

[58] I will refer here mainly to 'tissue' because there will be a stronger focus on the donor or the material 'source' side. Consider, however, the particular issues immortalization and 'conversion' of 'donated' tissue raises, as discussed for example in Sethe 2004.

adequate grasp on what is at stake in biobank research it is important to conceive of tissue for genomic research as a 'boundary-object':

> In legal and philosophical analysis, these fragmented bodies have been variously viewed as neither persons nor property, leaving them in a limbo that provides few answers as to what these parts are and little guidance about what can morally be done with them. Our categories of thought in science and the law simply are not able to do justice to the nature of "entities" that are neither "things" nor "persons." It is as if the attempts to stop conceptualizing the world in a dualistic, dichotomous way have failed in this case.
>
> (Rich et al. 2012: 2)

In an alternative perspective, for a donor, tissue in its material form is not of any interest and will be mostly akin to 'waste'. Tissue is more like, e. g., a CD, a mere container of information and the status of genetic information derived from it, though *sui generis*, is only a matter of legal definition (cf. Palmer 2005; Elger 2010; Stefanini 2010; European Commission 2012[59]). In my view, as least as concerns a widening of ethics to include governance – or rather, from the perspective criticized here, as concerns governance that incorporates ethics – this seems an inadequate reductionism. The problem is that donors can have interests in matters that seem more 'material' (disposal, sharing, research use) and/ or 'informational' (disposal, sharing, research use and information that could identify them and/ or be of medical relevance for them and others), and they are both *prima facie* morally legitimate.

Although the reductionist view might seem legalistic, it is legal scholars rather than bioethicists who have fostered debate on the normative status of tissue and data in this new context, some of which advocate property (or property-like) rights in the material which donors transfer to genomics projects and research infrastructures (Mason and Laurie 2001; Laurie 2003, 2004; Tallacchini 2005; 2013; Parry and Gere 2006; Dickenson 2007;

[59] European Commission. EUR 25302. 2012. Biobanks for Europe: A Challenge for Governance. Report of the Expert Group on Dealing with Ethical and Regulatory Challenges of International Biobank Research.

Nwabueze 2007; De Faria 2009; Price 2010; Macilotti 2013). For my purposes, tissue shall be considered as 'three-dimensional', and not only as a data-container. Accordingly, the question will be in which way this tissue for research can or should be subject to more than data protection, and more particularly, is to be considered in a wider sense also in terms of property and ownership.

3.1.2 Legal Rights and their Moral Contestation

Both in continental and common law, the body *in its entirety* is consensually considered mainly subject to personality rights. In the continental tradition, e.g. the German law, a number of scholars argue that also property-like control rights apply to the human body. These would stem from personality rights. Insofar property rights over the body, however, will lead to a restriction of personality rights, in particular dignity and autonomy, this level of property-likeness is largely superimposed by personality rights, and therefore the body remains for most practical purposes overall *res extra commercium*[60] (cf. Roth 2009; Schnorrenberg 2010: 226; Simon and Robienski 2010: 302).

Concerning detached *body parts* the situation is even more complex. Internationally these are rather *res extra commercium* or *res nullius*[61] (Laurie 2004; Simon and Robienski 2010: 302), while the German law again considers that detached body parts are things and therefore potential objects of property rights (Simon and Robienski 2010: 302/303; Schnorrenberg 2010: 226). Analogously to *prima facie* ownership over things, detached body parts *as* things become property of the person from which they originate rather than being e.g. *res nullius* or becoming immediately the property of a third party.[62] Both

[60] Not subject to contract or sale.
[61] Not belonging to anybody, and free to be appropriated.
[62] At least this is the common interpretation since there is no explicit rule or doctrine concerning how property comes about, cf. Schnorrenberg 2010: 227.

property and personality right overlap and continue to do so in the context of detached body material, which is in line with the idea that even the whole body is considered the object of property-like rights as part of personality rights.

According to this interpretation, the property 'as object' can be transferred, while the personality rights of the source of the material delimit the entitlements of a new potential owner. Overlap of property and personality rights will depend on the extent to which the body material allows for inferences concerning the originator of the material. Only if the body material is fully anonymized, this overlap would vanish, and the material is initially *res nullius* or abandoned property. Conversely, if the material is identifiable, the originator therefore gains an *additional* right of use and control over the detached material on top of the continuing personality rights (Simon and Robienski 2010: 304/305). Interestingly for the context of biobank research, this would mean that "the person from whom the body material originates could preserve his or her property rights only in case her or she would simultaneously allow for the retention of personal data."[63]

The transfer of property which according to these considerations exists is usually not made explicit in the context of consent covering only the removal of the bodily material (ibid.: 308). Consent to treatment and/or research, however, is not enough to declare transfer or that the donor has no further property interests following this conceptualization, except for an explicit declaration to this effect. This is because intention to give up any property interests is considered primary, and must be affirmed as such. Moreover, an automatic transfer of the property or its abandonment would seem to be contrary to an absolute right of withdrawal of the material. The right to withdrawal until removal and deletion of personal data or use and transfer of data are part of the protection of personality rights, while the continuing – unconditional and absolute – right of withdrawal of the biomaterial

[63] "Für den ehemaligen Träger des Körpermaterials bedeutet dies, dass er seine Eigentumsrechte nur wahren kann, wenn er es zugleich zulässt, dass zu seinem Körpermaterial personenbezogene Daten gespeichert werden", (ibid.: 319, translation B.S.).

would be considered a typical right of property holders (Simon and Robienski 2010: 316/317).

Property rights in term of control rights are considered to 'stick' rather naturally with the person from whom the biomaterial originates as long as the material is identifiable. This is an remarkable facet of this approach applied to the context of biobanks, as personality rights have a mainly protective, negative function as rights to bodily integrity and autonomy, while the rights over things imply (minimally) positive rights of disposal and as 'full-scale' would imply property commercial rights (cf. Schneider 2010: 163).

Despite the fact that the common law protects invasions of the human body, it has been argued that there is, as yet, no principled basis for recognition of property rights in human tissue for both sources and recipients and, differently from the continental tradition, that there "has been a distinct reluctance on the part of the "common law" courts to address the issue of tissue's susceptibility to ownership" (Macilotti 2013: 147). Exceptions have been body parts, in fact parts of corpses, to which 'work or skill' was applied, and which thereby has been considered to confer rights of possession to the person performing the transformation of the body material (cf. Hardcastle; Macilotti 2013: 147/ 148). There does seem a change though recently, and in particular in confrontation with the development of biotechnology and genetic databases, as scholars are re-considering the possibility to develop a normative and principled ground to recognize property rights in body parts (Laurie 2004; Hardcastle 2009; Nuffield Council 2011 – with reference to the case of *Yearworth* that is discussed below).

In particular, the 'work and skill exception' is questioned since tissue also as raw material has become a *de facto* valuable commodity even before ascription of any legal rights to either sources or recipients: "If in the past mere body parts could not acquire some value without the acquisition of different attributes, today, in the biotechnology era, tissue has

value *per se* […] This aspect can change, quite fundamentally, the nature of tissue. Property interests related to tissue can therefore be considered as a basis for a "revirement" (Macilotti 2013: 148). This shift in legal reasoning is accompanied by a moral debate, which provides an interesting entry point to disentangle the more technical aspects of potential property in tissue from the moral importance of the concept on the backdrop of research use to be elucidated here.

Hardcastle suggests with particular reference to English law that the following individual interests should be taken into account in reconceiving property rights in human body parts: interests in a potential economic value, in controlling disposal, use for research, the possibility to exclude commercial use, and the possibility to contravene immortalization. He argues that legally, the detachment of biological materials provides the most logical basis for the creation of property rights in body parts, which "support the creation and allocation of property rights to the individual source from whom the materials were removed " (Hardcastle 2009: 20). This line of legal reasoning, it seems, would therefore bring the English law closer in line with the continental approach.

The fact that, by becoming an object through separation from the body, tissue is susceptible to ownership is more obvious in the American case. In *Moore*, the conceptual result was not that ownership in the tissue had never existed, but that claims to it had been relinquished via consent. The cases of *Catalona* and *Greenberg* consider also clearly rights in the biomaterial dimension and have indeed been seen as cases of *gifts*, which, as we have seen, presupposes ownership. The prevailing general idea then seems to be that by detachment, tissue becomes *res nullius*, and property in it is created through 'occupation'. For research and the transfer of tissue to biobanks, this would mean that "whoever possesses it becomes their owner" (Macilotti 2013: 151), privileging parties that have

higher (bargaining) powers, usually the institutions and researchers involved, such as the surgeon/ researcher/ clinician, the research facility, hospital or biobank.

This view, together with the emphasis of the 'work and skill'-exception, likely explains the denial of property rights to the claimants in the American cases. Even if, according to this reasoning, donors had property interests, the process of consent is independent from the allocation of property rights – a view that shall be challenged here with reference to the legal and philosophical traditions informed by strong personality rights that persist in the informed consent regime. If this is true, disregarding for a moment the ethical issues with ascribing property to tissue, then the only legal or regulatory problem would be the extent to which consent-giving is a transfer of ownership in totality or in consideration of the 'sticks' in the bundle of property rights.

Whatever the exact conceptual nature of property and ownership in any consistent theory, it follows even from this basic preliminaries that one cannot start by asking "who owns the human body or tissue?" Besides theory, the relations and moral responsibilities of potential owners have to be clarified, and this is exactly what is absent in the case of research biobanks. Indeed the justification for property rights and how it comes about is a matter of long-standing dispute in political philosophy and as already hinted to, 'property' probably one of the most famous concepts that are 'essentially contested' (cf. Radin 1993).

With regard to the present debate, two kinds of traditions are of particular importance in relation to the asymmetry thesis. These are broadly Kantian and Lockean. Kant is often used to 'back up' non-commodification and non-commercialization of the human body and its parts *tout court*, and Locke, in contrast, to sustain property claims – mainly from the user side. More generally, one might say there are 'property-friendly' and 'property-skeptic' or 'property-ignorant' traditions appealed to in this debate, which in turn represent the extreme ends of a spectrum of possible positions. What is more, it seems that they are

employed distortedly in discussing developments in genomics and in commercialized environments, just as there is a *prima facie* asymmetry in the entitlements of donors and users.

The property-friendly traditions assume that property, starting from property in the body and its works, is in some way a fundamental moral and natural entitlement. It is useful to introduce some of these Lockean ideas here, while Kant-based arguments will be examined in more detail below.

Lockean theory, often referred to as a theory of 'natural rights', is of pivotal importance both in legal and ethical reasoning, and as for the (life) sciences in particular with reference to intellectual property (cf. Boyle 1997; Björkman and Hansson 2006). It is taken to be a theory that grounds property rights in desert and human 'labour', fitting on the face of it the common law doctrine of applying 'work and skill' which can confer property entitlements.

Locke's observations on property, however, must be understood in its historical context, i.e. as part of a larger project to ground the importance of individual rights in particular against political absolutism and tyranny in the pre-Enlightenment period and during the colonization of North America.

> § 27 Though the earth, and all inferior creatures, be common to all men, yet every man has a property in his own person: this nobody has any right to but himself. The labour of his body, and the work of his hands, we may say, are properly his. Whatsoever then he removes out of the state that nature hath provided, and left it in, he hath mixed his labour with, and jointed to it something that is his own, and thereby makes it his property. It being by him removed from the common state nature hath placed it in, it hath by this labour something annexed to it that excludes the common right of other men. For this labour being the unquestionable property of the labourer, no man but he can have a right to what that is once joined to, at least where there is enough, and as good, left in common for others.
>
> (Locke 2003: 111/112)

Independently from a particular authority such as the state then, individuals can acquire legitimate and exclusive ownership for instance of a piece of land by transforming it through labour and adding value to it. Any kind of excesses are prevented by at least two facets of the theory: the 'proviso' and the fact that though we can acquire legitimate private property, the earth and its fruits in totality are actually a kind of common heritage, held in trust by humanity (cf. Locke 2003; Tully 1980; Waldron 1988; Rao 2007).

It is therefore not particularly evident what the 'natural' rights Locke supposedly defended are. If the earth and its fruits belong to anybody in a natural way, that would seem to be God, and only 'in extension' there would be ownership by individuals. Jeremy Waldron explains the Lockean theory as primarily a theory with the function to safeguard human agency in the service of God rather than the absolutism that seems to be implied in the description as 'natural rights':

> As a matter of fact, individuals left to their own devices will gain control of natural resources in a variety of ways. Some of those ways (for example, being the first to labour on something) create relationships between the individual holder and the resources he controls which are, from a moral (or perhaps religious) point of view, so important as to impose duties on others to refrain from interfering with or undermining that control (either in general or in certain specified ways). These duties, then, correspond to natural rights to some sort of exclusive control of the resources, in other words natural rights of property. They are natural, not in the sense that the individuals concerned are born with them (in one of the ways that, say, rights to life and liberty are said to be natural), but rather in the sense that the force of these rights obtains and can be recognized as valid by moral and rational people quite apart from any provisions of positive law. And they are perhaps also natural in the sense that the sort of relationship out of which these rights and duties are generated has important roots in the nature of human beings.[…] Natural rights to property are, on Locke's view, rooted in certain relations that some individuals happen to establish between themselves and certain things – in particular the relation of labouring on virgin resources.
>
> (Waldron 1988: 19/20)

Notwithstanding these complications, the Lockean account was extremely influential in the development of a theory of individual personhood and individual rights, also due the objectified relation in which a person can stand to 'her' labours and thus as the main inspiration for 'self-ownership' (cf. Cohen 2008). It might, however, seem more appropriate that Locke was trying to ground private property in the products of labour rather than in the human body *per se* (cf. Waldron 1988; Nwabueze 2007). The more general appeal to self-ownership, which as we will see exerts a certain influence in the discussion on property in human body parts, can be illustrated following the reconstruction of the self-ownership argument that J.W. Harris has proposed. It runs as follows:

> *1.* If I am not a slave, nobody else owns my body. Therefore
>
> *2.* I must own myself. Therefore
>
> *3.* I must own all my actions, including those which create or improve resources. Therefore
>
> *4.* I own the resources, or the improvements, I produce.[64]
>
> (Harris 1996b: 68; 70)

Nozicks libertarian self-ownership, for instance, derives from running this argument backwards and claiming that most redistributive policies implicitly deny ownership of labour, and thereby ownership of the self, which in turn amounts to quasi-slavery.[65] Is self-ownership a meaningful concept? Does it have any bearing on the rights of individuals in genomic research? Recent scholarship suggests it does, an issue that we will return to.

[64] Harris distinguishes the liberal, Lockean-inspired version and the Marxist version. For the latter, point 3. would read instead "I must own all my actions, including those which produce a use value of any kind" and 4. is replaced by: "Every service contract into which I enter constitutes a conveyance of my labour power" (ibid.).

[65] In case one would have to partake in redistributive policies, implying the famous claim that "Taxation of earnings from labor is on a par with forced labor" (Nozick 1974: 169).

3.2 Tissue Ownership and Biobank Ethics

While legal scholarship – with resurgent interests in property in the body and its parts – abounds with property language and rhetoric, including 'self-ownership', guidelines for genomics and the bioethical discussion remain hesitant to follow suit, although it seems in cases such as *Moore,* property was not denied because of legal dogma, but due to controversial policy considerations, as well as economic interests. In bioethics, there is a indeed a strong presumption that the human body should not be conceived in terms of property at all and that efforts to this effect must lead to a merely 'material' perspective in which tissues are pure, commodifiable things rather than 'subjects' of personality rights. In some legal traditions, as we have seen, a potential overlap between personality and property rights as applied to the body is more familiar. The following sections explore the possibility to sustain argumentatively a breaking up of the dichotomy between these approaches.

3.2.1 The No-Property Approach as Default?

Cordell et al. (2011) take up the issue of developing a firmer basis for the establishment of property rights in particular in human body parts, and with reference to the storage of human tissue samples and genetic information in biobanks and genetic databases. Their considerations start from a discussion of the recent case of *Yearworth.* In this case, six men were undergoing cancer treatment in the UK. They had their sperm stored for potential later use in case of compromised fertility. The sperm, however, was destroyed due to negligence. Mr. Yearworth sued. In redressing the ensuing harm to the patients, the specification of the harm would have to be related to personal injury or loss/ destruction of personal property. Indeed the court considered that the men had had ownership in the bodily material. The question that triggered legal and ethical debate is whether this

recognition of property in bodily material, atypical in the common law, is of ethical concern – differently from the other important question of whether and under which circumstances potential property can be considered abandoned.

While the details of this case are peculiar and their potential for leading to 'revirement' might be limited (cf. Harmon 2010; Hoppe 2010; Macilotti 2013), Cordell et al. argue that this recognition of ownership contravenes a 'no property in the body'-principle and sets a precedent which is "ethically suspect, as it enhances the tendency towards the commodification of body parts". The 'no property' approach, in their view, must remain "the default position in cases of detached bodily materials" (Cordell et al. 2011: 747).

Whereas there seems to be agreement concerning the idea that historically, separated human body parts were mostly considered *res nullius*, subject to exceptions with reference to the 'work-and-skill-exception', in *Yearworth* the men were explicitly ascribed 'ownership' of 'their' bodily material in the sense of "a specific set of powers over and constraints on other's access that an agent holds regarding some object" (ibid.: 748), i.e. some sticks from the bundle of rights ownership would confer, in this case the most relevant ones seeming possession, use, and management. In particular a right to future usage seems to have been of importance, which the authors do not necessarily wish to deny.

The problem, in their view, is that a compensatory claim could have been established without invoking property at all, but their main concern is

> […] the confusion encouraged between the 'integral' conception of bodily property and the legal sense of a bundle of rights which supposedly arises from the men's relation to the stored sperm and the duty incurred by the National Health Service to maintain it. There is an intuitive temptation to mix the two conceptions, especially when we consider that the intended future usage of the sperm would have involved the men attempting to father 'their' children. But, as underlined by the Judge's correct rejection of the personal injury claim, once the sperm is

> outside of the body and is being cryogenically sustained, it is no longer a something that can be damaged or destroyed *as* a bodily material in this 'integral' sense.
>
> (ibid.)

It would hence be "at best unclear that the men's legitimate power or right to control and manage future use of the sperm should thereby make it an object of their property on a legal, transferable understanding: or that whether, if it does, it would then become property that was shared or contestable by its sole controller or 'keeper', the National Health Service. […] even having exclusive use of something *and* its being integral to the body may not necessarily imply ownership of that thing. The air that a person inhales into their lungs meets both these conditions but is, nonetheless, res nullius." (ibid.) Speculating that an intention behind the ascription of property to the material might have been to "capture and redress the erosion of autonomy that took place with its destruction", they continue to argue that relating these two concepts in any coherent view seems impossible. Autonomy – here "recognising facts about the frustration of the men's significant life projects, and thus the infringement of their control over their own lives" (ibid.: 749) – does not need to lead to the recognition of property.

On the only alternative reading, they suggest, property would have to 'entail' autonomy, but in this case one must instead start from assuming what is to be established since

> Autonomy *is* self ownership or control, and we cannot establish that the men's autonomy has been compromised by virtue of a violation of their property unless the sperm – now expressed and sustained by a third party – is in some sense already assumed to be just that: 'part of them' or *theirs*.
>
> (ibid.)

This is a puzzling argumentative strategy. Having first suggested that the *Yearworth*-judgement encourages a confusion of the' integrity' vs. bundle idea of property, they then reintroduce implicitly their preference for the essentialist integrity interpretation:

Autonomy and property must either be conceptually identical or exclude each other categorically, and thus the recognition of property in *Yearworth*, in particular with reference to autonomy, must be "conceptually inappropriate" (ibid.).

But why should that be the case, except if, in turn, what has to be established is assumed – that the only proper conception of 'property' is essentialist? Cordell et al.'s main concern, after all, seem to be the *consequences* of employing a property *language* to bodily material overall – consequences though that exacerbate an intrinsic harm that property language seems to convey:

> So the concern is that if there is a precedent set by this judgment, it allows that bodily material can effectively be deemed a commodity before any act of sale or transfer. Notice, then, that the objection is not that the property judgement sits at the top of a 'slippery slope' of legalising or decriminalizing more and more commodificatory acts, such as the sale of ova, in the future. Rather, in our view, insofar as the Yearworth judgement and such acts are connected, the judgement is already squarely at the foot of that slope. For the Yearworth judgement *itself* commodifies a material that was never donated, harvested or stored with any view to it being or becoming transferable property, and hence a commodity, in the first place.
>
> (ibid.)

One might agree that in the specific case of *Yearworth* it was not necessary to employ property ascriptions. Yet, the generalizing aspects of this argumentation are unconvincing. The authors suggest without further argument that the core of the concept of 'property' applied to the human body is some unspecified tendency of harm due to the idea of 'commodification', an issue that will be discussed in more detail in the next section. In fact, for them it seems to be established principle by referring to the French notion of 'non-patrimonialité', according to which property and the human body cannot be subject to monetary evaluation and all agreements to this effect are void.[66]

[66] "Le corps humain, ses éléments et ses produits ne peuvent faire l'objet d'un droit patrimonial. Les conventions ayant pour effet de conférer une valeur patrimoniale au corps humain, à ses éléments ou à ses produits sont nulls." French Civil Code, quoted ibid.: 750.

I do not aim to suggest that rhetoric more generally and property language specifically are exempt from potential for harm, but a clearly delineated idea of potential property theory and other concepts such as 'autonomy' – to be employed in specific contexts – are of crucial importance. Cordell et al. have not shown that the default must be the 'no-property'-approach because it is not evident that the employment of property rights necessarily leads to some way of harming people or treating them unjustly. In fact, one might equally claim that the non-recognition of property rights – moral or legal – in the human body and its parts violates the liberal harm principle that people should be able to perform any self-regarding action which do not cause harm to others (cf. Mill 2009; George 2004).

Rather, they also confuse meta-theoretical ideas about what kind of concept or thing 'property' is with the effects legal recognition or even only property language might have. Furthermore, it is implicit in their discussion that 'property' does not seem to be a basic or all-or-nothing concept. This can be seen from their dismissal of a property model via the concept of "self-ownership". Cordell et al. claim that property is self-ownership, or if it is not, then there is no way to relate autonomy and property in a coherent way. What is the function of self-ownership in these considerations? Let us recall Harris' reconstruction of the self-ownership argument:

1. If I am not a slave, nobody else owns my body. Therefore
2. I must own myself. Therefore
3. I must own all my actions, including those which create or improve resources. Therefore
4. I own the resources, or the improvements, I produce.

(Harris 1996b: 68; 70)

As Harris' and other authors have pointed out, the problem with self-ownership is that it cannot be sustained by this argument without further premises. From not being a slave it does not follow that I must own myself, or my body. That is, if there is any role for self-ownership and thereby, perhaps, ownership of the body, which we cannot exclude, it is certainly not straightforwardly entailed in this argument. With the help of Harris' reconstruction, it can be seen that the issue is instead how to relate a more substantive idea of the moral importance of individual autonomy with the interests and/or rights that 'property' seems to convey. Cordell et al., on the contrary, simply equivocate self-ownership and control, but only in their dismissal of property.

The appeal to 'self-ownership' is therefore not conclusive as to what 'property in the human body' could be: If self-ownership is not merely postulated to be identical to the morally primary autonomous human being and the strong property rights that some libertarians conclude from it, one needs an account of autonomous agency *plus* a specification of relationships with other potential rights-holders to specify what my 'owning myself' should amount to in *de facto* social contexts.

As a consequence, this view is *prima facie* opaque about the purpose of the individual or the values that should be expressed through property (rights): It seems to be some kind of autonomy, but it remains unclear what the underlying moral rationale is, a problem that indeed libertarians are typically criticized to be very weak on (cf. Cohen1995; Mieth 2007). Again, this does not imply that 'self-ownership' in general or specifically applied to questions of ownership in human body parts is necessarily nonsensical, as e.g. Dickenson holds (cf. Dickenson 2007). It does, however, suggest, that the kind of 'ownership' we are looking for is not a simple concept, rather there is some overlap with other morally important concepts, in particular the realm of autonomy.

In the last part of their analysis, Cordell et al. caution against the use of a property framework in thinking about the claims of donors and users of biological material stored in biobanks. If one would apply a bundle conception of property, such as in *Yearworth*, for instance to the right to withdraw or concerning the uses consent entitles to in terms of ownership, then this "could warrant competing claims from a research institution and a donor over genetic samples, the donor claiming to retain property rights, and the institution claiming that he/she has transferred their property to the biobank, which in turn has done so to the research institution" (Cordell et al. 2011: 751). As biobanks serve as a research infrastructure that should be accessible for long-term usage to different stakeholders, this, they seem to suggest, could inhibit an effective use of the resource, while fostering potential conflicts of interest. Excessive ownership and control claims on the side of research, however, "could be dissolved by assuming a strict concept of bodily property, such that donors to biobanks waive all of their rights to any genetic material transferred. Perhaps, but then in that case it would appear that a much wider range of donor's rights and control over their participation in biobank research would dissolve along with it. […] such potential dangers of adopting the property model tell against the Yearworth ruling" (ibid.).

This discussion, contrary to their intention, then plainly confirms the necessity of a critical evaluation of the pros and cons of invoking a framework of property claims and rights, at least from an ethical perspective: Why would it follow from the fact that there seems to be some conceptual problem here that invoking property is 'dangerous', and what exactly would that entail? Their perspective here, indeed, suggests a continuity of donor interests the concrete relation of which with the notion of (informed) consent and the language of property rights and interests still has to be illuminated.

It might be agreed that one should not "head down the proprietary route" prematurely in the case of biobanks both considering their being fit-for-purpose and a legal application to the human body and its parts more generally – and still insist that we need a much more fine-grained conceptual and ethical analysis of potential property claims involved. Having established that no-property as default is at least as dubious and opaque as self-ownership – these are the alternatives the analysis puts forward – we can try to understand better what the moral problem with even a general evocation of property language for some authors in these debates seems to be.

3.2.2 Commodification Concerns and Kantian Concerns

While some commentators recognize that property could be a means to deal with the challenges of a commercialized research environment also for participants, further thoughts tend to be brushed away by short-hand appeals to *commodification*. Ursin, for example, contends that "granting property rights of tissue to Mr. Moore or to biobank participants requires the bold step of blurring the line between a person and an object" (Ursin 2010b: 221). Clearly, however, tissue containing identifying, perhaps sensitive personal information is just this kind of blurry entity or border-object: an object, and treated very much in research and medicine as an object, but equally undeniably and un-reducibly of human origin and potentially of great individual and even communal significance. In this perspective, thinking about tissue in terms of property does seem everything but bold, only adequate to context.

As I have pointed out, however, in bioethics this is a minority position. Cordell et al. hint at the other extreme of relating property with central conceptions and values of human identity, which is commonly considered as broadly Kantian. As in Ursin's comment, it

seems to derive from the idea that there is a fundamental difference between a thing and a person, in Kant's terms:

> Man cannot dispose over himself, because he is not a thing. He is not his own property – that would be a contradiction; for so far as he is a person, he is a subject, who can have ownership of other things. But now were he something owned by himself, he would be a thing over which he can have ownership. He is, however, a person, who is not property, so he cannot be a thing such as he might own; for it is impossible, of course, to be at once a thing and a person, a proprietor and a property at the same time.
>
> (Kant 1997: 157)

Persons have, in virtue of their capacity for autonomous moral agency, the crucial attribute of 'dignity' (Kant 1998: 43) that elevates them above the realm of things exchangeable and replaceable for money.

> In the kingdom of ends, everything has either a price or a dignity. What has a price can be replaced with by something else as its equivalent; what on the other hand is raised above all price and therefore admits of no equivalent has a dignity.
>
> (Kant 1998: 42)

This inner worth, in turn, and the potential for morality "is the condition under which alone a rational being can be an end in itself, since only through this is it possible to be a lawgiving member in the kingdom of ends" (Kant 1998: 42). The ascription of dignity and the inadmissibility of treating human beings as things equalizes people and is therefore of major importance for the development of modern civil and universal human rights (cf. Lenk 2008: 15).

But tissue for research containing personal and potentially valuable information quite obviously does not fit the dichotomy of persons and things and their relevant attributes easily. Moral concerns about a blurring of this line are often referred to in terms of "commodification", as in Cordell et al.'s discussion above. Is it true then, as has been contended, that "granting Mr. Moore property rights to his spleen would amount to making

commodification of the human body legitimate"? (Ursin 2010b: 221). And if that is the case, what exactly is the moral problem involved?

In the sense of a legalistic ethics or the standpoint of behavioral economics it is indeed clear that the granting of property rights to Mr. Moore involves the act of commodification if commodification is considered the necessary step before an entity can become part of market interactions (cf. Brownsword 2009). In this sense, commodification is a social practice and/or legal system, i.e. an actual practice of legally permitted buying, selling or renting certain 'things'. This use of the term can be differentiated from a particular commodifying *attitude* that Margaret Radin describes as consisting of the following: "market rhetoric, the practice of thinking about interactions as if they were sale transactions, and market methodology, the use of monetary cost-benefit analysis to judge these interactions" (Radin 1987: 1859). In a formulation adapted from Ruth Chadwick, in a commodifying attitude one might consider the bodies of persons primarily as *resources* (cf. Wilkinson 2000: 191).

Cordell et al. presumably consider both meanings, though their worry seems to be a generally encroaching, commodifying attitude towards the human body, a potential devalueing and perhaps 'objectification' of entities that become part of market-like relationships, including the wider cultural influence this could have. Some 'things', however, should perhaps not only not be referred to in terms of 'property' and related interests and rights, and in particular not be part of markets. These might be *market-inalienable* entities, i.e. they might be given away or donated, but not sold (cf. Radin 1987), one of the main issues of contention being a potential market approach to what is now mostly organ donation with all the relevant embeddedness in a culture of altruism or reciprocity.

Stephen Wilkinson discusses how the reference to commodification is used in arguments which purport to show that organ sale is to be legally prohibited. While we will not follow the argumentation concerning the potential sale of organs in detail, his attempt to clarify the invocation of commodification is useful also for the context of various forms of human tissue more generally. For Wilkinson, "commodification" involves minimally:

(1) Denial of subjectivity: the commodified 'thing' either lacks consciousness or is something whose experience and feelings need not be taken into account.

(2) Instrumentality: the commodified 'thing' has only (or mainly) instrumental value.

(3) Fungibility: the commodified 'thing' "is replaceable with money or other objects; in fact, possessing [this] fungible object is the same as possessing money."

(adapted from Wilkinson 2000: 193)

Is commodification of the body *per se* wrong? Wilkinson disagrees in his discussion of organ donation, because "the three 'sub-attitudes' which make up commodification will normally be equally present in both types of organ recipient (those who receive sold organs and those who receive gifted ones" (Wilkinson 2000: 194). That is, in his view and perhaps not very intuitively, commodifying attitudes are present in various ways also in the absence of monetary exchanges and the establishment of markets, and therefore, we might add, without the moral recognition of property interests or the legal enforcement of property rights.

The real problem, if this is correct, might then be that the commodification of bodies causes the commodification *of persons*. Commodification of persons, again, seems to be wrong because it is incompatible with respect for persons, that is, respect for him or her being a person and having certain subjective characteristics that ought to be accounted for. Part of this is the Kantian idea that persons should never be merely treated in an

instrumental way which is incompatible with the duties they have to themselves and others as bearers of dignity and an irreducible potential for moral agency.

How strong is the link between the disrespect for moral personhood due to a commodification of persons and the negative effects of commodifying attitudes or social arrangements as concerns the human body and its parts? Can and should they be differentiated in moral assessment? After all, as Beyleveld and Brownsword underline, "dignity belongs to my person/agency, not to my body, unless I conceive of myself as my body" (Beyleveld and Brownsword 2000: 95). To some extent, the body is therefore indeed of instrumental moral relevance, "a thing generically instrumental to my agency, not my being as an agent or person itself, and not therefore an end-in-itself"(ibid.: 96). In the rights-respecting, liberal and empowerment-oriented reading of invoking dignity that Beyleveld and Brownsword seem to favour here (against the constraint-reading of dignity),[67] it follows that:

> Whereas to use my body as a mere means to the ends of others would be to violate my person as an end-in-itself, for me to will use of my body as a means is not for me to treat myself as a mere means, for to treat a person as an end in itself is basically to respect the will of that person.
>
> (Beyleveld and Brownsword 2000: 96)

Importantly then, an instrumentalizing attitude is not always and under all circumstances wrong, i.e. it is not intrinsically wrong ('*never as a mere means*', as Kant maintains).

As also Wilkinson emphasizes, there is no straightforward conceptual connection between the commodification of bodies and the commodification of persons and that is why it is so hard to draw the line where commodifying attitudes and practices turn into disrespect for persons. The ubiquitous practice of selling labour, for example, in most cases likely

[67] For a more comprehensive account of these readings cf. Beyleveld and Brownsword 2001.

includes some aspect of commodification following Wilkinson's definition (cf. Wilkinson 2000: 197).[68]

On the other hand, Kant does state clearly that persons are not their property and that the powers of disposal over their bodies must be limited:

> Man is not his own property, and cannot do as he pleases with his body; for since the body belongs to the self, it constitutes, in conjunction with that, a person.
>
> (Kant 1997: 157/158)

In other words, Kant stresses the importance of bodily integrity, in particular insofar it is relevant for the fulfillment of our moral duties and aims.

> […] Disposing of oneself as a mere means to some discretionary end is debasing humanity in one's person (*homo noumenon),* to which man (*homo phaenomenon)* was nevertheless entrusted for preservation.
>
> To deprive oneself of an integral part or organ (to maim oneself) – for example, to give away or sell a tooth to be transplanted into another's mouth, or to have oneself castrated in order to get an easier livelihood as a singer, and so forth — are ways of partially murdering oneself. But to have a dead or diseased organ amputated when it endangers one's life, or to have something cut off that is a part but not an organ of the body, for example, one's hair, cannot be counted as a crime against one's own person — although cutting one's hair in order to sell it is not altogether free from blame.
>
> (Kant 1991: 219)

These duties limit the legitimacy of extracting and transferring (or even destroying) parts of one's body for reasons that might not be unavoidable for self-preservation or in any other sense morally considerate (potential duties to assist and help others, for instance, such as through modern day blood transfusion or organ transplantation, and perhaps donation of tissue for genomic research). Moreover, this passage shows that Kant

[68] Following this analogy, "an individual can realize the value of the body part both as a sale and a gift simultaneously just as the worker recognizes the value of their work while earning money from their labors. This argument supports the notion that it is possible for commodification and non-commodification philosophies to co-exist simultaneously within one system" (Boyle 2002: 67).

disapproves of a commercialization even of renewable bodily material such as hair, though clearly not for reasons of threatening bodily integrity. In a more modern idiom, the reason might be that in however indirect a way, also disintegrating and/ or selling non-integral or functional parts of the body could foster a commodifying attitude to the body and thus be contrary to the aim of autonomous, rational, dignified human agency.

We can conclude that a Kantian would generally be suspicious of disintegrating and/ or commodifying the human body to the extent that this runs counter the fundamental aim of treating yourself and others as ends in themselves rather than means. To this end, in turn, bodily integrity plays an important role and should be considered the norm exceptions to which must rely on – if not medical emergency – serious moral judgment (cf. Lenk 2008).

Clearly however, particularly this latter consideration leaves space for disagreement. In fact, it is debatable if, based on this Kantian point of view, one should be very precautionary in the sense of emphasizing the potential for a slippery slope of de-humanization in all cases of relating even rhetorically and conceptually property, the human body and personhood; or, as Stephen Munzer suggests, the Kantian position more neutrally opens for a 'gradient' of concerns about body parts as commodities. In Munzer's terms, this second view includes the "derived status strategy", meaning that "parts of a living human being […] can have more or less personal connections with that human being. The status of the part has something to do with the status of the whole and its role in the whole. A gradient of appropriateness of treatment as a commodity suggests itself, and concern about the ultimate use of the part is relevant" (Munzer 1994: 275/276).

Both these views, if indeed different, are of course somewhat reductionist, and seem to invite misunderstandings – in particular the first one, as it can preclude further conceptual and contextual analysis. Munzer calls one effect of this the "fallacy of division": assuming that what is true of the whole must be true for its parts. Concerning the invocation of

dignity to argue against property rights in body parts, it is then concluded that because persons have dignity, human body parts have dignity or can suffer offenses against dignity (ibid.: 275).

In the first instance, the idea of a slippery slope of the harm of commodifying attitudes as derived from Kant does not imply that property talk and legal acknowledgement of any form of property rights in body parts are *per se* degrading and/ or violating moral norms (as Cordell et al. suggest). Although Kant denies 'self-ownership', his point is not directly concerned with the property status of an entity or property theory. Not even some forms of instrumentalizing or treating the body as a 'commodity' that could be related to this are wrongs in and by themselves. They can, however, be wrong if and insofar they inhibit the aims Kant has laid out for his moral philosophy more generally (cf. Gerrand 1999; Lenk 2008; Herrmann 20011). As for the second, more neutral view, though it seems to imply some relativism in relation to property and similar rights, the acceptable *treatments* of the bodies of persons have an absolute moral limit in the concept of dignity (cf. Lutz 2010).

The idea of a slippery slope of instrumentalization (rather than directly commodification) implicit in Kant is a limiting condition of the ascription of the primary individual rights of self-determination or 'autonomy'. These rights, however fundamental, are restricted by direct and potential threats to human integrity, to not treating myself and others as a mere means to an end. In research, for example, the requirement of consent is directly based on the respect for human (traditionally mainly bodily) integrity and dignity. Equally, the general requirement of non-commercialization of the human body is based on a precautionary spectrum from direct violations of human dignity in a free market of human bodies and body parts to the indirect threat to dignity by an encroaching culture of commodification if e.g. human reproductive material and 'performance' could be traded in markets.

On the other hand, it must also be clear that purely Kantian considerations of dignity do not have a lot of direct bite as reasons for a general condemnation of commodification tendencies in cases of *detached* bodily material and for instance the research rather than direct-treatment cases. This is because, as long as the fundamental requirement of consent is respected, additional indirect threats to human dignity and autonomy in theory must still be shown to encroach by legitimizing certain practices. The legal judgment in *Yearworth* does – in Kantian terms – not directly and in itself violate dignity. Kant would probably nonetheless agree with Cordell et al. that the men did not own their bodies and their sperm in the strong sense of having unlimited powers over its use, but he might still agree that we have a privileged relation to it that somehow must be acknowledged.

The fundamental question is then what this Kantian approach – so vital for the foundation of human rights law generally and bioethics more specifically – implies for the context of the storage of genetic material in biobanks. The body, in Kantian terms, should be kept out of the realm of 'things' as far as possible to make autonomous agency possible. But this dichotomy that leads to what one might now call 'empowerment' of the individual does not apply well to the case of genetic research on detached body materials. Kant's teleological approach to autonomy is confronted with serious limitations in the age of virtual biobanks and highthroughput-sequencing. The embodied individual on the one hand seems to disappear as a point of reference in both science and bioethically-approved policy making, and on the other hand individuals clearly are also not the only ones at stake, so that an empowerment through consent and information seems quite restricted.

More generally, there is no direct inference from the wrongness of the commodification of persons or via invoking dignity or autonomy to the moral illegitimacy of ownership in detached human bodily material akin to Cordell et al.'s default 'no-property-rule'. Conceptually and morally, body material can *prima facie* not only legally but also morally

be owned, but its use will have to be limited so as to protect a personal and interpersonal sphere that is conducive to a respectful, non-instrumentalizing treatment of human beings among each other. Also, the appeal to non-commodification or dignity of the person does not by itself demand a purely altruistic or charitable transfer of bodily material, in particular if third parties are potentially or *de facto* dealing commercially with these materials (Schnorrenberg 2010: 239). A decontextualized invocation of an unspecified harm of commodification as the core tenet of property ascription or property language confuses the meta-theory of property with the harms particular social practices might legitimize, and is not appropriate to account for the complexity of phenomena to be adjudicated in the life sciences (cf. Campbell 2009: 26; Caulfield and Ogbogu 2012).

Moreover, it bears repeating that the concept and value of dignity still plays a fundamental role if properly understood in its relation to the protection of fundamental rights of integrity and autonomy. This is important, because the larger part of biomedical research uses *prima facie* morally inconspicuous human tissue containing genetic information, while dignity, if not dismissed as only a restricting concept or too vague to give any guidance (Macklin 2003), is often considered of ethical importance only in relation to specific body parts such as embryonic tissues (Kirchhoffer and Dierickx 2011).

In what Kirchhoffer and Dierickx call a 'multidimensional reading' – both compatible with rights-based and pluralistic values – human dignity is not grounded in either an absolute or contingent value, but reflects the multidimensionality of the human person and thus should not be employed in a reductionist fashion (ibid.: 553). Though a piece of tissue following the discussion above clearly does not have dignity in itself, since dignity concerns the human person's possibility of moral agency, it is still implied in manifold ways in biomedical research on tissue and therefore also in biobank-based genomics. Kirchhoffer and Dierickx distinguish two senses: dignity in relation to an inherent human potential, and

dignity in relation to "acquired self-worth". The first sense covers the potential for human identity and identification through genetic information stored in tissue, both as being generally of human origin, and as a matter of an individual belonging to particular groups, such as female/ male, black/ white skin, healthy/ sick etc. The second sense concerns the relations and interactions between tissue donors, study participants and beneficiaries who often have a moral motivation to participate in research (Kirchhoffer and Dierickx 2011: 554).

In this way, although reference to dignity cannot provide concrete answers as to which uses might constitute violations of dignity,[69] it has high symbolic significance in that it

> points to where the tissue comes from, and the ends for which it will be used. So, when we work with human tissue in the research context we are in effect 'touching' the human dignity of the donor and indeed of humans in general. A person has 'entrusted' an aspect of his or her dignity to us, both in terms of his or her genetic identity (absolute) and in terms of the values that may have motivated his or her donation in the first place (contingent). Moreover, because it is human tissue, the research will have potential consequences for all humankind, and thus also implicates human dignity in the broadest sense. Therefore, even if the samples are anonymized, human dignity is still implicated.
>
> (Kirchhoffer and Dierickx 2011: 555)[70]

In sum, both this symbolic sense and the rights-respecting character of the concept of dignity are morally relevant. However, while from a Kantian perspective non-instrumentalizing human agency and relations are crucial for how we conceive of research ethics in general, it is still unclear how this translates into the use of consent or alternative measures for research use of tissue in genomics or 'human non-subject research'. More specifically, if a property-like dimension of the relation between an individual and his or

[69] Yet, as argued above, because dignity and autonomy 'enforce' each other, there seems to be a strong presumption that tissue donors should be able and enabled to choose or at least have the possibility to decline certain uses or forms of research.
[70] Cf. Andrews 2005 and Campbell 2009 for similar considerations.

her body parts cannot and should not be excluded from consideration, how can it be characterized?

3.2.3 A Hidden Property Logic

Legal scholars Deryck Beyleveld and Roger Brownsword, for instance, have argued that the requirement of informed consent as part of the Convention on Human Rights and Biomedicine – which can be considered the ruling European position – is not compatible with a strict interpretation of the principle of non-commercialization of the human body required by the same Convention. More concretely, they propose a reading of the consent requirement that presupposes the very idea of a property-like right in the body.

The requirement of consent is stated in article 22 of the Convention as follows:

> When in the course of an intervention any part of a human body is removed, it may be stored and used for a purpose other than that for which it was removed, only if this is done in conformity with appropriate information and consent procedures.[71]

"Body parts" is explained to refer to "organs and tissues proper, including blood". It does not apply to bodily products such as hair and nails "which are discarded tissues, and the sale of which is not an affront to human dignity" (Beyleveld and Brownsword 2000: 88). As concerns "intervention", Beyleveld and Brownsword propose to interpret it as covering both cases of treatment and non-treatment, although the Explanatory Report only specifies that body parts "are often removed in the course of interventions, for example surgery" (ibid.:89). The report also specifies that "information and consent arrangements may vary according to the circumstances, thus allowing for flexibility". Overall, as pointed out

[71] Convention on Human Rights and Biomedicine [Oviedo Convention].

before, it is not specifically designed to take into account the contextual features of genetic databases and biobanks, and yet, it does represent the central concepts of reference.

To advance their argument, Beyleveld and Brownsword introduce the distinction between two kinds of rights: rights relating to the *taking* of body parts – labeled "Rights A" – and rights that relate to *use and control* of body parts, labeled "Rights B". "Rights A" seem to be the key rights that the requirement of informed consent protects as based on the right of self-determination and bodily integrity. In particular in relation to the challenges biobank-based research faces, "Rights B" seem of at least potential relevance, as they should be protected whenever a post-removal use of a human body part goes beyond what was intended at the time of consent: "Rights B under Article 22, in other words, give us control over the post-removal use of our body parts, by granting us not only the right to set the initial bounds of permitted use but also to sanction any deviation from such initial permitted use" (ibid.: 90).

Are "Rights B" property rights? Alternatively, "Rights B" might protect the cases of 'conscientious objections', for instance to a specific research use seen as incompatible with a religious belief. However, Beyleveld and Brownsword argue that the regime of informed consent as outlined in the Convention on Human Rights and Biomedicine does not seem to be designed to take into account this purpose. This is because the intention of avoiding religious or conscientious harm leads to the recognition of a right to *veto* specific uses, to a list of prohibited uses, as it were, but not to a broader right to control intended new uses and deviations from previously established ones: "In a regime designed to avoid religious harm, where it is proposed to use the removed body part in a way that goes beyond the terms of the original consent, the only question is whether that use is on the prohibited list. If it is not, there is no need to obtain fresh consent. Provided, therefore, that the original

consent has ascertained the full extent of the religious objection, the requirement of fresh consent is inappropriate" (ibid.: 92).

The insistence on the consent requirement, also in new technological circumstances and within biobank research, protects a person's interests in how his or her body parts are put to use, and the specification of this interest does not seem to rest only on the avoidance of a conscientious harm. Instead, Beyleveld and Brownsword conclude, it could also be based on the idea of a privileged relation between persons and their body parts, including after removal. The foundation of "Rights B" in the regime of informed consent is therefore an interest that looks closest to a general conception of property that the authors base on the idea of the so-called rule preclusionary conception of private property. This strong conception of ownership or a property right expresses "the essence of what has traditionally been viewed as private property in capitalism", and refers to "*prima facie* rights to use what one owns (X) for any purpose one chooses and of rights to exclude others from access to or use of X, *even if* the owner's proposed use of X *in any particular instance* is of no benefit to the owner and access to or use of X is of benefit to others" (ibid.: 94).

Beyleveld and Brownsword hint to the justification of this conception by reference to a *Gewirthian* theory of agency, but do not follow this line of argument, and it is not necessary to provide any details of this theory for my present purpose. They anticipate, however, that if agency is central to the justification of the institution of private property rights, then the paradigm example of what can be owned in the rule preclusionary sense is the body (ibid.: 95).

We can now return to the initial observation that the requirement of informed consent in conjunction with the non-commercialization principle is supposed to exclude the body from the conceptual map of what can or should be owned. While the authors have not

shown that these doctrines are inconsistent in any strong sense, they observe that their line of argument points in the opposite direction of what seems to be the current orthodoxy in European bioethics, in which "property in our sense (which entails commercial property) cannot be had in one's body. It can only be had in physical objects independent of one's body". According to an agency-based justification of property "this gets things altogether the wrong way around. If there can be property at all there can be property in my body" (ibid.).

"Rights B" as part of the universal requirement of informed consent in medical research and therapy, then, minimally, are not alien to many aspects of – indeed – human agency such as control 'rights' and rights of disposal, use, and exclusion. The non-inconsistency of informed consent and non-commercialization principle however is due to their common moral source, what I have called *safeguarding integrity and autonomy*. This in turn means that autonomy and integrity delimit how the person and her body and body parts can be 'used', but these concepts could not exclude each other. It is not obvious, for example, at which point and due to which internal or external motivational causes a potential organ sale is an affront to the person's dignity or her duty to respect mankind in herself. As a consequence, there is considerable space for interpretation where indeed fundamental human rights are violated or endangered by particular research practices and where commodification or indeed markets in body material should be restricted.

This has interesting ramifications for an application to research biobanks: Insofar the non-commercialization principle relies primarily on the limiting power of appeals to human dignity, there is a possible conflict with the same moral undercurrents of dignity in the requirement of informed consent as also protective (or rather, the enhancement) of autonomy. Respect for the human *body* – the dignity that is implied in it qua relation to

autonomous personhood – in this way can overshadow the respect for the dignity and autonomy of *persons* (cf. Elger 2010: 68).

3.2.4 Gradual Commercialization, Constructing Property Rights, and Limitations

As should have become clear by now, a general norm of non-commercialization of the human body and its parts as outlined in the Convention on Human Rights and Biomedicine is both as a matter of facts and morals questionable and of little use in dealing with the challenges of the ever more 'transactional nature of dealings in human bodily material' (Nuffield Council 2011) and tissue for research (and transplantation).

In a recent article, Lenk and Beier outline a more appropriate picture, beginning with an overview of the situation in various European countries. Their findings can be summarized in a gradual model of tissue commercialization with four general categories:

(1) *Strict anti-commercialization*: body material cannot be property at all, even against a tissue donor's will.

(2) *Constricted use*: donor's or patient's right to determine further use of samples, possibility of excluding commercial use of the sample.

(3) *Fixed tissue prices by government*: no further control rights of the donor.

(4) *Full commercialization of body material*: free market prices; no further control rights of the donor.

(adapted from Lenk and Beier 2012: 343)

This is in quite striking opposition to what seems at first sight an outright dismissal of commercialization tendencies in biomedicine and research according to the non-commercialization principle respectively the default no-property rule. Levels (1), (2), and

(3) are hence compatible with a strict interpretation of the wording of the non-commercialization principle. This includes the principled possibility of tissue to become legal property, the procurement, transfer and trade for "wider purposes" and also compensation, though not income or gain from the processing of tissue and body material (Lenk and Beier 2012: 343). From this perspective, indeed, it would seem that the main question is how the relations of ownership leading to property arrangements and rights are organized rather than if there should be any considerations of property or commercialization of tissue. So far, I have principally sustained this line of argument, mainly by a critical re-assessment of the Kantian position as well as by outlining the conceptual fragmentation (cf. Harris 2006a) within property talk and theory.

In conjunction with the pragmatic assessment of a gradual model of commercialization practice, a constructivist approach to property in human body parts and tissue for genomic research more specifically emerges. This seems to sit well also philosophically with an approach that Björkman and Hansson term 'social constructivist' approach to property. It can be traced to the utilitarian criticisms of Locke's 'natural' rights view and was then developed by legal constructivists. According to this view, property rights originate in law making and express historically relative social values and functions. Property is 'invented', and thus stabilizes and promulgates particular conceptions of individual and social good in relation to, for instance, questions of promoting economic efficiency, productivity and distributive justice. Its particular forms are created through social decision-making and installed by public authority. In contrast to the view that there is an essential link between owner and owned entity in the natural rights tradition, the *excluding* function of property rights and the relational aspects in a larger social context tend to be emphasized (cf. Björkman and Hansson 2006).

Björkman and Hansson propose a general matrix to resolve contemporary questions of ownership in human biological material. It consists of 7 potential legal rights (which have similarities with Honoré's list) making up the bundle of full-blown ownership and 5 underlying moral principles of 'bodily rights', which are defined as "a person's privileges with respect to her own body. A bodily right may, but need not, give rise to a property right" (Björkman and Hansson 2006: 212). The guiding moral principles are specified as follows:

(1) No material may be taken from a person's body without that person's informed consent.

(2) Under conditions of informed consent, removal of bodily material is allowed as a means to obtain significant therapeutic advantages for the person herself.

(3) Under conditions of informed consent, removal of bodily material is allowed as a means to obtain significant therapeutic advantages for one or more other persons, provided that the removal does not cause serious or disproportionate harm to the person from whom the material is taken.

(4) If there is a significant risk that a certain practice in dealing with a biological material will result in exploitation of human beings, then that practice should either be disallowed or modified so that the exploitation is brought to an end.

(5) The system of legal rights should promote the efficient distribution of biological material for therapeutic purposes to patients according to their medical needs.

(ibid.: 213/214)

This framework can then be readily applied to particular types of biological material. Generally, differences in treatment between different types of body material stem from considerations pertaining to the perspective of the person from whom the material is removed such as need, dispensability and replaceability for normal biological functioning. Equally though, the perspective of the 'user' or recipient and general distributional aspects

such as scarcity of the body material in question must be considered (cf. also Douglas 2012).

The approach that Björkman and Hansson defend offers flexibility and potential guidance that the natural rights approach cannot provide since it "views property rights as an indivisible unit that is analytically prior to society" (Björkman 2007: 222). The entitlements that property conveys are accordingly decidedly not monolithic, but can be adapted to purpose and explain why, for instance, different persons and institutions involved in the research process can have different, sometimes conflicting forms of 'ownership' in, for instance, a stem cell line: A patient/ donor might be entitled to certain 'control rights', whereas researchers and doctors might need entitlements of 'possession' and use.

While this appears to be an attractive feature of their approach, the application to concrete cases reveals that the potential for a nuanced analysis for certain entities might be limited. This concerns moral and policy aspects, but also the ontological issues of categorization that pertain to biological material of human origin that is sought for mainly because of its potentially valuable informational content. Björkman and Hansson mention the example of stem cells and stem cell lines. In their view, stem cells are of great need for an individual in their natural constitution, which at first sight precludes propertization and potential commercialization, but at the same time, they can be duplicated "to the enjoyment of many" and thus are neither scarce nor rivalrous[72] anymore.

> The person from whom the material originates does not necessarily get deprived of anything—one of the fantastic qualities of stem cells is that they can be duplicated […] it has been shown in numerous experiments that stem cells can be removed from a bodily context, grown in vitro and then inserted into both the body they were taken from and into another individual. This brings copyrights and intellectual property to mind; transplanting this type of biological

[72] A rivalrous good is a good the use of which by one person prevents simultaneous consumption/use by another person and diminishes supply of the good.

> material does not (necessarily) involve depriving the source in order to enrich the recipient. In light of this it seems plausible to argue that e.g. the disadvantages of a market system will be smaller, and the advantages greater, for duplicable material such as stem cells and genetic material than for non-duplicable material such as complete organs.
>
> (ibid.: 230)

In fact, these stem cells have become essentially information and as information they presumably retain no morally relevant link to the material 'resource' of origin. The source does not lose anything valuable and others can 'profit'. This apparently win-win situation, however, mixes moral and economic rationality: Need for the donor is defined in terms of bodily function, and what is not needed (is 'redundant'), can be technically replaced or duplicated and is assimilated to an economic resource. Also, the informational component of stem cells for research and their presumed moral inconspicuousness seems to give at least *prima facie* plausibility to an altogether different issue: the economic effectiveness and moral or social acceptability of a potential market in stem cells or stem cell lines.

Björkman and Hansson, in short, assume that the dividing line between moral value in human tissue of various kinds and justifiability of stronger forms of commercialization in the form of markets is very thin. The flexibility of the constructivist theory of property rights is taken to imply that the moral value of body material can be rationalized and 'calculated' for the most part. Again, a meta-theoretical approach to property, moral considerations and policy suggestions tend to be conflated. The moral principles outlined do not mention considerations of potential moral limits in terms of the value of autonomy, dignity, or instrumentalization, even though a principled basis for ascribing bodily rights, grounded in the moral primacy of informed consent, seems to be envisioned. For the authors, "the primary normative issue is what combination of rights a person should have to a particular item of biological material" whereas "whether that bundle qualifies to be called 'property' or 'ownership' is a secondary, terminological issue" (Björkman and

Hansson 2006: 209). However, the analytical usefulness of the constructivist approach does not obviate the question at which point property logic might start to serve the legitimization of certain scientific and social practices rather than moral argument.

This implicit assimilation to economic rationality is criticized in a commentary on the article by Karlsen et al. aptly entitled "To know the value of everything". The authors stress that it is too far from "the context of the realities of health care, patients, medical practice, and research" and instead framed to comply as a mere 'technical' issue with "modern capitalist societies" (Karlsen et al. 2006: 215). Following this critique, the constructivist account can be compatible with concern for fundamental rights of research participants. Its real strength, however, is in its potential to focus on and clarify the purpose of property entitlements in a larger context. Björkman and Hansson criticize the Lockean view as rigid, but in turn construct a matrix of entitlements in which every form of tissue must fit, a task that clashes with the ethical necessity to consider the interests of the supply-side in a more encompassing way, comprising 'material', 'informational' and 'moral' aspects and the continuity of the underlying complex of autonomy-dignity that does not find mention.

As can be anticipated, an important consequence might be that strong claims to property in body material and information derived from it are hard to justify morally, not only because of limitations in individual rights in terms of autonomy and dignity, but because these might conflict with the larger social aims they should serve. This, of course, presupposes to specify these goods and aims for healthcare and research. Some proposals to this effect have been made for biobanks and genetic databases, and will be discussed in section 3.2.6, *infra*. Beforehand, it is useful to illustrate some potential perils of invoking the importance of property rights in bioethical debate while not sufficiently attending to the moral foundations of the personality rights involved.

The constructivist approach can imply concern for the position of individuals and social critique in commercialized research environments. Donna Dickenson, similar to Björkman and Hansson, is critical of the common reliance on Locke (if not Kant) in these debates. She approaches the problem of property in the body from a feminist angle, one of her main foci of concern being the exploitation of women's reproductive 'labour' in the context of ova donation and evolving stem cell technologies. But she also argues that we need a property model to enable the empowerment of donors more generally, including for biobank research. Informed consent in its current form, instead, would rather lead to a disempowerment, while

> A consistent consent regime […] would also imply property rights for patients far beyond those minimal entitlements given by many biobanks, particularly the recently established UK Biobank. Personal rights such as consent are not actually opposed to or separate from a property rights approach; […] limited property rights for donors and patients will in fact give teeth to personal rights.
>
> (Dickenson 2007: 128/129)

This would increase trust in UK Biobank, since it has been shown that participants are concerned about commercial use and it would only be fair to let donors decide on usages given that we expect and count on their altruism: "Donors to UK Biobank, however, have no right to insist that any products or services developed through their gift should be used to benefit the National Health Service rather than commercial biotechnology companies" (ibid.: 132).

Dickenson criticizes the neo-liberal framework of research ethics as a combination of the primacy of voluntary and autonomy-supporting informed consent with a mistaken use of Lockean theory (ibid.: 38; 43). As we have seen, the libertarian (and Marxian) varieties of the latter theory imply that we own our bodies in some substantive sense, an idea only recently appealed to again in bioethical discussion. In this model, the realm of autonomy as

mere choice is pervasive, and the subject in full voluntary control over his or her body: Parts of it can be abandoned, either via informed consent or as we are in 'full liberal possession of our body' (cf. Quigley 2007). This analysis mirrors the current discussion, as the common law assumption of abandonment of tissue is questioned (Quigley 2007; Hardcastle 2009; Harmon 2009), but crucially, commentators do for the most part not consider non-Lockean, alternative explanations for potential property rights, in particular the idea that property institutions and ownership relations might be constructed – from a moral point of view – around *human agency*.

This is, *prima facie* paradoxically, also true for Dickenson, because though it is claimed that self-ownership is 'non-sensical', the labour theory of property can presumably be sustained. Property rights, in the end, are mainly conferred by desert or labour, and the most legitimate form of property in the human body is women's property in their reproductive tissue. Other forms of legitimate property in different tissue could, nonetheless, give rise to limited rights in the bundle of property. Yet,

> Do other claimants than ova and cord blood donors have sufficient grounds to be regarded as having some form of property right in the first place, so that the bundle notion can then be brought into play? We might, for example, grant biobank donors proportionally fewer rights, since they contribute proportionally less labour, but still allow them some of the rights in the bundle. The same might apply to people who donate DNA swabs used in patenting.
>
> (Dickenson 2007: 130)

Dickenson contends that though politically it would be desirable to have some form of property for donors, philosophically there is little space. The reason is that participation is almost risk-free, incurs no labour and it also does not seem that a property interest can be grounded in 'genetic identity.' Rights of donors should be commensurate to risk, labour and 'intentionality' involved in the body material of concern, and these are minimal compared to those in ova donation and cord blood banking. In biobanks, the property rights

to be recognized are rights against unauthorized taking, and *some* more downstream rights. These "weaker rights of ownership can be acknowledged through the creation of a charitable trust to govern the biobank, enabling them to exercise those rights *at a distance*" (ibid.: 137).

Is this all to be concluded? In biobank research, the moral problem is that through an disproportionate but still often superficial focus on consent, underlying property-like interests – and in fact all interests unrelated to physical or perceivable risk – tend to be disregarded. The trust model, to be presented *infra* in Chapter 4, could be a useful remedy, however, from Dickenson's analysis it remains vague what follows for a different form of consent that could indeed empower donors.

Some additional conceptual and practical doubts are worth pointing out. The author hints to the fact that donors 'disappear' from the ethical debate in favor of research legitimization by way of the exclusive focus on consent. Although the bundle theory of property is at first glance applied contextually, is the strategy of empowering donors through accentuating labour not indirectly undermining the aim of making vulnerable donor groups and their interests and rights visible? This is, but not only, because the assessment of 'desert' seems very complicated and would immediately disqualify for example sperm donors and biobank participants in comparison to ova donors.

The reconstruction of Lockean ideas and the strong, autonomous individual in bioethics is eased in a partly Lockean or perhaps rather neo-liberal fashion, by insisting on the nature of desert for justifying property. This is likely related to the fact that Dickenson is primarily interested in making women and their exploitation in various biomedical and biotechnological contexts 'visible'. It seems, however, a form of reasoning that plays into the hands of advocates of strong property rights and commercialization in general, since no

arguments explicating the specific *moral* dimension of property and/ or the larger social effects of commercialization in research are proposed or told apart.

If we were to give property rights to tissue donors 'commensurate' to their labour (even disregarding what this might practically involve), it still remains unclear what has been won from a moral point of view, while the arguably more worrying implications of pervasive commercialization have not been questioned. Women's reproductive labour then is 'equalized', but essentially the situation is the same. For biobanks, the question of 'invisible' and longer-term risks has not been dealt with, or the question what this would mean in practice for the requirement of consent. How can property of this form be expressed or enacted through mere consent? Most importantly though, the invocation of labour is somewhat misleading in this context, and probably favors the status quo, as the real power of labour expectedly would stay with companies and researchers rather than individuals.

In sum, the recent discussion of a constructivist turn to property in tissue gives reason to think that the primary moral problem with invoking property terms in this context is its spurious relation to some form of human identity and autonomy, which however, does not entail its irrelevance. Rather, it seems that a justification of strong private property rights will have to establish this connection in particular as regards the human body, as Beyleveld and Browsword (2000) suggested. The notion of 'self-ownership', however, has not solved this problem. The conclusion, yet, is not a retreat to the modified labour model, especially not across biomedical and research contexts, as there also seems to be tendency of conflating the idea of 'mixing labour' with the importance of moral agency and much larger questions concerning innovation policy. In the application to biobanks, donors then might be at risk to 'disappear' again, their purported rights only to be exercised, as Dickenson indeed suggests, *at a distance*.

3.2.5 Beyond Privacy vs. Property

Graeme Laurie shares Dickenson's suspicion about the inadequacy of consent and the ambivalent role of autonomy that might lead to a disempowerment of tissue donors and research participants. He approaches the issue from an interest in the limits of the traditional idea of medical confidentiality and underdetermined ideas of privacy in dealing with the problem of the familial nature of genetic information, and proposes a conceptual framework of "genetic privacy" that should help to give patients control and choice over genetic information. This novel concept is larger than in particular confidentiality, and conceives of privacy as an elementary part of an individuals' personality.

For the context of donation of tissue and DNA samples including potentially sensitive information to research more specifically, Laurie argues that it seems necessary to complement this notion with a kind of 'property in the person', which would be "the ultimate expression of respect and control over one's own existence" (Laurie 2004: 301; cf. Radin 1996). Since the right to privacy is always just 'negative', a protection from unjustified invasion into a sphere of only personal interests (including information), it

> suffers from limitations similar to those that afflict the principle of respect for autonomy; namely, it does not provide for any continuing control over personal matters once they enter the public sphere. Autonomy in the guise of consent reduces control to the giving or withholding of that consent, after which an individual is largely powerless to dictate what happens […] while her privacy regarding any information derived from those samples may continue to be protected, any residual authority depends on the nature of her original consent and, more importantly, on the assumption that its terms will not be violated.
>
> (Laurie 2004: 300/301)

In short:

> A personal property paradigm could, in fact, serve an all-important role in completing the picture of adequate protection for the personality in tandem with other protections such as autonomy, confidentiality and privacy. This means that meaningful, legally relevant and

> enforceable conditions could be placed on any transfer of the property and so ensure that a research participant or indeed a community retains a vested interest in samples and in the goals and outcomes of any research for which those samples are provided. By the same token, restrictions on the inclusion of undesirable clauses by either side could easily be imposed by law.
>
> (Laurie 2004: 318)

Laurie seems rather optimistic and advocates a new age of, again, self-ownership. While many of his concerns are shared in the present analysis, there are two potential problems within this vision: one is similar to the criticism in Dickenson's proposal on the lack of an adequately strong normative ground for a paradigm shift in research governance in which property is central, while the second is more practical and requires to outline some potential conceptual and legal limitations.

The first point is that though there is even an intuitive link between privacy and property, it is not clear that self-ownership is a way of filling it with meaning which could be effective to inform research governance in an innovative way, as Laurie suggests. Questions about property rights in bodies indeed are primarily about *private* property. The link is not merely etymological though. Descriptively, it stems from the idea of privacy as control over the private sphere of a person's body and information relating to it. In a normative conceptualization, the link could be drawn in pointing out that what is subject to privacy and what is private property encompasses what a person can justifiably refuse to allow others access to without consent. This idea can lead to strong rights of privacy or even private property in the person such that "a person's ownership of something would involve not merely that she could justifiably resist it being physically taken from her, but that she could justifiably resist other attempts to gain access to it that she does not consent to—including placing restrictions upon her ability to transfer it to consenting third parties. On this normative understanding of private property, then, a person's property is inherently commodifiable should she consent to this condition" (Taylor 2010: 176).

We do not have to look for an ultimate definition of "property" or "privacy" here, but there is a clear overlap of concept that centres around the idea of protecting fundamental interests in the self or human identity, and presumably a sphere of something akin to 'autonomy'. As I have suggested before, the notion of 'self-ownership' is used in the debate on property in the body and its parts vaguely and/or metaphorically. What is to be explained seems to be presupposed: the relation between important interests in the self and the potentially large spectrum of rights that ownership confers to the exclusion of others – including a morally dubious right to commodification. In this roughly libertarian vein, privacy rights and rights in the body therefore inevitably converge.

Contrary to this project, I have suggested that though claims to property *in body parts* cannot *prima facie* be excluded, there is a normatively strong basis in the rationale of the traditional requirements of research ethics that points in a different direction. This can lead to a weak position of the research subject in the research context we are looking at, in particular if the value of autonomy and integrity as well as the concept of informed consent are narrowly interpreted. Also the appeal to privacy cannot redress this imbalance for both conceptual and empirical reasons, and is moreover inextricably linked with the requirement of consent.

In the face of the epistemic insecurities and unclear risks of large-scale, data-intense genomic research, the most defensible moral starting point seems to be the insistence on established rights: a more liberal element of safeguarding autonomous agency through the possibility of voluntary, non-coercive, informed choice *and* a more protective element in limiting autonomy by appeal to integrity or dignity. This is the normative baseline to be translated to the ethics of biobank participation. Although it is tempting to fall back to a narrow concept of consent as a guiding idea, it should be remembered that it cannot be scaled up to this new research context. For the time being, we should focus on the two

normative elements singled out: the possibility of 'real choice' for an individual research participant or sample donor, and the integrity of research uses on tissue more generally (rather than as concerns a single human being in a treatment context or a clinical trial).

The proponents of a paradigm shift towards some form of property model instead use a language of self-ownership to strengthen the position of the tissue 'sources'. With the exception of the development of conceptual tools to differentiate legitimate from illegitimate uses of these powers, an important part of the initial concerns about commodification of tissue and general commercialization practices in research cannot be addressed on any strong normative basis. The second major problem is the relative inconcrete nature of how the envisioned property model could indeed be implemented without collateral effects on the baseline model of respecting participant rights. Last but certainly not least, the model should also be compatible with a generally defensible interest in effective and successful genomic research (cf. Bovenberg 2004).

Interestingly, there have been various proposals in different legislations that are in line with Laurie's and others' approaches (though not in Europe). The most concrete plans of installing property in the context of protecting the personal right to privacy for sample donors were put forward in the US (cf. Purtova 2011). In 1995, Oregon became the first state in the country to declare DNA the private property of an individual. After lobbying from pharmaceutical industry and representatives of biotechnology research who saw this proposal as stifling innovation and investment, long-lasting debate involving also stakeholders of the public and healthcare services followed. In 2001, the property clause was eventually replaced with a statement relating again to the protection of confidentiality and privacy (Everett 2003; 2007).

Why was that? Withholding rights to property is associated with loss of control in samples and data – the 'disappearance' of legitimate interests of research participants and their trust

in research. The installment of (traditional) individual property rights, on the other hand, faces manifold theoretical and practical problems. First, the idea of making consent more transparent within the regular consent paradigm as a kind of enforceable contract (cf. Dickenson 2007) is inhibited by the problem of a lack of concrete information within biobank research.

In terms of legal construction, 'property in the person' in Laurie's sense can be envisioned similar to intellectual property, that is, one could have rights to information from the sample similar to copyright protection in an aesthetic work for the creator. This right can be abandoned and therewith any future claim to control unauthorised copying of the work. Laurie points out that European legislation protects nonetheless moral rights in aesthetic creations, the personality of the creator as embodied in the work, so to say. Therefore, even after abandonment, "Inter alia, they protect against derogatory treatment of the work if this will adversely affect the reputation of the creator, and they ensure due recognition of the creator's identity whenever the work is placed in the public domain" (Laurie 2004: 325).

It is thus not enough to counter this proposal by reference to a strict distinction between tangible and intangible property aspects that would be a conceptual or legal necessity, and assume that *therefore* there can be no property in samples and information for an individual. After all, there are various forms of intellectual property covering these aspects, although some of them seem to be more policy tools than personality protection. This analogy, however, could also lead us to think of property claims in terms of what kind of role we want participants to play in a research process that fosters innovation.

Matteo Macilotti has used the description of human tissue 'in 3 dimensions', that is, material, informational, and moral or 'relational' as the actual governance challenge, because "the distinction between these three dimensions […] is only theoretical, given that in nature these three dimensions of human tissue are inextricably linked to one another and

the bundles of rights originated from them overlap. Therefore, to understand the rights of the human subjects, it is not sufficient to study the characteristics of these three dimensions, but it is also necessary to analyse how these dimensions are related to each other" (Macilotti 2013: 144).

More than that, it is necessary to determine the border between person and thing normatively, and not rely on a fixed and inherent limit of the law. Therefore, in the constructivist perspective, it would also be possible to circumvent the problem of self-ownership or self-commodification by, for example, innovatively disassembling the sticks of the bundle of property and propose a new kind of 'bio-property' (cf. De Faria 2009; Hoppe 2009) which might avoid problematic consequences in terms of commodification. In theory then, one can stick with what would remain essentially a gift model, but with more control powers for the individual donor: gifts with particular 'strings'.

However, some issues remain problematic as the assignment of property is not an assignment of *de facto* powers:

> The reality is that biological material can be transferred and dealt with in ways which do not involve legal ownership, but rather issues of possession and use. Consequently, ownership may in fact be far less important than the question of how the party that uses the biological material has obtained that material.
>
> (Otlowski 2007: 137)[73]

This means that legislation could focus on access policies and restricting using and sharing rather than empowering donors via property rights (cf. Roche 2010; Bellivier and Noiville 2011), even if this certainly would not seem to echo the trend of massive networking and data-sharing.

[73] Cf. Janger 2005.

What one should not conclude in normative terms taking into account these limitations, is that we are then back with privacy, or the ambivalence of autonomy as the only guiding normative ideas for governing research. Conceptually and morally, both aspects of the privacy paradigm and property-like concepts continue to be of importance. Even though the normative border between person and thing is loose, this can be deployed in a number of ways. Traditionally, effective and enforceable property seems to presuppose 'thingness', and the possibility to split the 'thing' from, for example, the 'self', which some authors assimilate indeed with a moral fragmentation via notions of property:

> Property produces a fragmented relationship between the body and its owner, the person 'inside' the body, in contrast with privacy, which creates an indivisible corporeal identity. By uncoupling the body from the person and undermining the unity of the physical being, the property paradigm facilitates fragmentation of the body itself, both literally and figuratively. […] Privacy theory, on the other hand, forecloses such bodily fragmentation by identifying the person with his or her physical presence. Hence, privacy shields the individual against corporeal invasion and alteration and preserves the unity and integrity of the embodied being.
>
> (Rao 2000: 429)

Similarly, Herring and Chau stress the interconnectedness of human bodies (Herring and Chau 2007; 2013):

> an important part of the picture of our bodies is that they are giving and taking not only from the world around, but also from other bodies. This, we suggest, is part of the difficulty in finding an appropriate legal response to the classification of bodies. No single model can capture the nuances of bodily life: that our bodies are ours; are in relationship with others; are in constant flux; and yet central to our identity of ourselves.
>
> (Herring and Chau 2007: 52)

However, as Rao adds, property is powerful, and therefore naturally perceived to offer not only a shield to invasion into my private sphere, but positive claims against the remover of what is 'mine', and also third parties.

> The property paradigm […] alone affords a complete bundle of rights that are enforceable against the whole world. In the face of strong property rights on the part of researchers and research institutions, the theoretical freedom to contract and the meager interest in privacy leave those who supply body parts vulnerable to exploitation.
>
> (Rao 2007: 380)

The claims of a right to privacy or bodily integrity, instead, "may only be effective against the remover." This presumption, Herring and Chau clarify, "may however depend on a particular notion of rights of autonomy or privacy" (Herring and Chau 2007: 44). This consideration brings us back to the underlying property logic of consent, which as I have argued is an irreducible and morally important dimension of the complex of rights that underlie the universal requirement of consent and the protection of research subjects in general. It would need a very refined new concept of privacy and autonomy that could incorporate this property dimension and also be effective in confrontation with the hybrid entities between person and thing created and perpetuated by life science research.

The distinction between privacy and property, independently from their concrete legal conceptualization and real-world effectiveness, seems even less sharp then many commentators propose.[74] In particular, the notion of property is not only a signifier of a disaggregation of the body, an issue that is of particular relevance for long-term research in genomics. Ironically, property-like notions and rights are needed to establish *continuing* interests in both selfhood and what has been called (bio-)informational self-determination. This already convoluted outlook is augmented since 'property', in itself, is conceptually fragmented.

Margaret Radin, for example, in discussing 'Contested Commodities', puts forward a distinction between 'personal property' and 'fungible property'. Personal property or 'property for personhood' concerns what is quintessential for a thick notion of personhood

[74] For a defense of privacy and property as fundamentally different, cf. Suter 2004.

in terms of wellbeing and flourishing. The human body as a whole, in this sense, will be property for personhood. But this normative notion can also cover functional aspects, in that material, technical 'objects' can be central to this concept of personhood (such as a cardiac pacemaker). 'Fungible property', on the contrary, can be traded. It is alienable, in particular market-alienable, i.e. it can be sold in the marketplace (cf. Radin 1987; 1996). Using Radin's distinction, it is clear that for a donor, a tissue sample containing DNA is a multifaceted conglomerate of personal and fungible property aspects. This complexity increases as the sample gets involved in the research process and might be transformed into other forms or 'bio-objects', slides or a cell-line, and as data tied to the sample accumulate concerning the donor and the research. The sample is alienated from the source, but still retains a morally important link to a person.

In summary, invoking the notions and quasi-rights of property is a necessary corrective to the overemphasis on often thin accounts of patient or donor autonomy and their ill-defined and potentially ineffective rights to confidentiality and privacy. Property is also used to navigate the question of individual identity and its protection in confrontation with genetic/ genomic information and to determine the boundaries or non-boundaries of the self (cf. Widdows 2007). As Rich et al. have formulated: "What circumscribes the body-self (i.e., where are its boundaries)? What 'belongs' to me or is a part of me and what is not? And, therefore, what should be considered with some respect of personhood or dignity, or, at least, come under my own decision-making control?" (Rich et al. 2012: 4).

While legally recognized property rights normally presuppose alienability, tissue rights would have to point to an *extension* of the self to familial and new group identities, in particular with an eye on their genomic 'content':

> because of the nature of genes, it may be argued that genetic information about any individual should not be regarded as personal to that individual, but as the common property of other people who may share those genes, and who need the information in order to find out their own

> genetic constitution. If so, an individual's prima right to confidentiality and privacy might be regarded as overridden by the rights of others to access to information about themselves.
>
> (Royal College of Physicians 1991, quoted in Sommerville and English 1999)

However, this is a non-technical usage of 'property' that also has its perils, and so it seems that new interpretations and implementations of autonomy as a key reference in bioethics are at least equally relevant.

Cautiously contra Herring and Chau it can also be argued that property-like entitlements as applied to body parts convey an important sense of 'territorial integrity', as Courtney Campbell has proposed. She distinguishes three moral meanings or *topoi* of the property paradigm in biomedical ethics: *territorial integrity*, *alienation* and *empowerment*, of which territorial integrity seems to have moral priority (Campbell 1992) – in contrast, as we have seen, to the interpretation in legal theory, in which alienability tends to be central. For biobank research, this again would presuppose that we think of body parts and even minute samples to a certain extent in terms of corporeality and not as pure or quasi-pure information (cf. Halewood 1996; Parry and Gere 2006).

The main concrete, and more positive moral aspect of the property framework that should be incorporated into the ethics of biobanks is the issue of a legitimate donor or participant control interest.

And what about 'income rights'? Arguments against remuneration and sale of bodily material, including to a biobank, are not of a very strict principled nature, but based on interests, in particular interests in efficient use of biomaterial by researchers and product developers. This must be kept in mind if, in terms of policy, we decide against the payment of participants. The arguments against this policy from the perspective of participants are that payment in most cases would not be part of the best justified moral rights of the

participant of continuing control – given that the only 'technical' or legal ascription of a property right does not solve the problem of unequal representation of powers and interests.

Also, insofar the slippery slope problem of commodification of tissues cannot be thoroughly banned *ex ante*, pleading for a widespread remuneration would seem wrong. Participants have an interest in an effective and yet respectful use of their material, and therefore in limited use rights of researchers, plus, if properly informed, third parties. This is a qualified argument against remuneration, based on two considerations, a more structural and a moral one. In the structural, the ascription of property is considered recommendable if it can be anticipated that this will help to distribute scarce resources efficiently. Yet, it seems unlikely that strictly individual rights over single samples can be used to help the efficient allocation of resources and information for research. This is partly because it is hard to anticipate the valuableness of the material, and partly because in the face of this uncertainty individuals would suddenly have gained an enormous power over their material that might nonetheless remain only theoretical.

The more stringent worry seems to be the moral one: there are good reasons to be skeptical that we would want markets in tissue samples and DNA that could not only change drastically how human beings view bodily material, but also research organization more generally if turned into a matter of mainly bargaining and contracting. In contrast to control property rights, income property rights of individuals do not sustain basic moral rights in the same way control rights would, and they seem to conflict more straightforwardly with the shared interests providers and users have.[75] All of this, however, is based on the demanding requirement that there actually is a sense of shared interests that

[75] Potential income rights are to be distinguished from individual benefit-sharing in case of commercialization of an invention based on 'donated' bodily material. In both cases the individual contribution to an end product of knowledge or a pharmaceutical product might, however, be impossible to determine. This does not preclude that in special cases such as *Moore*, contractual agreements could settle financial aspects. Cf. Schneider 2010.

is transparent for all parties to the research project, and that gives people on this basis choices for exercising their quasi-property rights.

These quasi-property rights that attach to the personality rights of participants insofar their tissue remains 'personal' has to be made explicit in the context of large-scale research. Participants have no particular interests or rights in strictly anonymous tissue, but insofar it is not, they have primary rights that are not only 'technical' rights pertaining to data flow but rights that pertain to moral agency. While the rights over the tissue in itself are *prima facie* strictly individualistic, genomic information, sequencing data etc. can be relevant for other individuals and groups, which in turn limits the individual claims to quasi-property as an expression of individual moral agency. Insofar we want to look at tissue for research in three-dimensional fashion, this significantly complicates a solution to the individual control rights through legally recognized property. It would presumably require to clarify the question of the right to know and/ or not to know, and will be an issue when the distinction between research, diagnostics and/ or treatment has become even more clearly blurred. Here, I have concentrated more on the supply side of biobanking, though with flanking considerations about the larger effects on biobank ethics and governance.

For the questions of governance that we will focus on in the remainder, property, privacy and consent are all not enough by themselves to provide control, which must also be possible to be limited by the claims of others. While there is an irreducible aspect of personality and self in every sample that leads to the *moral* recognition of a quasi-property right, researchers have strong claims to possess and use samples within the limits of what a donor considers his fundamental interest. As we have seen, making these interests visible and giving participants choices in practical terms can seem overwhelmingly complicated and therefore appear perhaps neglectable.

We might, however, draw some attention from individualistic interests in strong control rights to *morally defensible uses* of large-scale research projects and the fair distribution of research 'resources'. Naturally, these two aspects converge, as can be seen for instance in the controversies surrounding patentable organisms and genetic sequences. Often, not necessarily patents in themselves are considered problematic, but effects and 'transaction costs' on research culture, research priorities, and the involvement of stakeholders in contexts of great power differences. While this is a topic that cannot be adequately introduced here, it is a project that must complement the questioning of donor rights in biomaterials and information. If individual rights to property in body parts are limited – though actually rather for lack of concepts than moral title (cf. Holm 2006) – then certainly, in a further step, we should equally question the strength of moral title users rather than providers have.

The second conclusion is that individual control rights and the more overarching interest in research uses and fair distribution as 'co-owners' in particular in 'public' projects should be accounted for in other ways. Currently, interests in control as participation and as both individual and communal interests in sustaining the overall endeavour are frequently not or not adequately acknowledged. As a consequence,

> people feel disenfranchised from, and disempowered by, the modern machinery of research [and] that we face the current public crisis of confidence in research in general and genetic research in particular. Individuals who provide samples for research purposes are not, and do not feel like, stake-holders in the enterprise. The continued participation and support of the public in research activity can only be ensured by a fundamental reappraisal of the relationships with the subjects that have traditionally been accepted.
>
> (Laurie 2004: 311)

The alternative seems to be sustained by neglecting the conceptual and normative issues related to property, "justifying a distorted gift paradigm while fuelling inconsistencies that

ultimately undermine public confidence in research" (ibid.: 317). As Laurie hints to himself, perhaps property in body parts, tissue, genetic information and research data is not the solution by itself, but rather finding innovative ways of *relating* participants and the research enterprise.

This, furthermore, is not a supererogatory task, a mere advisable option. It is a clear demand that arises from the limitations in the protection and safeguarding of privacy, property and control rights of the traditional model of one-time upfront consent to research participation. The proposers of the research are in charge to involve participants if they so want to win their confidence and support and to encourage debate on the goods involved (cf. Williams and Schroeder 2004). Notwithstanding the conceptual, moral, legal and practical problems that plague the property model, so that donor-participants cannot and presumably should not claim strongly enforceable property rights, their moral claims remain. In fact, they are implicated in the universal requirement of consent and additionally have an expressivist function, since without them, consent might be reduced openly to an issue of non-liability rather than protection of personal rights (cf. Porter 2004; Ram 2009).

This deceptively simple conclusion has to be 'translated' adequate to the scope of large-scale research infrastructures in which potential harms and wrongs of research or other and future (mis)use are threatened to become invisible. Insofar we stick with consent, consistency requires a presumption of primacy of individual rights, and this covers property-like rights.

Some authors would disagree: they infer from the non-conclusiveness of strict individual full-blown property rights in bodies and tissue that this primacy is to be questioned, and in fact, that what is not strictly private is thereby subject to public interest, and perhaps public ownership.

3.2.6 Human Tissue in the Public Sphere: A Communitarian Turn?

In discussing the case of *Moore* and the potential property rights in 'his' spleen as well as the cell line produced from the biomaterial, Herring and Chau submit:

> The difficulty is that the property approach might ensure he was over-rewarded. […] There is a danger that valuable research into stem cell lines and DNA will be hindered if patients are able to claim an interest in the products. […] as our bodies partake of the great giving and taking between all bodies, there is an argument that it is only just that a body be made available to other bodies, if it holds the key to assisting them. In other words, there could be a moral obligation to allow one's bodily material to be used for the benefit of others. This might even lead to a presumption that an individual consents for her material to be used for medical research.
>
> (Herring and Chau 2007: 53-55)

Thus, if my body and its parts do not strictly belong to me, do they become public in some relevant sense? Is there actually not a moral presumption in favor of personal property or (misleadingly) self-ownership but rather a presumption that bodies and body parts be available, even *made* available for "the benefit of others", for instance through research?

In fact there is a thread in the bioethical literature proposing a link between the 'public' or 'common' goods that biobanks and research databases are or provide, and the justification of deviations from traditional requirements of informed consent and the individualistic ethics it presupposes. Bartha Knoppers, Ruth Chadwick and others have advocated the need for a new ethical framework that should be established through a 'communitarian turn'. In this vision, the role of individual autonomy and the related strong emphasis in ethics and governance of large-scale research on informed consent is to be corrected by innovative forms of gift-relationships and 'collective consent' to solidary participation in genomic research. In addition to solidarity, also other values such as reciprocity, mutuality, universality, equity and citizenry are part of this framework.

"Reciprocity" here is associated with the emerging trend of consent as 'informed choice', as Knoppers and Chadwick explicitly say, and signifies in extension of this development "recognition of the participation and contribution of the research participant" (Knoppers and Chadwick 2005: 75) in terms of various possibilities of research participation, but also in an expanded version "from exchange with the individual or his/her family to the community or population."[76] Similarly, "mutuality" refers to the emerging need of sharing genetic information with family members in contrast to the traditional emphasis on medical secrecy (ibid.: 76).

"Universality" is taken to relate to the collective sense in which the genome itself, rather than particular values in gene-ethics, are universal: "This understanding of the human genome at the level of the species has led to the specific emergence of the principle of universality in relation to the genome. Often expressed as the common heritage of humanity and justifying obligations to future generations, it highlights and reinforces the approach of benefit-sharing (also grounded in equity) and of genomic knowledge as beneficial to the public" (ibid.: 77).[77]

'Benefit-sharing' is a concept that stems from other than human genetic research contexts. It was applied in international policy to promote equity in access to non-human genetic resources, scientific inquiry and its commercial products, in particular patents in the biotechnology industry, for example in the UN Convention on Biological Diversity.[78] The UNESCO Declaration on the Human Genome states that "Benefits from advances in biology, genetics and medicine, concerning the human genome, shall be made available to all, with due regard for the dignity and human rights of each individual"[79] (cf. Simm 2005: 30). The concept of "citizenry", finally, concerns public involvement in genomics through

[76] Cf. in particular on reciprocity and the potential for a new contract between science and society in genomics Meslin and Cho 2010.
[77] Cf. Ossorio 2007.
[78] Convention on Biological Diversity (CBD). United Nations 1992.
[79] Declaration on the Human Genome and Human Rights. UNESCO 1997.

‘citizen science’ and the effects of genomic knowledge on collective identity (Knoppers and Chadwick 2005: 77). For most authors in this debate, a turn to community interests is necessary as a matter of pragmatism, albeit not in contradiction to ethical principles and individual rights. Strong emphasis on individual rights and benefits must, however, be rethought given that this framework would provide the key to adapting the different principles to incipient scientific developments.

The concrete normative undercurrents are left somewhat unexplicated, but do nonetheless afford strong claims of overcoming the priority of individual rights – in continuation with the proposal of informed consent as first and foremost informed choice. As I have argued above, this move does imply a serious divergence from the traditional model of participant protection, and so it is necessary to illuminate the motives other than pragmatism which might ground the novel community-orientation. Interestingly, part of the proposal emphasizes the supposed historical contingency of the individualistic approach. Accordingly, present thinking in this area is at least in part the result of a response to crimes against humanity in totalitarian states which occurred more than half a century ago — “a situation with little similarity to present research or the medical uses of databases” (Chadwick and Berg 2001: 320).

Genetic information, however, would be communal, and from this it would follow that communal values and solidarity are more apt to genomic research uses. In particular, this kind of solidarity is something that is provided or enabled by the health care and research system, but must nonetheless start from the individual person. Accordingly, solidarity is in actual fact construed as a quasi-duty to participate in research, which would be very strong in the case of rare genetic diseases, but seems to extend to research in genomics more generally:

> It is not obvious, however, why a right to refuse to participate in genetic research, when it could be to the benefit of others, should be overriding. On the contrary, it could be argued that one has a duty to facilitate research progress and to provide knowledge that could be crucial to the health of others. This principle of solidarity would strongly contradict a view that no research should be conducted if it would not directly benefit those participating in a study.
>
> (Chadwick and Berg 2001: 320)

While I will leave aside the issue of historical comparability (recall, however, my suspicion of Elgers' view that the appropriate protections seem to evolve 'naturally') some differentiations in terms of disease have to be anticipated. The appeal to solidarity in the case of specific, rare diseases might be immediately convincing, but we have to look here at claims that are made with respect to much more generic forms of research into often common, multi-factorial diseases involving different smaller and larger sections of a population. From the case of rare genetic disease, however, Chadwick and Berg move to the question of general duties of beneficence that they seem to assume are often neglected for unjustified or dubious reasons:

> It is questionable whether individuals should be free, from an ethical point of view, to refuse to help in an effort to relieve suffering for what could be regarded as trivial reasons, such as refusing to allow samples to be reused for research on drug abuse because of the disapproval of drug users.
>
> (Chadwick and Berg 2001: 321)

Although Chadwick and Berg do not conceal that benefits from genomics could be substantial in particular for pharmaceutical companies (ibid.: 319) they assume concurrently that the goods and benefits brought about by this research are 'common goods', referring to knowledge concerning the molecular basis of disease, preparing the basis for later and new therapeutic modalities as well as the progress in diagnostics and treatment of disease which will accrue to society at large as well as patients and families. Can this general appeal to benefits and goods in these proposals with reference to different forms of research and different types of disease considered ground nonetheless equally

strong duties – in fact, the overturning of a presumably obsolete model of individualistic research ethics?

Certainly this trend is confirmed by the language that high-level policy documents employed in particular around the turn of the millennium (cf. Chadwick 2011). In 2002, for instance, the Human Genome Organization designated human genomic databases 'global public goods'[80], a notion also appealed to by Bartha Knoppers. She suggests to conceive of these databases rather in analogy to the 'public health model', constructed around the problem of epidemic control. Genomic databases then would fall under the category of 'global public goods' since the benefits of genomics are comparable to the non-divisible benefits of 'epidemiological intelligence', accruing globally (Knoppers 2005b: 1185; cf. Thorsteinsdóttir et al. 2003). Chadwick and Wilson, in discussing the relevance of this proposal for population biobanks and genomics generally, advise that the notion must be understood rather as a strategic, policy-oriented one. But what does this imply in ethical terms?

In their reconstruction, the argument for genomic databases as 'global public goods' runs as follows:

(1) Public goods are goods which are non-rivalrous and non-excludable.[81]
(2) Global public goods are public goods the enjoyment of which is not limited to any specific geographical area.
(3) Knowledge is the archetypal global public good.
(4) Genomics is a form of knowledge.
(5) Genomics knowledge is a global public good.
(6) *A fortiori*, genomic databases, in so far as they contain genomics knowledge, are a global public good.

(Chadwick and Wilson 2004: 125)

[80] Human Genome Organization (HUGO). Statement on Human Genomic Databases, 2002.
[81] Non-excludable goods denote goods from access or enjoyment of which others cannot be excluded.

According to Chadwick and Wilson, it must be clarified whether a global public good in this sense is 'natural' or 'social', and also what the "global" refers to more specifically, i.e. who exactly benefits in terms of socio-economic classes, present and/or future generations etc. As a first concretization, the authors propose to look at the economic dimension that seems to be implicit in the argument and the policy-driven appeal to label genomic databases 'public goods'. This means, beyond a descriptive level, to consider externalities, benefits or burdens including spill-over effects; long-term consequences, or savings in healthcare.

Generally, as Chadwick and Wilson point out, in economic terms "goods are public because there is insufficient incentive for the market to provide them publicly. This is because the non-excludable nature of an item means that it is not possible to charge very much, if anything at all, for it, as persons will not pay for an item they can access for free. That is, the property of non-excludability leads to a 'free-rider' problem" (ibid.: 127). In the case of the Icelandic Health Sector Database, for example, "commercial ownership also demonstrates that genomic databases will be provided by the market where there is deemed to be sufficient financial incentive to do so, contrary to the economic definition of public goods as a response to market failure" (ibid.: 132). In fact, while the knowledge contained in the HSD is *prima facie* non-excludable, full access to the database requires paying a fee. Here, Chadwick and Wilson point to a mingling of descriptive and normative levels in the general appeal to genomic databases as public goods in which conditions of access are downplayed, while benefits that could accrue to the public are emphasized. This works since the theoretically non-rivalrous and non-excludable human genome *in abstracto* is the basis for the information held in the databases, and thereby grounds arguments claiming that genomics knowledge is a global public good.

In the Human Genome Project, for instance, both public and private aspects of genomics became very pronounced as a publicly financed and a commercially supported project were racing to finish the sequencing efforts first. Now, the sequences are public, but of course it remains still true that "each individual's genome is very much private and 'rivalrous' – my genome is my genome and cannot be used by anyone else. Similarly, there is a way in which the genome is not non-excludable, as currently access to a person's genome is fully excludable, controlled by that person (or perhaps by parental authority)" (ibid.: 130). In short, the human genome can be species level 'common heritage', but tokens are *prima facie* private. The appeal to the public good of genomics and as genomic databases accentuates the species-level of human rights and interests at stake, and the genetic similarity of human beings (cf. Kauffmann 2011).

Notwithstanding these characteristics, the extent to which research knowledge is indeed a 'pure' public good (cf. Stiglitz 1999) is increasingly questionable in particular in relation to genomics. There is a certain extent of excludability due to patentability, trade secrets in biotechnology etc. This is a complex policy problem, since the excludability or a limited access to information and exploitation of a 'resource' is morally justified by the assumption that overall knowledge increases and will be widely accessible. Certainly, 'access goods' (such as education and infrastructure) as well as social arrangements play a role, and can lead to large differences in technologically advantaged vs. technologically disadvantaged parts of the world – indeed an issue international organizations have tried to draw attention to by promoting benefit-sharing.

For Chadwick and Wilson, the result for genomics as a 'global public good' is mixed:

> Knowledge generally, and in the specific instance of genomics knowledge, is illustrative of a continuum from public to private, excludable to non-excludable, along which goods may be placed […] Despite some strong global public good characteristics, genomic data-bases as they

> are currently being developed are generally following a private good model, primarily because of the restrictions in access imposed through either financial or technological constraints.
>
> (Chadwick and Wilson 2004: 128; 133)

In particular, commercial research use can seriously delimit non-excludability. As to the strategic policy use of what now seems rather a metaphor with vague normative connotations, they cautiously remark that 'end goods' such as the specific goals in healthcare and problems in global justice remain relatively implicit. Yet, given that these ends goods have not been specified, it would seem more appropriate to renounce reference to global public goods for the time being.

Chadwick and Wilson assume that the appeal to the public-good nature of genomics is equally important for various forms of biobanks. As we have seen, there is undeniably a strong tendency of conceptualizing all the relevant ethical issues in terms of access to and protection of information, the prototypical public good. Indeed, also the statement of the Human Genome Organization has changed the order of priority with regard to traditional research ethics, as sharing of data and genomics knowledge is considered primary to the "choices and privacy of individuals, families and communities with respect to the use of their data."[82]

The large gap between defenders of the 'public good approach' – even if they admit some limitations – and other voices raising strong concerns is striking and parallel to the debate on the viability of high informed consent standards. Some authors have considered the supposedly firmly grounded 'communitarian turn' part of a more pervasive movement towards increasing social control also to be witnessed in other developments such as biometrics, so that eventually technological innovation will be linked increasingly with public health control and security policy (cf. Rommetveit 2011; Kauffmann 2011).

[82] Human Genome Organization (HUGO). Statement on Human Genomic Databases, 2002.

As an example of how individualistic medical ethics adapted to such a trend with reference to 'common goods', Rommetveit uses the recent set up of the digital Norwegian Health Registry. In a white paper concerning ethical questions, in particular privacy, it is contended that the four principles of medical ethics – autonomy, beneficence, non-maleficence, and justice (cf. Beauchamp and Childress 2012) – " were primarily intended for the healthcare context, that is, aiming at treatments for individual patients. Health registries, on the other hand, are different, because their primary purpose is aimed at the collective level." Consequently, "the white paper immediately translates the four principles into the ''parallel'' principles of integrity, safety, utility, and solidarity", while specific consent to such an endeavour is devalued as too cumbersome, even meaningless for the health registry participants, quite analogous to the case of research biobanks. In a nutshell: "the common good is equated with the perceived needs and interests of science" (Rommetveit 2011: 586).

Yet – is this really as problematic as Rommetveit suggests? Some analysts, for instance John Harris, have tackled the issue from the opposite direction (Harris 2005; Irving and Harris 2007; Chan and Harris 2009).[83] Harris thinks that there is an unjustified presumption *against* scientific research and medical research more specifically which is sustained by international guidelines and recommendations that not only advocate for strong safeguards – in particular: informed consent – but assume that people do not "wish to act in the public interest." In effect, "the overwhelming presumption has been and remains that participation in research is a supererogatory, and probably a reckless, act not an obligation" (Harris 2005: 245; 242). This is wrong-headed, according to Harris, and instead there is a positive moral duty to sustain and participate in research based on a duty of beneficence and the principle of fairness. A position that, as VanderWalde and Kurzban

[83] For direct criticism of Harris see Brassington 2007 and 2011; see also Caplan 1984; Herrera 2003 and Rhodes 2005 for similar arguments; for a more critical perspective Jonas 1969 as well as Wachbroit and Wasserman 2005 in reply to Rhodes 2005.

point out, had already gained a wide appeal in the 1960s at least in the US, before the scandals of Tuskegee and others lead to reconsiderations (cf. VanderWalde and Kurzban 2011: 544/ 545 and Jonas 1969). The public good of medical research has to be sustained by public participation, similar to institutions such as mandatory jury service. Harris clarifies that

> we are talking of research directed toward preventing serious harm or providing significant benefits to human-kind. In all cases the degree of harm or benefit must justify the degree of burden on research subjects, individuals, or society. […] Of course the research must also be serious in the sense that the project is well designed and with reasonable prospect of leading to important knowledge that will benefit persons in the future. […] the argument is restricted to research projects that are not merely aimed at producing knowledge. Unless an increase in knowledge is a good in itself (a question I will not discuss here) some realistic hope of concrete benefits to persons in the future is necessary for the validity of our arguments.
>
> (Harris 2005: 242)

What do we make of this for biobank research? In Harris' view it is evident that "minimally invasive and minimally risky procedures such as participation in biobanks, provided safeguards against wrongful use are in place" (ibid.: 247) are covered by the moral duty to participate in research. In contrast, I will maintain here that, as in the earlier discussion of Hansson's, Sheehan's and Stjernschantz Forsberg's arguments, this proposal lacks sufficient grounding in reality to be of moral guidance. Most importantly, the issue of risk is bracketed, and instead benefits taken for granted. Harris' reasoning cannot circumvent this gap, because larger-scale research projects such as biobanks do not provide obvious significant benefits without incurring any costs to participation. As I have been discussing before, while it is true that the concepts and arguably their interpretation and application of traditional research ethics are strongly individualistic, it remains to be shown why basic individual rights can literally be 'risked', i.e. only be important if they are about to be vitiated.

This is not, in fact, what Harris is arguing, I am only stressing that this might be the result if there remains too little clarification of what is indeed controversial: the specific goods and risks biobank and genomics research can provide. Public goods cannot survive if there is increasing free-riding, but a general appeal to the benefits of research is far too weak to ground a duty to participate in research if clearly there is disagreement about benefits, risks, and the adequate safeguards in place. Notably, safeguards for participation in biobank research must be considered in a long-term horizon. As we have seen in the debate concerning the notion of genomic databases as global public goods, the public aspects of this research are in no way 'natural', but would have to be strategically fostered.

Harris argument is therefore, if not wrong, abstract and rather a counter-declaration that could sustain Chadwick's and Knoppers' communitarian turn *if* there was some clarification of the aims at stake (cf. Holm et al. 2009). He does, however, invoke the 'public interest' of the liberal tradition. This seems to denote the majority interest, i.e. a broadly utilitarian summation of choices or preferences rather than respect for e.g. the interests of minorities (cf. Bialobrzeski et al. 2012; Simm 2011). As biobanks are planned and initiated often by public bodies, it is clear that some form of wider, 'public' interest is at stake. However, most biobanks and in particular their networking and use as a platform for translational medicine and new health products will require close interaction with commercial partners. Evidence of this potential and concrete benefits, however, are not widely available to the public. One might even consider that these are large-scale, real-time experiments with insufficient 'public' consent, acting on expectations and promises rather than proof (cf. Rommetveit 2011).

In this perspective, the appeal to a more substantive notion of the common good to be created through biobank-based research is useful only if it leads to a debate of the core values to be promoted in health research. Both liberal and communitarian ideals will

involve some form of public participation in defining and deliberating about essential values of society, though these values might diverge in the details. Nevertheless, public interest and a more substantive 'common good' might be reconciled or brought to converge by deliberation (cf. Sutrop 2011; Simm 2011). Public debate, however, is largely absent, notwithstanding the Council of Europe's recommendation "for the widest possible participation by citizens in the discussion on the human genome through the involvement of the European media and suitable and accurate information by the Council of Europe."[84]

Only few attempts have been made in the philosophical literature to answer the question when genomics research contributes to public interest or common good, including potential consequences for ethical safeguards and their relaxation. Hoedemaekers et al.'s (2006; 2007) articles will be used here to give a preliminary assessment. A key precondition of their effort is the assumption that privacy risks are under control and that consent can serve to control personal data and biomaterial. First, the broad aim of genomics research – health – must be related to a generic conception of "common good". The authors distinguish two versions, 'corporate' and generic common good: in the corporate conception something poses a threat to the common good only if it jeopardizes the continued existence or proper functioning of society as a whole, e.g. war, famine, terrorism, in which restrictions of autonomy can be justified. As for diseases, this will concern only contagious diseases, pandemics, not most common diseases, in which the generic conception of common good means that basic and fundamental values, such as well-being, self-realization, and freedom of choice will be promoted, while the common good is threatened if diseases restrict pursuit of (individual) values of this kind (Hoedemaekers et al. 2006: 420).

Therefore, the next problem that must then be specified is how *individual* health relates to the common good, to which different values can be ascribed: from intrinsic to more

[84] Recommendation on the Protection of the Human Genome, No. 1512 (2001).

instrumental. By and large, we can assume that "individual health can be seen as instrumental for the realization of core values in a society without which the fulfillment of these individual life-plans would not be possible" (ibid.: 421). Moreover, diseases are a threat to participation in public life, to individual maintenance and deliberation about core societal values and of course to economic performance.

Genomics is supposed to have an enormous impact on healthcare, and consequently the relation between the system of healthcare and common good has to be established. According to the authors, the necessity of health*care* rests on these main factors: restoration of autonomous functioning, social functioning, and effectiveness. Additionally, in terms of necessity, conditions with a greater disease burden support stronger claims of necessity of healthcare, while generally, "the degree of impairment of individual, autonomous, and social functioning is a fourth guiding principle to determine when health care services contribute to the common good" (ibid.: 422).

We can now approach the next level to establish how genomic research might contribute to the common good. In this perspective, economic gains are not a practicable point of reference yet since there are high expectations of saving costs through the realization of Personalised Medicine, whereas currently most research is at a basic stage. The focus should consequently be on the research itself and its priorities. Clearly, common complex diseases affect large numbers of individuals and so more effective diagnosis and interventions could indeed have an immense impact with subsequent health care savings. The preliminary conclusion is thus that "genomic research which aims to develop new (or more effective) interventions for diseases which seriously impair individual autonomous and social functioning will contribute to the common good" (ibid.: 423).

While this point is crucial in giving some content to the notion of common good – i.e. disease burden calculation is crucial – what does this imply for potential individual

sacrifices? One possibility, as Hoedemaekers et al. propose, is to try to establish the link between the loss of control by donation/participation and loss of autonomy expected from not undertaking research, and thereby make sacrifices and benefits in genomics commensurable. One could accordingly balance: loss of control that a proposed consent procedure involves and loss of control involved in the condition that is the subject of a specific genomic study. In case of a serious disease which involves loss of control over mind or body, weaker forms of consent that entail a certain loss of control might be justified (ibid.: 424). The assumption is that apart from inevitable dis-analogies loss of control boils down to emotional distress and can be assimilated on this basis.

A more complicated problem might be the balancing of imminent harms and future benefits. Here, the authors assume that small sacrifices are defensible:

> We can assume that future generations will share our vulnerability to physical and mental disease and suffering and that they will be in need of effective medical services. Present-day genomic research can contribute to this aim […] from a health perspective there are good reasons to include the next few generations in our moral community. The expectation is that in the future most genomic research will actually contribute to the relief of suffering of patients with serious diseases or disabilities. We now have the possibility (in terms of personnel and financial resources) to reduce their suffering and this means that we also have a duty to do so.
>
> (Hoedemaekers et al. 2007: 349)

A balancing in terms of loss of control seems a useful guiding principle, however, as the authors add, concrete context will be crucial – i.e. which genomic research and which forms of consent are practicable.

The final conclusion is that loss of control might be justified in case the following provisos hold: (1) a certain loss of control is necessary, (2) the degree of loss of control involved in a proposed consent procedure use is examined precisely, and (3) this is undertaken on a case-by-case basis. Importantly: "The burden of proof here is on the researchers. They

should propose and defend any consent procedure which diverges from the ideal standard" (Hoedemaekers et al. 2006.: 428).

A point that I have been insisting on, however, and that is not discussed in their reconstruction, is that loss of control and expected benefits cannot be made strictly commensurable if we stick with the primacy of the protection of individual rights through informed consent. This, of course, relates also to the fact that the precondition of Hoedemaekers et al.'s proposal is that risks to individual privacy are under control, which seems *de facto* rather uncertain. Informed consent implies the primacy of individual rights, and these rights are wider and deeper than informed choice, covering property-like aspects in the case of identifiable material. While we might think that all rights are tied to duties, there do not seem to be any strict duties to research participation that can in any straightforward sense be related to the protection of integrity and autonomy in research.

The invocation of a public good cannot foreclose the primacy of these rights, or, vice versa, the primacy of individual rights and therefore consent are incommensurable were the provision of sufficiently 'public' or 'common' goods is concerned (O'Neill 2003; 2004b). In the case of biobanking for genomics, the goods and in particular their publicness are rather underdetermined. The public is largely excluded from the possibility to have more transparent information and/ or involvement in the research, but even if they were not, and a biobank project was planned and controlled publicly, there is no specific duty that the goods these infrastructures provide must be sustained 'in kind', in particular, again, if there are risks attached.

The arguments towards a dilution of rights do not rest on a sufficiently strong normative basis. First, while consent can be broader for purely epistemological reasons to *some* extent, the primacy of the individual in the traditional model is quasi-absolute. It certainly is in the treatment context, while there are exceptions to privacy protection in the case of

emergency etc. Second, limitations to individual interests could be based on a common agenda of health research in the public interest or as a common good. Both cases demand a certain amount of deliberation, and the definition of aims and conditions of valuable research (cf. Christensen 2009). In terms of genomics as providing the public good of knowledge, we have seen that this might imply restrictions on intellectual property (cf. Spinello 2004). In the more radical or substantive version, biobank genomic research would have to *promote* the common good e.g. in the way Hoedemaekers et al. propose. In the most radical version, genomics could be part of a normative regime of a commons, in which the aim is more symmetric access to the resources on the ground and the benefits that are to be expected from the research.

This would have considerable implications for sharing of samples, data and knowledge derived from research, however, it is to a certain extent implied by the new policies of open data and similar trends. 'Commons' in genetic resources and information, yet, would not be strictly property regimes. In analogy to the sovereignty claims of states in the context of global genetic commons concerning e.g. plant genetic resources, the individual property-like claims to individual samples and information would remain primary. At the same time, access to genomic information relevant for e.g. family members must be secured. This would not be possible by strictly individual legal rights. Rather, the commons for genomics would be an expanding normative regime of knowledge governance (cf. Schmietow 2012).

In sum, individual property-like rights are an irreducible part of the requirement of consent for research participation. This is particularly evident if we concentrate on informational and privacy-relevant aspects. Contrary to what many authors suggest, however, the perceived tension between individual and society cannot be smoothened through broader versions of consent without trade-off effects. The question of governing knowledge flow

downstream is a separate one – in the larger picture, indeed, we might rather want to overcome excessive property claims based on policy interests.

While there is no direct conceptual tension between rights and interests – and therefore between the moral rights of donors and for instance the policy interests in a patented genome sequence, in practice there is a tension because biobank research requires risk-taking in a long-term orientation, and the promotion of the openness of data proceeds without adequate oversight and the recognition of differences in bargaining power involved (cf. Porter 2004).

In the last part, I will illustrate that this discussion, extended to notions of property, ownership and the claims of the public must not lead to anti-community oriented over-rewarding or overprotection of individual participants, but instead helps to outline a more comprehensive and balanced picture of individual and social interests in this research. This has wide-reaching implications for the property-structures in place, new dimensions of consent in large-scale infrastructures for future science and indeed the overall relation between individuals, researchers and genomics as a social project.

4. Implications for Governance

4.1 The Technical Solution: The Tissue Trust

The property-like control rights of individual participants attach to ‘donated’ bio-material insofar it remains ‘personal’, i.e. concerns sensitive information, but also insofar control rights are necessary to safeguard uses of research tissue that are in accordance with an individuals’ wishes. Therefore, following the legal reasoning of e.g. the German law, strict anonymization is not necessary, but this would imply that property interests must be accounted for. This means in turn that data are to be held ‘in trust’, as limited ‘real’ property and precluding strong ownership, for instance the totality of the rights Honoré’s bundle approach lists (cf. Schnorrenberg 2010).

As for the perspective of property in tissue that has been developed here, participant interests extend into the public sphere, so that both individual *and* communal rights can be considered: privacy and property are concepts describing also important *relational* interests, rather than only control over and exploitation of biomaterial and genomic information. To maintain individual rights and further the public dimension, what is needed is therefore a governance model that is able to bridge these aspects. Contractual or commercially oriented models which have been proposed (cf. Porter 2004; Noiville 2009; Bovenberg 2005; 2006), in contrast, do not seem suitable to protect donor rights while simultaneously maximizing scientific value. It is hence crucial to complement a research framework based on contractual kinds of consent alone that might in reality preclude further control and in which “when patients agree to donate tissue or blood, they sign away their control and oversight. Patients might disagree with a particular commercial or scientific use of their material, but they have no right to be kept informed about it.” As a

result, the "patient's right of withdrawal is worth little without a constant flow of new information" (Winickoff and Winickoff 2003: 1181).

In the model of a '*Charitable Trust'* or '*Biotrust*' (Winickoff and Winickoff 2003; Winickoff and Neumann 2005), the ongoing relation between body parts and person is 'institutionalized', "instead of allowing donated materials to disappear into the unaccountable vortex of "research" or the market exchange" (Winickoff and Neumann: 14). Participants explicitly transfer property rights to an intermediate party under conditions of a fiduciary relationship in which a trustee holds title to the property, but is bound by obligations to use it for the beneficiary or other specified purposes. This might prevent misuse of altruistic intention to provide biomaterial, but it would also have to be ensured that the bio-repository has a duty to make the property in human material productive, and provide for mechanisms to counter power imbalances between the sources, the trustee and the beneficiaries – in particular the public (Andorno 2007: 42/43). The Charitable Trust model does not exclude involving private funding but would separate functions related to funding and control functions (Boggio 2005). Concerning the bundle of rights the trustee is entitled to, emphasis is clearly on use and control, and would exclude in particular rights to unrestricted sale. Winickoff's model aims at implementing property-like interests of donor-participants in human tissue in the restricted moral sense that has been defended here, which

> is not tantamount to endorsing a full spectrum of alienable property rights, for example the right to sell tissue at any time for cash compensation. […] the charitable trust is a legal tool for effecting this norm of non-commodification. The structure relies on the recognition of a property-like interest in donated materials only for the narrow purposes of creating an enforceable trust relationship, one that embeds control of tissue in a managed network of non-commodity exchange.
>
> (Winickoff and Neumann 2005: 13)[85]

[85] Cf. the criticism in Boggio 2005.

Hospitals and research institutions accordingly act as stewards, researchers as 'custodians'.[86] The model can implement also donor control rights, while assuming that most donors would participate for largely altruistic reasons, perhaps preferring 'gifts without strings'. The trust as an intermediary would allow for the data flows and updates that research on common complex multifactorial diseases necessitates, but the fact that donors allow for some openness of this kind does not need to imply that all further potential participant interests are 'signed off' upfront. Instead, the aim would be a rethinking towards more community-driven governance in different genomic contexts, and shifting attention to "constitutional powers, control of resources, and public benefit" (ibid.: 8; 10).

A trust structure could also facilitate participation of a donor group or community on, e.g., a donor committee which has veto powers over research projects, or even in the form of serving on the board of trustees (Winickoff and Winickoff 2003: 1182/1183). Based on the aim of re-balancing control, Winickoff et al. anticipate recent proposals of 'dynamic consent' (*infra*), in which the trust engages with the donors through dedicated websites, specifying periods of updating consent or potential withdrawal from particular projects, in addition to community consultation, for instance if a particular ethnic group is to be involved.

> In its ideal form, this architecture would help foster […] public deliberation and learning not only about the use and operation of the biobank, but also about the new genetics and its effect on the political economy of health.
>
> (Winickoff and Neumann 2005: 18)

As an expression of a 'third way' between commodification and inalienability of tissue, the trust does not exclude the involvement of commercial partners sustaining funding, however, this would have to be transparent to all stakeholders in terms of 'real'

[86] Cf. Yassin et al. 2010.

partnership. In Winickoff's proposal, "The notion of 'partnership' works against the idea of exclusive ownership, and at its core connotes a form of cooperative human relations with respect to shared conditions and mutual aims" (Winickoff 2008: 14).

Here, the example of *PXE international*[87] is remarkable. PXE (pseudoxanthoma elasticum, a connective tissue disorder) international is a rare disease organization which started up their own research when pharmaceutical companies would not invest in a disease affecting only few individuals. They established their own private biobanks and negotiate access by researchers to samples and data such as family histories. In cooperation with researchers, they even managed to be named as co-authors on scientific articles and patent applications (Rao 2007). Initiatives such as this one represent a new form of 'biological citizenship' (cf. Rose and Novas 2005) in which lay people indeed seem to 'co-produce' and 'co-own' scientific knowledge and the necessary resources, trying to overcome if not the expertise in science, at least some of the asymmetry in the details of setting a research agenda and its ethical pursuit (cf. Saha and Hurlbut 2011).

There seem to be signs that not only smaller-scale, more homogenous study populations, but also the involvement of healthy participants, including 'exploratory' biobank research, can be channeled through digital tools and a bottom-up approach. Saha and Hurlbut take the personal genomics companies *23andMe*[88] and *PatientsLikeMe*[89] as another potential reference: "These companies have achieved trust, while still protecting privacy. The result is that participants have chosen to give more than the minimum. They are rewarded by witnessing scientific progress in process — including what new knowledge means for them as individuals" (Saha and Hurlbut 2011: 313; cf. Kohane and Altman 2005).

[87] Cf. http://www.pxe.org/.
[88] https://www.23andme.com/.
[89] http://www.patientslikeme.com/.

Coming back to trust structures, these would presumably involve not only digital, but physical participation, allowing for accountability. Critics have pointed out that transparency and involvement of participants as equal partners in the board of a trust or a similar structure, however, might be limited and not representative, since people are suspicious of the possibility to eliminate vested interests (Hunter and Laurie 2009). While larger-scale governance approaches of this type might be more complicated to implement, the normative rationale seems to be convincing even for international collaboration. Winickoff and Winickoff early on mentioned the possibility of an international organization as a tissue trustee to be created for larger-scale genomic research (cf. Winickoff and Winickoff 2003).

In the UK Biobank, for starters, it seems that some form of a trust model has been put into practice (Winickoff 2007; Mullen 2009). Winickoff has analysed the matter in more detail: has a substantive partnership approach indeed been realized, or is it perhaps a somewhat rhetoric move? On the face of it, public and private interests have certainly been tried to be kept in balance. While UK Biobank officially appropriates samples, and it is declared that participants will not have property rights in the samples, their use is limited in ways similar to what Winickoff's model specified:

> U.K. Biobank does not intend to exercise all of these rights; for example, it will not sell samples. Rather, U.K. Biobank will serve as the steward of the resource, maintaining and building it for the public good in accordance with its purpose. This implies both the judicious protecting and sharing of the resource. It also extends to the careful management of any transfer of parts or all of the database or sample collection.
>
> (UK Biobank Ethics and Governance Framework 2007)

Moreover, in explicit reaction to public concerns about commercialization and transparency (and the deCODE experience), an extensive governance framework was developed and public consultation conducted (Wellcome Trust 2002). The Ethics and Governance Council has the function of independently monitoring, guarding and reporting

to the public on conformity of research with the governance framework set out as well as potentially advise for revisions when new interests of participants and the public emerge. The mere advisory function has been considered as too weak by some observers, since it does not include effective veto powers. It could, however, exploit its function as informing the public to draw attention to potential issues of concern or controversy (cf. Winickoff 2007: 445).

The Governance Council has nevertheless been termed a "toothless tiger" (McHale 2011) and public engagement activities as driven by political agenda (cf. Weldon 2004b; Petersen 2005; 2007). According to Alan Petersen,

> public engagement' has proceeded as a kind of risk management strategy rather than as a genuine attempt to involve publics in shaping the overall aims, direction and management of the project or to open debate about the project's value and implications. […] UK Biobank's 'engagement' efforts thus far convey the impression that these have been largely about managing perceived *mistrust* and engineering consent rather than creating the conditions for trust.
>
> (Petersen 2007: 37; 40)

As Winickoff dissects, the terminology and normative reasoning associated with property and ownership were for the most part rejected in favor of 'partnership'. In fact, it has been noted by other commentators that since the 1990s the 'gift' as a public policy keyword for tissue donation started to be conjoined or replaced by the new keyword 'partner', which can be adapted to a wide spectrum of normative models underpinning governance, spanning from pure altruism to a market approach (Tutton 2009; Sýkora 2009).

Undeniably, the trust structure does not by itself provide solutions to potential ethical quandaries such as controversial research uses, concerns about commercial interactions, or imply more public oversight and accountability. As a consequence, it must be considered only *prima facie* more suitable for responsible biobank governance. Questions concerning the institutional structure cannot be separated from the ethical questions of how the value

of different research priorities should be judged, how limited resources for health should be used, and what protection of interests and autonomy donors should receive (Mullen 2009).

Remarkably therefore, though explicitly designed as a novel form of governance in the interest of public trust, it seems that also UK Biobank rather evaded some contentious ethical issues by way of employing the rhetoric of 'partnership'. Participant choices in terms of consent are limited and participants have no rights e.g. to veto commercial uses. Yet, they retain rights to withdrawal – a position that seems both internally contradictory and counterproductive (cf. Dickenson 2007; Brownsword 2007a). As we have observed above, it seems that the altruism of an imagined participant is taken for granted, while potential concerns tend to be circumvented by a kind of preventive ethics strategy.

If it is correct that people do indeed largely participate for altruistic reasons and so immediate benefits to them are not at play, while indeed later public benefits cannot be as of now anticipated, it becomes evident that in fact 'benefit-sharing' largely functions as motivational rhetoric. According to Winickoff, it actually "effectively silence[s] the claims of individual property rights in excised tissue and bioinformation that, if recognized, might perform a much more radical type of redistributive project" (Winickoff 2008: 5).

Thus, the trust or trust-like governance structure is only a first step of taking participant rights seriously. As a legal and institutional concept, it is rather 'morally neutralizing'. Winickoff's approach and the initial appeal of the UK Biobank Governance Framework proposal of a 'partnership', however, might perhaps be turned into something quite different – a questioning of the goods involved not only in terms of potential and future pecuniary and non-pecuniary benefits, but also in terms of sharing power in genomic research governance. This is indeed because Winickoff's proposal derives from the idea of 'translating' some of the legitimate property interests participants have into a democratic reorganization of genomic governance.

So far, two kinds of interpretations of realizing this project emerge: a corporately oriented structure, emphasizing shareholding,[90] which would fit with the emphasis on benefits, but remains vague, and a 'partnership' approach, that can be used for a whole spectrum of involvement with participants. Although UK Biobank has emphasized partnership, in fact a more radical questioning of an expert regime of biobank governance or genomics does not yet seem to be envisaged.

4.2 Governmentality Precluded? New Participant-Centric Initiatives

Not only theoretical reasons, but also empirical studies suggest that trust is not easily achieved via public consultation and proclamation of partnership approaches in genetic/ genomic research contexts. Social scientists have expressed skepticism concerning the question whether the "expert agenda of policy-makers and medical ethics" can sufficiently address participant concerns (Levitt and Weldon 2005: 311; cf. Winickoff 2007: 447; Petersen 2005). This expert agenda might persist even if there are ethics committees and increasing promotion of ethics institutionalization, in particular if these remain mostly within the ambit of the research organization.

First, is it appropriate for individual biobanks to develop their own ethics and governance structures and thereby their guiding ethos independently, or is a more centralized, actually public regulatory approach required? (cf. Mullen 2009: 156; McHale 2011: 241). Generally, strong public opinions regarding the control of samples would seem to raise important questions of donor representation in the distributional decisions of biobanks. This does concern not only individual, but also collective interests (Winickoff 2008: 21). Facing changes in the political economy of research, the "distributive agency" of biobank

[90] Bovenberg proposes taxation of tissue collections (2005) or shares in tissue samples (2011) to reach more equity.

managers is amplified. In democracies, as Winickoff recalls, distributional choices would, however, tend to be allocated to representational bodies, not experts, because they implicate basic values and visions of a good society, not just technical concerns.

As yet, participants or other societal stakeholders are excluded from

> policies on access and IP [which] will set the balance among the potentially competing goals of assuring scientific openness, incentivizing commercial investment in the life sciences, and promoting public access to future therapies. Value hierarchies have not been made clear […]. The broad discretion of biobank managers is less of a problem to the extent that we believe that their actions will align with the preferences of donors. But alignment is unlikely, and the likely gap in values increases the probability of problems with recruiting and retention.
>
> (Winickoff 2007: 448)

The proposed benefit-sharing arrangement in the policies of international organizations alone cannot address the principal agency problem of representing donor interests, although, "looking at the situation prior to donation and the transfer of entitlement, the group of donors as a collective possesses a crucial form of material, informational and biological capital that could be used to demand a share of power" (Winickoff 2008: 13). Therefore, what is needed is also a translation of participant interest into *procedural* power.

Winickoff's ideas are related to the so-called '*participant-centric turn*' that has lately gained attention in the bioethical discussion surrounding genomics. This umbrella term refers to governance approaches which employ digital and social media in the public and private sphere to improve the process of informed consent, provide information and control over data, while simultaneously aiming to permit the pooling of data for upcoming research (Kanellopoulou et al. 2011; Kaye 2011; 2012; Kaye et al. 2012; Saha and Hurlbut 2011; Kuehn 2013).

> Current practices in managing biobanks tend to see the public as little more than a resource for mining data and materials, and as a potential source of resistance. Participants provide information or tissues with little or no knowledge of the researchers' priorities, goals or expected outcomes. Barriers are erected. Materials and information are 'de-identified' to protect people's identities. Participants neither see how their donations are used, nor what the research produces.
>
> (Saha and Hurlbut 2011: 312)

PCIs (Participant-Centric Initiatives) instead suggest to empower autonomous decision-making via user-friendly digital interfaces, tools and projects. Jane Kaye et al. specify that a

> key feature of all PCI interfaces is that they are based on the principles of respect and empowerment for individuals and are orientated towards participant concerns: patients and research participants are located at the center of decision making as equal partners in the research process.
>
> (Kaye et al. 2012: 372)

Already available technologies, similar to direct-to-consumer genetic services are used to make efficient use of data for future studies and sustain continuous influx of new data. Potential research participants and researchers are connected, communication and recruitment is eased, and ongoing interaction between the parties envisioned to be established.

The model is therefore clearly first and foremost a *technical* development in line with the digital infrastructures that co-evolved with biobanking. At the same time, these initiatives aim at counteracting shortcomings of the broad consent model and to streamline the demands of the scientific endeavour with the new *ethical* demands that are created by it: as data sets and techniques advance, consent has to be made 'future-proof' and provide the participants with the possibility to get updates on changing research objectives. Digital interfaces bind people for longer term interactions into the research process, which seems a

moral demand as a matter of control over samples and genomic information. This might be relevant for the various aims people have in research participation, both 'altruistic', but also in case clinically relevant information about them is revealed.

These initiatives therefore could offer a wide array of flexible options tailored personally – just in the spirit of Personalised Medicine – to the needs and wishes of an individual participant *and* in sharing data (cf. Kuehn 2013). At the same time, *citizen science* is implied by participant-centrism, allowing people "to drive the research agenda and to carry out their own research projects" (Kaye et al. 2012: 372). Examples include online-only approaches such as *Registries for All* [91] by Genetic Alliance, an online portal collecting and surveying health information that can then by compared with others. Users can set quite specific limits concerning the kind of data they would like to share (Kuehn 2013: 679). The system itself can be used for different purposes surrounding patient engagement, e.g. to approach people for further research options.

Another US project tool is *Portable Legal Consent*, which aims at sharing genomic data that participants received through private genome testing for wider research use: "The idea behind PLC is that participants' consent is not tied to a particular study but rather "is something that patients carry around with them like organ donation status" (Wilbanks in Kuehn 2013: 679). Users of the database created on this basis agree to specific open access policies tied to the work to be published from the database material.

An approach that seems to fit particularly with biobanked tissues and data is the *Dynamic Consent approach* developed in the UK within the EnCoRe (Ensuring Consent and Revocation) project, a web-based platform with an interface that allows research participants to have an interactive relationship with the custodians of biobanks and the research community. It is used for three kinds of biobanks in Oxford, but can be extended

[91] https://www.reg4all.org.

for flexible application in different research and healthcare contexts, in particular as these are converging. These approaches seem to follow naturally from the digitalization of research infrastructures and perhaps will lead to a fostering of long-term and more transparent relationships between participants and researchers, a feature that is indeed absent and often excluded from consideration in the generic broad consent model.

But is there also a more normatively informed grounding in the PCI and dynamic consent approaches in the sense of Winickoff's partnership governance, including the democratizing effects of understanding genomics in the first place, along with the new forms of biological citizenship? What is the function of the appeal to *citizenship*: are participants offered choices, for instance choices that give them a control share or a sort of co-ownership in the resource as the trust model would envisage? Advocates have not yet been explicit on the ethical implications of indeed putting the formerly passive donor as a participant in the centre of attention and also in charge (cf. Levitt 2011). Nevertheless, rather trenchant criticism has already been addressed to the model, the discussion of which might help to elucidate its ethical function, and the potential to overcome shortcomings of traditional informed consent and broad consent models.

Steinsbekk et al. (2013a) reiterate a line of argument that has been criticized above in relation to a premature and often theoretically shaky move towards a generic broad consent model for biobank participation. In brief, the authors pose a dichotomy between a broad consent model and the new dynamic consent model, and argue that – though initially appealing – the latter might turn out to have undesirable practical consequences in terms of recruiting adequate numbers of participants. In addition, and more importantly for the purposes of the discussion here, they claim that the normative rationale of the dynamic consent model is flawed and tendentious, in that it indirectly promotes paternalistic attitudes, is prone to illiberal elements and therefore ethically untenable. As a consequence,

a broad consent model must be considered ethically superior all things considered (Steinsbekk et al. 2013a).

To my knowledge, Steinsbekk et al.'s article is the first analysis taking issue with some of the normative undercurrents of the participant-centric approach and dynamic consent. As I have suggested, choices for more information and involvement seem at least part of a remedy for some of the conceptually, legally and ethically thorny issues concerning autonomy and control in research biobanks. Minimally, it would seem that they can help navigate the interests – including property-like interests – of participants, while – if adequately supplemented by additional measures towards public engagement and 'scientific citizenship' – limiting excessive control claims, including at later stages the ones by e.g. researchers and commercial partners.

Steinsbekk et al's outlook, however, is very different. First, they draw a distinction between broad and dynamic consent, broad consent meaning that a participant would be consenting to a general governance framework, supervised by ethical review, including potential re-contact if this framework changes. This is still an 'informed' consent in the classical sense, according to the authors, while dynamic consent has been proposed "to solve the perceived problem of lack of 'real-time' specific information about individual research projects seen in the broad consent procedure used in many research biobanks today" (Steinsbekk et al. 2013a: 1). The focus is on dynamic consent with "active opt-in strategies", and the claim that dynamic consent proponents clearly advocate a moral supremacy of this model: "The implication is that broad consent results in passive participation, and that this is ethically problematic" (ibid.: 2). The authors identify a number of particular 'claims of superiority': dynamic consents respect participants' autonomy far more than broad consents, keep participants better informed, increase

participation, are preferable since they transfer control to participants, and are necessary to enable the return of research results and incidental findings (ibid.).

Before, we have focused on the first claim, which is the Achilles heel of the debate. Some of the others involve empirical claims, in particular as concerns the inclusiveness of e-governance tools, and their potential to enhance participants' perceptions on being well-informed. This also comprises the issue of trust often emphasized as a key factor in sustaining long-term relationships in biobanks. Here, I will comment on the claim that e-governance tools overburden participants, and the closely related claims concerning the role of ethical expertise and democratization.

The argumentation is based on endorsement of the broad consent model I have criticized as inadequately justified and contextualized in Chapter 2:

> The fundamental difference between the two is disagreement on whether consent to 'unknown' future activities, can be labeled 'informed consent' and be viewed as an expression of an autonomous will. […] we regard many ordinary decisions people make as properly informed without having all the specifics – thus they are still 'perfectly acceptable autonomous decisions' in most people's minds. The model of broad consent follows such decision patterns.

And further:

> In the dynamic consent model, participants should always make an informed consent to both primary and secondary use of their data. It does not matter whether a new project Y is only slightly different from an initial project X. And it does not matter whether it is possible or impossible to find any kind of 'rational' justification for taking part in X and saying no to Y. As such, dynamic consent takes people's preferences as the point of departure.
>
> In the broad consent model, on the other hand, people are asked to re-consent only when there may exist an ethically relevant difference between X and Y. Participants in such situations are asked to re-consent, because a research ethics committee or the biobanks institution believes there is something to ask them about, something that matters.
>
> The difference between dynamic consent and broad consent is then made clearer: In a dynamic consent model, participants will be asked for consent continuously, simply because each new project is a *new* project. Thus, they will be asked to re-consent both for trivial and essential

> reasons, and often the former. In a broad consent model, participants will seldom be asked to re-consent, but when they are asked, they are asked for a non-trivial reason.
>
> (ibid.:2)

What is wrong here? The idea that there is a direct and general relation between the concept of consent and autonomy relies on the concept of a full-blown and perfectly informed consent which, however, is a philosophical abstraction. More information will generally always be better, but this will strictly depend on context. As a result, Sheehan's and other commentators' analogies are not really to the point: Biobanking is not like choosing, for example, in a restaurant, because a trust-relation of delegating choice does not obviously exist, and because there is a primacy of individual rights to be respected that has no relevance in the restaurant case. The adequate form of consent cannot be made contingent on the technical possibility to safeguard these rights.

There is, furthermore, nothing in the dynamic approach that would *force* people to decide continuously; more importantly, it could not be like that, because there are still decisions about the relevance of information to be made; plus the overall epistemic situation concerning future, potentially controversial research uses is the same, if there is a digital tool to facilitate information flow or not. Steinsbekk et al. also claim that there is no need for dedicated informational or e-governance tools to address shortcomings in information provision for participants. E-mail updates and newsletters, as already practiced in some biobank projects, would be enough. They make the important observation that the idea of transferring ethics largely to e-governance – if implicit in the proposals of dynamic consent – harbours its own challenges, as it might involve predominantly persons that have already an advanced knowledge concerning biomedical research, access to newest technology etc. This typical technology-critical argument of a problem of 'trickling down' to the average

or even disadvantaged citizen, yet, is not the authors' real worry and so will not be discussed here in more detail.

The theoretical point that autonomous decision-making and the amount of information provided in a consent procedure are merely loosely related has already been granted. More critical is the assumption that not the amount, but the *relevance* of provided information is decided by experts, and we can safely assume that this will be in participants' best interests. The main concern that Steinsbekk et al. implicitly express is consequently that a dynamic consent model, properly implemented and spelled out, would change the relation between a biobank and the researchers and participants in a profound way. It would, indeed, seriously question the expert regime of research in general. Nevertheless, the authors suggest that this conclusion is unwarranted, because empowerment of participants is unnecessary if personal health is not directly at stake and risks due to research involvement are very low (Steinsbekk et al. 2013a: 3/4). They seem to concede that broader involvement of participants and the public in deliberation and decision-making might sometimes be justified, at least in case "there are uncertainties surrounding the consequences or outcome of the scientific activity or where values are at stake" (ibd. 4).

On the other hand, they argue that within the dynamic consent model, real participation cannot be achieved, as "the 'participation' here is participation inside an already established research arena where only minor changes of policy are up for discussion." Further, however: "We do not deny that increased user participation is possible to achieve. However, we doubt that there is a moral imperative to try to achieve this within today's framing of biobanks research" (ibid.). In fact, according to the authors, the outlook of increased participation of non-experts in biobank governance and genomics is interpreted as leading to a weakening of ethical assessment and the danger that unpopular research could be inhibited by the mere opinions of lay people.

Both the depiction of what is pragmatically envisaged and the normative argumentation by Steinsbekk et al. suffer from a number of problems. First, the assessment deliberately caricatures both the theoretical and practical implications of implementing a dynamic consent or similar model. Second, though suggesting that real participation is actually not foreseen in the proposals as of now advanced, this does not seem to be a point the authors dare to comment straightforwardly on. Instead, a tendency of utilitarian research ethics is applied asymmetrically to researchers and biobanks governors vs. participants: if a particular research project is not popular with participants in the imagined scenario, this should not be taken as a reason to question the research. In contrast, if benefits – as communicated by researchers and funders – are to be expected mainly for the future rather than for donor-participants, then the interests and rights of current donors or participants appear as neglectable. Third, this is coupled with the uncharitable suggestion that – in any case – people are and should not be expected to be able and interested in getting into closer relationships with science. Indeed, this could in the end undermine trust in research ethics committees and researchers, while becoming a burden for their 'autonomy' as "they fall short on the implicit demands of participation" (ibid.: 5), and not the least producing potentially negative effects on recruitment.

"Being confronted with the detailed complexity of biomedical research, and being asked again and again for an 'opinion' (a consent), it is likely that at least some people will struggle with feelings of falling short – that their own competence or knowledge do not suffice. This could easily be interpreted as a 'lack of respect' for the passive participant, and result in lower participation as people would rather choose to stay away from such studies than face shortcomings" (ibid.: 3). The authors even add that "For most people, we suspect that biomedical research is complex, complicated and rather boring stuff" (ibid.: 4).

While Steinsbekk et al. rightly ask for illumination in regard to the way a participant could indeed be central in the new governance framework, they also perpetuate a conflation of descriptive and normative assessment and the mixture of utilitarian with, it seems, implicitly strongly paternalistic ethics. As we discussed in relation to consent, the *rights* of participants cannot be traded off against future potential benefits in a theoretically sound argument. Admittedly though, individual rights indeed do not feature explicitly in this kind of account anymore, but have been replaced by *interests* that presumably are just private. The idea that an individual participant could be both concerned about his privacy and certain research uses and still be convinced that research should be undertaken with support by the population – which seems a position that many people might hold[92] – is becoming inconceivable.

According to Steinsbekk et al. the implicit preference for private interests in empowering participants via dynamic consent tools also finds expression in the movement towards returning research results. Also more generally, this could lead to a change in research culture including "a cost to the traditional values and feelings, which lie in acts of altruism and participation towards common goods. This might then enforce ideas of individualism and of 'what's in it for me' even in aspects of human conduct relating to contributing to biomedical research" (ibid.: 5).

In contrast, their line of thought advocates what might be called 'Research-centrism', though unfortunately with a more worrisome implicitness and tendentiousness than the sometimes vague rhetoric of genomic empowerment they rightly lay their finger on in the participant-centric approach. While research is 'boring' for potential lay contributors, and there is no need for 'biobank exceptionalism' in the perspective of participants, at the same time they claim that there is a need for solid ethical expertise "in a time when evaluating

[92] Cf. e.g. Hallowell et al. 2010.

potential impacts connected to this kind of research seems to increase in scope and complexity" (ibid.).

This seems to be, if not incoherent, at least in tendency an anti-liberal and indeed anti-democratic approach. A potential contributor to a genomic research project would accordingly be free to 'sign off' further interests via broad or open consent, but not to have continuing or more substantive concerns, including interests in public or common goods. In particular, it is not apparent how these disinterested individuals should simultaneously be motivated by 'genetic solidarity' and the altruism the research-centric approach would typically ascribe to them. In sum, though Steinsbekk et al. charge the dynamic consent approach with implicit paternalism, what they advocate has a stronger tendency to paternalism: defining interests of potentially very different participants *for* them. There can be no strong paternalism intended, rather, e-governance tools aim to provide choices: including the choice for blanket consent and no further contact (cf. Árnason 2009; Saha and Hurlbut 2011).

The emphasis on *choice* is important and an improvement over the vague appeals and the 'responsibilization' of donors, and this is continuous with the problem of consent and the intermingling of privacy and property-like aspects that we have discussed above. Consequently:

> The bioethical principle of autonomy as 'respect for persons' should not be narrowly construed in the context of biobanking to mean only freedom from coercion — in effect, the right to sign a consent form. It should also entail a respect for the ability, willingness and right of participants to share in imagining the futures to which research aspires.
>
> (Saha and Hurlbut 2011: 313)

The overall normative conclusion from this is that what matters rather than active vs. passive involvement, more or less information in and by themselves is that individuals have a real choice if they want to, and this is certainly something dynamic consent could

facilitate. Again, it is important to underline that dynamic consent, similar tools and the related movement of 'putting participants in control' should not be artificially opposed to the broad consent model.

A limitation that Steinsbekk et al. not discuss is that the transfer to a more dynamic participant-researcher relationship must be put into the context of both rights and social aims generally. This is also why dynamic consent is not a genuine new form of consent and could not be, and there is more to account for in terms of these contextual features. The underlying arguments in relation to rights, and the broader social horizon to be anticipated, should be exposed and made clear. In this respect, broad consent still seems to be used and advocated in particular in scientific publications as a new ethical gold standard that can be interpreted to be in line with 'autonomy', securing concurrently the advancement of science without the supposed hindrance by more enlightened donors, that perhaps will become participants or even 'scientific citizens'. While admittedly there is still lots of clarification to be done, the expert regime of detaching donors from what they can and should not be concerned for seems profoundly undemocratic.

This is especially the case since we know of the concerns people express in relation to genetics and genomics, because of their human rights and interests in medical advance, and because there are no signs that the knowledge and power imbalance between donors or 'sources' and experts will decrease by themselves. Based on the ethical framework underlying my analysis here, however, this strength of combining liberty and accountability in using e-governance tools can only be an improvement over broad consent under specific conditions. Indeed there does seem to be a danger, that, by offering choices, a purely digital approach would collapse into a consumerist model of 'consent' or a technocratic model that communicates the idea that risks can be technically managed. In that case, one would be faced with a re-iteration of problematic approaches already

encountered, that "have addressed citizens as individual passive citizens with individual subjective concerns – in effect as consumers – given a choice whether to accept a participant role or not" (Weldon 2004a: 177).

Reference to 'scientific citizenship' is ambivalent on this. It could be envisaged by the approach of a participant-centric movement as not merely some kind of new configuration in relation to the current bio-scientific developments described with the broad term towards 'biological citizenship' (Rose and Novas 2005) but also as a normative perspective grounded in deliberative democracy or even stronger forms such as a republican ideal of responsible citizenship. A more continuous, dynamic view on individual and societal interests reinforcing each other might instead overcome the dichotomy between protection from (moral) harm vs. material benefits in biobank-based research and bridge what Árnason calls the 'protective view' and the 'benefit view' (cf. Árnason 2009: 138).

In this perspective, which has been illustrated above specifically in relation to large parts of the debate in both ethical and scientific publications, citizenship in relation to science is underdeveloped, as the individual is concerned either as a passive patient to be protected, or else as a fully independent contributor to and consumer of the population health. Importantly, though in particular the latter approach makes strong appeal to the language of public goods and benefits, also this perspective sees the individual in research primarily as a private, passive person (cf. Árnason 2011). In the extreme then, both positions "do not provide reasons for implementing policies that facilitate actions of the citizens in the public sphere. In this way they are part of a research culture which contributes to scientific illiteracy and disregards the active elements of human agency which are crucial for the democratic citizen" (Árnason 2009: 135).

At the same time, the duties of researchers, the state and the (public) health care system fade into the background, which is in fact a typical sign of encroaching *governmentality*, in

which multi-form tactics of governance in liberal societies are accompanied by using the ambivalent effects of the stress on 'autonomy'. Individuals are supposed to be 'autonomous', responsible and self-directing, but at the same time become governed and directed through 'regulated choices', in the present case to 'autonomously' donate and be 'altruistic', but excluded from further involvement with scientific expertise (cf. Rose 1996; Corrigan 2004; Ursin 2010b).

In this respect, the potential of a participant-centric approach should be carefully guided by more focus on the institutional and political arrangements as well as research priorities (Winickoff 2003, 2007, 2008; Brekke and Sirnes 2006; Hunter and Laurie 2009; Schneider 2010). A publicly accountable trust structure with common goals means that the aim should be the democratization of science with particular stress on more accountability and transparency rather than mere 'empowerment' of participants as the only possibility to "transform the debate from questions of public good versus individual autonomy, cost versus practicality to one where the concerns of the patient are aligned with the needs of medical research" (Kanellopoulou et al. 2011).

It also leads back to issues concerning property. More specifically, for the establishment of a third way of genomic 'property', it will not be enough to appeal to the language of biobanks as 'community resources', 'biocommons' or the promises of benefit-sharing. For example, rather than the broad appeal to the anonymity of solidaric donation, the involvement of participants in a research structure that is legally bound to charitable purpose forces all parties to decide on research priorities. Equally, independent (perhaps centralized) oversight will be important to ensure that the project serves goals that are considered important from the perspective of public health (cf. Campbell 2007: 242/243).

The rhetoric of digital empowerment can suggest that there are no risks involved, and that the success of research lies only in the hands of participants acting like bio-entrepreneurs

rather than co-creators of a public good. Though in dynamic consent and similar approaches individuals are given more choices, these choices should not be pre-governed by researchers' or funders expectations. To be an improvement on broad consent therefore, the focus on choice must be complemented with the privacy and property rights-based discussion, public debate and engagement, sustained by researchers themselves.

In that sense, the labeling of participant-led research and the immediateness of 'citizen science' for larger-scale projects might well be an overstatement and diffuse the responsibilities of care that researchers will continue to have as part of a consent process. Campbell, for example, sustains that "Ensuring genuine participation and partnership is not part of the project of protecting individual rights. Rather, it supports and reinforces the altruism that motivated the participants in the first place" (Campbell 2009: 68). This, however, does not seem to follow if the analysis of the dis-analogies between clinical treatment and genomic biobanks is appropriate, because it does not move the debate beyond property vs. consent or private entitlements vs. top-down participant protection.

Campbell himself thinks that Dickenson's approach of control rights (a consequence of endorsing the labour-model of property rights) "seems a surrender to the idea that the tissue market is no more than another instance of the need to regulate vendor-purchaser relationships, in other words a market like any other" (Campbell 2009: 72). On the other hand, the rights of participants concerning 'their' tissue and genomic information are more than symbolically related to property, and the idea of a continuous, dynamic consent could be an attempt to make practical sense of the ownership dimension underlying consent. Also, the implementation of this model does not obviate the need to assess what 'altruism' or, respectively, solidarity might require as for genomic research on banked tissue in a common, public interest. The future question, therefore – and the *leitmotif* in the discussion on the property-like entitlements of participants – remains to what extent the traditional

model of research ethics with its strong demands on individual freedom and individual rights will be overturned by these developments.

4.3 The Remains of Consent

Keeping in mind the previously outlined trends, what remains of consent in the application to biobanks seems to be necessarily ambivalent. On the one hand, consent will remain the cornerstone of ethical approval also in large-scale research networks because it is based on the fundamental right to integrity of the person and her private sphere. On the other hand, there is the potential that informed consent is on the verge of collapsing either into a *contradiction in terms* or lead to a *legal fiction* – a form of category mistake with uncertain consequences – if certain conceptual and practical limitations are not taken into account.

The 'contradiction in terms'- issue is a combination of the argument that choice is crucial for autonomy and that the provision of information in a procedure of consent has only a loose connection to the safeguarding of individual decision-making. Consent requirements can become diluted if information on future research use is limited and important public goods are at stake. I have argued that what is 'reasonable' information is contentious both in legal and ethical terms (and that means there is *prima facie* a wide scope of what constitutes valid consent), but there is an inherent ethical problem with this position in that other dimension of autonomy are neglected, in particular a sense of control and agency, whereas risks are downplayed in favour of potential future benefits.

What remains of informed consent is then both too strong an ethical demand *and* too weak, and this tension is indeed the dominating picture in the bioethical debate. It is too strong because consent must carry all the ethical weight, while the complicated relation between

the procedure, content and the various functions of appealing to autonomy remain underdetermined. A liberist focus on choice and information provision tends to devalue social context and the concerns of minorities concerning, for instance, moral harms and genetic discrimination.

The 'legal fiction'- problem is the issue that because the concept of informed consent must be coherent across applications in networked genomic infrastructures, the distinctive features of biobanks are disregarded or redefined in the interest of coherency. This is a formalistic or technocratic approach. The ensuing ambivalences can be 'hijacked' by the interests that are in the more powerful position.

Both approaches are problematic in that they misrepresent and neglect the human rights underlying the protection and empowerment of research participants. Almost by definition, consent in the biobank context is not consent to a specific research project, but is at least partly consent *to a model of governance* (cf. Hansson 2010; Steinsbekk and Solberg 2011; Macilotti 2013). If we take this thought seriously, and consider it in conjunction with a comprehensive picture of individual and social interests that as I have argued are incomplete without the moral and conceptual dimension of property in human tissue, form and function of consent are to be converted in the interest of a more socially robust science (cf. Nowotny et al. 2005).

Insofar not only individuals are at stake, informed consent must incorporate governance structures and measures of public accountability that mitigate the interests of all stakeholders. Here, a certain democratic erosion can be observed to influence bioethical discussion. As concerns the notion of the more concrete ethical task of safeguarding a new form of autonomy, the possibilities within the conceptual framework of consent (and particularly some of the interpretations I have discussed) are limited. Partly this is related to internal limitations mentioned above, and partly to external issues that have come up

with the extensive scientific use of genetic and genomic information, i.e. since the withholding and sharing of it concerns *relational* autonomy and the specific organization of biobanks as open-ended and future-oriented research infrastructures.

An important ethical constraint in this context is also that the over-emphasis on consent diverts attention from questions that require more focus in the move to a *public* health ethics of genomic research and biobanking, in particular as concerns research priorities that would contribute to a more concretely defined public or common good.

Overall, to make consent more future-proof, appeals to autonomy have to be redefined in two important ways: they are to be considered less individualistic and more relational, but equally as not only concerning informational aspects, but also as reminding the bio-material basis. Winickoff, who seems to advance a similar position, has coined the term 'bio-autonomy' to combine these aspects (Winickoff 2003: 204; cf. Santosuosso 2013). In the perspective developed here, the moral 'three-dimensionality' of tissue as material, informational and moral is crucial to this (cf. Macilotti 2013).

Consent, again, is a matter of individual rights, and the loosening of moral demands can threaten what Brownsword has discussed in relation to the 'community of rights' (cf. Brownsword 2007b). In particular, we have observed not only a deflation of consent norms, but disregard to flanking contextual and social factors (cf. Barr 2006a; 2006b). Instead, if the specificity of consent is tied to the context and social relations that adhere in any medical or research context (cf. Ursin 2010b), then this must also be the case for biobanks.

Larger biobanks and networks in which material relations disappear must substitute for this lack – there is, in fact, no automatic empowerment of donors. Worse, there can be a danger of non-legitimate research. As we have seen, the problem of commercialization, for example, is not only a problem because of intrinsic concerns some people might

legitimately hold, but because of encroaching conflicts of interests that can disturb the content and value of research.

A mitigation of epistemic indeterminacy and risks might be increased within a largely traditional model that provides more options and enhances trust, though this will put researchers in charge (cf. Boniolo et al. 2012). In a complementary approach of digital consents, e-governance tools have a potential to facilitate involvement, but cannot replace public deliberation and further study of the normative implications of a shift towards digitalized research environments.

While reconsiderations of expert regimes are starting to be considered, this movement goes hand in hand with the idea that research is just like any other activity in life (cf. Vayena and Tasioulas 2013), which should be carefully considered as a rationale for overarching and international policies. Similar to genetic exceptionalism, it would seem that biobanking and genomic research more generally might not be *sui generis* in absolute terms with regard to their organizational features and risks attached, but still peculiar. In this respect, it might be worth recalling with Francis Collins the ”First Law of Technology: we invariably overestimate the short-term impacts of new technologies and underestimate their longer-term effects” (Collins 2010: 674).

Conclusion

I have argued that the traditional framework of research ethics, specified as comprising the three main conceptual pillars of informed consent, protection of privacy and an ideal of altruistic, non-commercialized research participation and respective research environments faces significant challenges in the application to large-scale genomic research. Ambivalences that derive from a misinterpretation of its sources, and a mingling of ethical with political rationale in ever-enlarging research contexts lead to a dilution of requirements for safeguards in this research which is to be enabled by the spread of biobanks. Some of these challenges, however, are not appreciated sufficiently in the bioethical debate, which instead focuses on and strikingly often supports deflationary accounts of 'autonomy' and its role in justifying participant rights.

My main objective has not been to argue for a return to stronger measures of protection and, as a consequence, increasing rather than *different* regulation, which would be in contradiction with the research in the way it necessarily must be done given the particular characteristics of global and digitalized genomics settings. The role of ethical reflection, yet, cannot be limited to confirm social and scientific developments considered as inevitable (such as 'the end of privacy'), and thus potential adjustments in the framework should be based on critical assessment of the status quo and the moral legitimacy of the claims of all the parties involved.

Alas, the topic of governance – the word itself seeming a surrender to the complexity of the issues – is too encompassing to be dealt with in one stroke, as all the key concepts of research participant protection and also new issues are at stake. In a debate that has been dominated by a presumed clash between individual and societal interests, I have, to begin with, tried to liberate some conceptual space for a convergence of interests by focusing on a topic that, although fundamental, has been relatively disregarded – the moral and

conceptual importance of property claims, and here in particular the ones of research subjects.

This choice was strategic towards the aim of underlining the role I think bioethical reflection should take, faced with the necessity of an innovative view on large-scale projects. It is a subject matter that potential research participants care about in one guise or another, and that at the same time is so complex as well as morally and politically charged that neither legal theory nor public discourse can easily provide guiding answers. At the same time, bioethics has been very reluctant in re-connecting with political and legal philosophy and to potentially inform both the academic and public debate on this front. While it must be hoped that the benefits of the turn to *Personalised Medicine* enabled by genomics can indeed be realized, it has been argued here that the rights of participants are of crucial importance in a research culture based on human rights protection and democratic values of liberty, plurality and accountability.

Research participant rights – which seem to converge more and more with every citizen's human rights as different forms of e-healthcare are being implemented – are insufficiently characterized as purely 'informational', a conceptual move that is advocated by authors which tend to sustain technocratic expert-regimes and inconsistent views on participants' interests. These are considered as merely 'private', while tissue donations should be performed in the public interest, and yet, donor-participants are not allowed further moral judgement or an interest in closer interaction with the evolving research structures.

In this density, I have tried to elucidate the more specific roles property-like rights in human biological material can and should play from the supply side, and also its limitations, trying to connect the present debate with some classic sources of political philosophy and legal theory. First, by reference to property concepts it can be shown that the model of a 'thin' autonomy grounding informed consent is flawed and serves to justify

societal aims that are, in their innocuous form, not very clearly defined. The adequate justification of consent is the protection of the donor or participant against harm, but it is also an expression of respect for the person's moral status. Both the right to withdraw consent and the right to veto in the classic consent requirement suggest property-like moral control rights for individuals.

As a consequence, notwithstanding the general reliance on a no-property rule concerning human body parts and tissue in genomics, consent seems to presuppose at least some form of moral property-like 'rights'. This is independent from claiming that there is an uncontroversial and unlimited, enforceable property right in human bodily material, that there should be markets in tissue or similar scenarios. Although there is conceptual space to this effect – there could be property and indeed there seems to be a 'property dimension' underlying consent – moral and practical reasons caution against the commodification and commercialization of tissue.

While a number of authors have discussed these connections for the particular application in biobank ethics, implications for governance scenarios should be brought more clearly into the picture. A preliminary step has been made, in that e-governance tools have been discussed as a possibility to bring science and society into closer alignment. If sovereignty over personal life retains an important place in bioethics, both individual and communal control rights in human tissue and genomic information will have to be discussed further and more publicly, precluding uncritical advances towards the 'datafication' of persons and their basic rights.

Bibliography

Case Law

Greenberg v. Miami Children's Hospital Research Institute. 2003. 264 F. Supp.2d 1064. (S.D. Fla. 2003)

Havasupai Tribe v. Arizona Board of Regents, No. 07-CV-0454 and CV-0801 (D. Ariz. 2007)

Havasupai Tribe et al. v. Arizona State University, No. 04-CV-1494 (D. Ariz. 2004)

Moore v. Regents of the University of California, 793 P. 2d 479, 271 Cal. 146 (1990), 490

Washington University v. Catalona. 2003. Case No. 4-03-CV 010655NL

Washington University v. William J. Catalona, 2007. 8th U.S. Circuit Court of Appeal, Nos. 06-2286 & 06-2301

Yearworth and others v. North Bristol NHS Trust. 2009. EWCA Civ 37

International and Regional Treaties and Conventions

Convention on Biological Diversity. United Nations. 1992.

http://www.cbd.int/doc/legal/cbd-en.pdf

(accessed 13 July 2013).

Declaration on the Human Genome and Human Rights. United Nations Educational, Scientific and Cultural Organization (UNESCO). 1997.

http://portal.unesco.org/en/ev.php-URL_ID=13177&URL_DO=DO_TOPIC&URL_SECTION=201.html

(accessed 12 July 2013).

International Declaration on Human Genetic Data. United Nations Educational, Scientific and Cultural Organization (UNESCO). 2003.

http://portal.unesco.org/en/ev.php-URL_ID=17720&URL_DO=DO_TOPIC&URL_SECTION=201.html

(accessed 12 July 2013).

Universal Declaration on Bioethics and Human Rights. United Nations Educational, Scientific and Cultural Organization (UNESCO). 2005.

http://portal.unesco.org/en/ev.php-URL_ID=31058&URL_DO=DO_TOPIC&URL_SECTION=201.html

(accessed 13 July 2013).

Charter of Fundamental Rights of the European Union. 2000. [2000/C 364/01].

http://www.europarl.europa.eu/charter/pdf/text_en.pdf

(accessed 8 April 2013).

Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine. [Oviedo Convention]. 1997.

http://conventions.coe.int/Treaty/en/Treaties/Html/164.htm

(accessed 14 September 2012).

Directive 95/46/EC on the Protection of Individuals with regard to the Processing of Personal Data and on the Free Movement of such Data. [Data Protection Directive]. 1995.

http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:1995:281:0031:0050:EN:PDF

(accessed 5 July 2013).

European Convention for the Protection of Human Rights and Fundamental Freedoms. 1950.

http://www.echr.coe.int/Documents/Convention_ENG.pdf

(accessed 17 October 2012).

Recommendation on Research on Biological Materials of Human Origin. Rec(2006)4.

http://www.coe.int/T/DG3/Healthbioethic/Texts_and_documents/Rec_2006_4.pdf

(accessed 14 September 2012).

Policy Documents

Council for International Organizations of Medical Sciences (CIOMS) and World Health Organization (WHO). International Ethical Guidelines for Biomedical Research Involving Human Subjects. 2002.

http://www.cioms.ch/publications/layout_guide2002.pdf

(accessed 3 April 2013).

Council of Europe. Recommendation 1512 (2001). Protection of the Human Genome.

http://assembly.coe.int/Main.asp?link=/Documents/AdoptedText/ta01/EREC1512.htm

(accessed 14 July 2013).

European Commission. Horizon 2020 –The Framework Programme for Research and Innovation. COM(2011) 808 final.

http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2011:0808:FIN:en:PDF

(accessed 14 May 2013).

European Commission. EUR 25302. 2012. Biobanks for Europe: A Challenge for Governance. Report of the Expert Group on Dealing with Ethical and Regulatory Challenges of International Biobank Research. Luxembourg: Publications Office of the European Union.

European Commission. Public-Private Partnerships in Horizon 2020: A Powerful Tool to Deliver on Innovation and Growth in Europe. COM(2013) 494 final.

http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2013:0494:FIN:en:PDF

(accessed 2 August 2013).

European Science Foundation. 2011. European Biobanks and Sample Repositories – Relevance to Personalized Medicine. Position Paper.

http://www.esf.org/fileadmin/Public_documents/Publications/personalised_medicine_01.pdf

(accessed 4 October 2012).

Human Genome Organization. 2002. Statement on Human Genomic Databases.

http://www.hugo-international.org/img/genomic_2002.pdf

(accessed 8 August 2013).

Nuffield Council on Bioethics. 1995. Human Tissue. Ethical and Legal Issues. London: KKS Printing.

http://www.nuffieldbioethics.org/sites/default/files/Human%20tissue.pdf

(accessed 23 April 2013).

Nuffield Council on Bioethics. 2011. Human Bodies: Donation for Medicine and Research. London: Nuffield Council on Bioethics.

Prainsack, Barbara and Buyx, Alena. 2011. Solidarity: Reflections on an Emerging Concept in Bioethics. Report commissioned by the Nuffield Council on Bioethics.

http://www.nuffieldbioethics.org/sites/default/files/NCOB_Solidarity_report_FINAL.pdf

(accessed 17 September 2012).

Presidential Commission for the Study of Bioethical Issues. 2012. Privacy and Progress in Whole Genome Sequencing. Washington: Presidential Commission for the Study of Bioethical Issues.

http://bioethics.gov/sites/default/files/PrivacyProgress508_1.pdf

(accessed 23 July 2013).

UK Biobank Ethics and Governance Framework. 2007.

http://www.ukbiobank.ac.uk/wp-content/uploads/2011/05/EGF20082.pdf

(accessed 9 April 2012).

People Science and Policy Ltd. 2002. Biobank UK: A Question of Trust: A Consultation Exploring and Addressing Questions of Public Trust. A Report Conducted for the Wellcome Trust and Medical Research Council.

http://www.ukbiobank.ac.uk/wp-content/uploads/2011/07/A-Question-of-Trust.pdf

(accessed 22 January 2013).

World Medical Association. 2013 [1964]. Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects.

http://www.wma.net/en/30publications/10policies/b3/17c.pdf

(accessed 15 May 2013).

Literature

Alta Charo, Robin. 2006. Body of Research – Ownership and Use of Human Tissue. *New England Journal of Medicine* 355 (15): 1517-1519.

Anderlik, Mary R. 2003. Commercial Biobanks and Genetic Research. Ethical and Legal Issues. *American Journal of Pharmacogenomics* 3 (3): 203-215.

Andorno, Roberto. 2007. Population Genetic Databases: A New Challenge to Human Rights. In *Ethics and Law of Intellectual Property: Current Problems in Politics, Science and Technology*, edited by Christian Lenk, Nils Hoppe, and Roberto Andorno. Aldershot: Ashgate, 27-45.

Andrews, Lori B. 2005. Harnessing the Benefits of Biobanks. *Journal of Law, Medicine, and Ethics* 33 (1): 22-30.

--- 2006. Who Owns Your Body? A Patient's Perspective on Washington University v. Catalona. *Journal of Law, Medicine, and Ethics* 34 (2): 398-407.

Annas, George J. 1993. Privacy Rules for DNA Databanks. *Journal of the American Medical Association* 270: 2346–2350.

Árnason, Vilhjálmur. 2004. Coding and Consent: Moral Challenges of the Database Project in Iceland. *Bioethics* 18(1): 27-49.

--- 2009. Scientific Citizenship, Benefit, and Protection in Population-Based Research. In *The Ethics of Research Biobanking*, edited by Jan Helge Solbakk, Søren Holm and Bjørn Hofmann. Dordrecht: Springer, 131-141.

--- 2011. Database Research: Public and Private Interests. *Cambridge Quarterly of Healthcare Ethics* 20: 563-571.

Austin, Melissa A., Hair, Marilyn S., and Fullerton, Stephanie M. 2012. Research Guidelines in the Era of Large-scale Collaborations: An Analysis of Genome-wide Association Study Consortia. *American Journal of Epidemiology* 175(9): 962-969.

Barr, Michael. 2006a. 'I'm not Really Read up on Genetics': Biobanks and the Social Context of Informed Consent. *BioSocieties* 1: 251-262.

--- 2006b. Informed Consent and the Shaping of British and U.S. Population-Based Genetic Research. In *Shaping Science and Technology Policy: The Next Generation of Research*, edited by David H. Guston and Daniel Sarewitz. Madison: The University of Wisconsin Press, 291-311.

Bauer, Keith, Taub, Sara, and Parsi, Kayhan. 2004. Ethical Issues in Tissue Banking for Research: A Brief Review of Existing Organizational Policies. *Theoretical Medicine* 25: 113-142.

Beauchamp, Tom L. 2011. Informed Consent: Its History, Meaning, and Present Challenges. *Cambridge Quarterly of Healthcare Ethics* 20: 515-523.

Beauchamp, Tom L. and Childress, James F. 2012. *Principles of Biomedical Ethics*. 7th Edition. New York; Oxford: Oxford University Press.

Beier, Katharina. 2010. Das Prinzip der informierten Zustimmung in der Biobankforschung. *Berliner Debatte Initial* 21(4): 51-63.

Bellivier, Florence and Noiville, Christine. 2011. The Circulation of Human Body Parts and Products: When Exclusive Property Rights Mask the Issue of Access. In *Biobanks and Tissue Research. The Public, the Patient and the Regulation*, edited by Christian Lenk, Judit Sándor and Bert Gordijn. Dordrecht: Springer, 201-211.

Berg, Jonathan S., Khoury, Muin J. and Evans, James P. 2011. Deploying Whole Genome Sequencing in Clinical Practice and Public Health: Meeting the Challenge One Bin at a Time. *Genetics in Medicine* 13 (6): 499-504.

Beskow, Laura M., Burke, Wylie, Merz, John F., Barr, Patricia A., Terry, Sharon, Penchaszadeh, Victor B., Gostin, Lawrence O., Gwinn, Marta, Khoury, Muin J. 2001. Informed Consent for Population-Based Research Involving Genetics. *Journal of the American Medical Association* 286 (18): 2315-2321.

Beyleveld, Deryck and Brownsword, Roger. 2000. My Body, My Body Parts, My Property? *Health Care Analysis* 8: 87-99.

--- 2001. *Human Dignity in Bioethics and Biolaw*. Oxford; New York: Oxford University Press.

Beyleveld, Deryck. 2007. Data Protection and Genetics: Medical Research and the Public Good. *King's Law Journal* 18: 275-289.

Bialobrzeski, Arndt, Ried, Jens and Dabrock, Peter. 2012. Differentiating and Evaluating Common Good and Public Good: Making Implicit Assumptions Explicit in the Contexts of Consent and Duty to Participate. *Public Health Genomics* 15: 285-292.

Biesecker, Leslie G. 2013. Secondary Variants and Human Subjects Research. *Genetics in Medicine* 15: 157.

Björkman, Barbro and Hansson, Sven Ove. 2006. Bodily Rights and Property Rights. *Journal of Medical Ethics* 32: 209-214.

Björkman, Barbro. 2007. Different Types—Different Rights. Distinguishing between Different Perspectives on Ownership of Biological Material. *Science and Engineering Ethics* 13: 221-233.

Bledsoe, Marianna J., Grizzle, William E., Clark, Brian J. and Zeps, Nikolajs. 2012. Practical Implementation Issues and Challenges for Biobanks in the Return of Individual Research Results. *Genetics in Medicine* 14: 478-483.

Bobbert, Monika. 2007. Die Veräußerung von Körpersubstanzen, der „Informed Consent“ und ethisch relevante Charakteristika der Handlungskontexte. In *Kommerzialisierung des menschlichen Körpers*, edited by Jochen Taupitz. Berlin; Heidelberg: Springer, 235-256.

Boddington, Paula. 2012. *Ethical Challenges in Genomics Research*. Berlin; Heidelberg: Springer.

Boggio, Andrea. 2005. Charitable Trusts and Human Research Genetic Databases: The Way Forward? *Genomics, Society and Policy* 1 (2): 41-49.

Bohannon, John. 2013. Genealogy Databases Enable Naming of Anonymous DNA Donors. *Science* 339: 262.

Boniolo, Giovanni, Di Fiore, Pier Paolo and Pece, Salvatore. 2012. Trusted Consent and Research Biobanks: Towards a ‘New Alliance’ between Researchers and Donors. *Bioethics* 26: 93-100.

Bovenberg, Jasper A. 2004. Inalienably Yours? The New Case for an Inalienable Property Right in Human Biological Material: Empowerment of Sample Donors or a Recipe for a Tragic Anti-Commons? *SCRIPT-ed* 1 (4): 545-584.

--- 2005. *Whose Tissue is it Anyway? Nature Biotechnology* 23 (8): 929-933.

--- 2006. *Property Rights in Blood, Genes and Data: Naturally Yours?* Leiden; Boston: Martinus Nijhoff Publishers.

--- 2011. One Sample, One Share! A Proposal to Redress an Inequity with Equity. In *Biobanks and Tissue Research. The Public, the Patient and the Regulation*, edited by Christian Lenk, Judit Sándor and Bert Gordijn. Dordrecht: Springer, 81-94.

Boyle, James. 1997. *Shamans, Software, and Spleens. Law and the Construction of the Information Society*. Cambridge, Mass.; London: Harvard University Press.

Boyle, Joyce. 2002. To Pay or not to Pay, That is the Question: Finding an Intermediary Solution Along the Moore Spectrum. *Michigan State University College of Law Journal of Medicine and Law* 55: 56-78.

Brassington, Iain. 2007. John Harris’ Argument for a Duty to Research. *Bioethics* 21: 160-168.

--- 2011. Defending the Duty to Research? *Bioethics* 25 (1): 21-26.

Brekke, Ole A. and Sirnes, Thorvald. 2006. Population Biobanks: The Ethical Gravity of Informed Consent. *BioSocieties* 1: 385-398.

Brenner, Steven E. 2013. Be Prepared for the Big Genome Leak. *Nature* 498: 139.

Broström, Linus and Johansson, Mats. 2011. Broad Consent. In *Translational Stem Cell Research: Issues Beyond the Debate on the Moral Status of the Human Embryo*, edited by Hug, Kristina and Hermerén, Göran. New York: Springer, 237-250.

Brownsword, Roger. 2003. An Interest in Human Dignity as the Basis for Genomic Torts. *Washburn Law Journal* 42 (3): 413-487.

--- 2007a. Biobank Governance: Property, Privacy and Consent. In *Ethics and Law of Intellectual Property: Current Problems in Politics, Science and Technology*, edited by Christian Lenk, Nils Hoppe, and Roberto Andorno. Aldershot: Ashgate, 11-25.

--- 2007b. Genetic Databases: One for All and All for One? *King's Law Journal* 18: 247-273.

--- 2009. Property in Human Tissue: Triangulating the Issue. In *Altruism Reconsidered: Exploring New Approaches to Property in Human Tissue*, edited by Michael Steinmann, Peter Sýkora and Urban Wiesing. Farnham: Ashgate, 93-104.

--- 2013. Regulating Biobanks: Another Triple Bottom Line. In *Comparative Issues in the Governance of Research Biobanks. Property, Privacy, Intellectual Property, and the Role of Technology*, edited by Giovanni Pascuzzi, Umberto Izzo and Matteo Macilotti. Berlin; Heidelberg: Springer, 41-62.

Budimir, Danijela, Polašek, Ozren, Marušić, Ana, Kolčić, Zemunik, Tatijana, Boraska, Vesna, Jerončić, Ana, Boban, Mladen, Campbell, Harry and Rudan, Igor. 2011. Ethical Aspects of Human Biobanks: A Systematic Review. *Croatian Medical Journal* 52: 262-279.

Calabresi, Guido. 1991. Do We Own Our Bodies? *Health Matrix* 1: 5-18.

Callahan, Daniel. 2003. Individual Good and Common Good. *Perspectives in Biology and Medicine* 46 (4): 496-507.

Cambon-Thomsen, Anne. 2004. The Social and Ethical Issues of Post-Genomic Human Biobanks. *Nature Reviews Genetics* 5: 866-873.

Cambon-Thomsen, Anne, Rial-Sebbag, Emmanuelle and Knoppers, Bartha M. 2007. Trends in Ethical and Legal Frameworks for the Use of Human Biobanks. *European Respiratory Journal* 30: 373-382.

Campbell, Alastair V. 2007. The Ethical Challenges of Genetic Databases: Safeguarding Altruism and Trust. *King's Law Journal* 18: 227-245.

--- 2009. *The Body in Bioethics*. London; New York: Routledge-Cavendish.

Campbell, Courtney S. 1992. Body, Self, and the Property Paradigm. *The Hastings Center Report* 22 (5): 34-42.

Caplan, Arthur L. 1984. Is there a Duty to Serve as a Subject in Biomedical Research? *IRB: Ethics and Human Research* 6 (5): 1-5.

--- 2009. What No One Knows Cannot Hurt You: The Limits of Informed Consent in the Emerging World of Biobanking. In *The Ethics of Research Biobanking*, edited by Jan Helge Solbakk, Søren Holm and Bjørn Hofmann. Dordrecht: Springer, 25-32.

--- 2012. Why Autonomy Needs Help. *Journal of Medical Ethics*, doi: 10.1136/medethics-2012-100492.

Casado da Rocha, Antonio and Seoane, José A. 2008. Alternative Consent Models for Biobanks: The New Spanish Law on Biomedical Research. *Bioethics* 22 (8): 440-447.

Caulfield, Timothy and Brownsword, Roger. 2006. Human Dignity: A Guide to Policy Making in the Biotechnology Era? *Nature Reviews Genetics* 7: 72-76.

Caulfield, Timothy and Kaye, Jane. 2009. Broad Consent in Biobanking: Reflections on Seemingly Insurmountable Dilemmas. *Medical Law International* 10: 85-100.

Caulfield, Timothy and Ogbogu, Ubaka. 2012. Stem Cell Research, Scientific Freedom and the Commodification Concern. *EMBO reports* 13 (1): 12-16.

Caulfield, Timothy and Weijer, Charles. 2009. Minimal Risk and Large-Scale Biobank and Cohort Research. *Health Law Review* 17 (2-3): 53-58.

Caulfield, Timothy, Upshur, Ross E.G., and Daar, Abdallah. 2003. DNA Databanks and Consent: A Suggested Policy Option Involving an Authorization Model. *BioMedCentral Medical Ethics* 4. doi:10.1186/1472-6939-4-1 (accessed 29 January 2013).

Caulfield, Timothy. 2002. Gene Banks and Blanket Consent. *Nature Reviews Genetics* 3: 577.

--- 2007. Biobanks and Blanket Consent: The Proper Place of the Public Good and Public Perception Rationales. *King's Law Journal* 18: 209-226.

Chadwick, Ruth and Berg, Kåre. 2001. Solidarity and Equity: New Ethical Frameworks for Genetic Databases. *Nature Reviews Genetics* 2: 318-321.

Chadwick, Ruth and Wilson, Sarah. 2004. Genomic Databases as Global Public Goods. *Res Publica* 10: 123-134.

Chadwick, Ruth. 2011. The Communitarian Turn. Myth or Reality? *Cambridge Quarterly of Healthcare Ethics* 20: 546-553.

Chan, Sarah and Harris, John. 2009. Free Riders and Pious Sons – Why Science Research Remains Obligatory. *Bioethics* 23 (2): 161-171.

Christensen, Erik. 2009. Biobanks and Our Common Good. In *The Ethics of Research Biobanking*, edited by Jan Helge Solbakk, Søren Holm and Bjørn Hofmann. Dordrecht: Springer, 101-114.

Cohen, Ed. 2008. A Body Worth Having? Or, A System of Natural Governance. *Theory, Culture and Society* 25 (3): 103-129.

Cohen, Gerald A. 1995. *Self-Ownership, Freedom and Equality*. Cambridge; New York: Cambridge University Press.

Cohen, Shlomo. 2011. The Gettier Problem in Informed Consent. *Journal of Medical Ethics* 37: 642-645.

Collins, Francis. 2010. Has the Revolution Arrived? *Nature* 464: 674-675.

Cordell, Sean, Bellivier, Florence, Widdows, Heather, and Noiville, Christine. 2011. Lost Property? Legal Compensation for Destroyed Sperm: A Reflection and Comparison Drawing on UK and French Perspectives. *Journal of Medical Ethics* 37: 747-751.

Cordell, Sean. 2011. The Biobank as an Ethical Subject. *Health Care Analysis* 19: 282-294.

Corrigan, Oonagh. 2003. Empty Ethics: The Problem with Informed Consent. *Sociology of Health and Illness* 25 (3): 768-792.

--- 2004. Informed Consent: The Contradictory Ethical Safeguards in Pharmacogenetics. In *Genetic Databases. Socio-Ethical Issues in the Collection and Use of DNA*, edited by Richard Tutton and Oonagh Corrigan. London; New York: Routledge, 78-96.

De Faria, Paola Lobato. 2009. Ownership Rights in Research Biobanks: Do We Need a New Kind of 'Biological Property'? In *The Ethics of Research Biobanking*, edited by Jan Helge Solbakk, Søren Holm and Bjørn Hofmann. Dordrecht: Springer, 263-276.

Dickenson, Donna. 2004. Consent, Commodification and Benefit-Sharing in Genetic Research. *Developing World Bioethics* 4(2): 109-124.

--- 2007. *Property in the Body: Feminist Perspectives*. Cambridge; New York: Cambridge University Press.

Douglas, Simon. 2012. The Argument for Property Rights in Body Parts: Scarcity of Resources. *Journal of Medical Ethics* doi: 10.1136/medethics-2012-100788.

Dworkin, Gerald. 1988. *The Theory and Practice of Autonomy*. Cambridge; New York: Cambridge University Press.

Editorial. 2013. The Case for a Cohort. *Nature Genetics* 45 (6): 579.

Einsiedel, Edna and Sheremeta, Lorraine. 2005. Biobanks and the Challenges of Commercialization. In *Handbook of Genome Research*, edited by Christoph W. Sensen. Weinheim: Wiley-Vch, 537-559.

Elger, Bernice and Biller-Andorno, Nikola. 2011. Biobanks and Research: Scientific Potential and Regulatory Challenge. In *Biobanks and Tissue Research. The Public, the Patient and the Regulation*, edited by Christian Lenk, Judit Sándor and Bert Gordijn. Dordrecht: Springer, 37-52.

Elger, Bernice and Caplan, Arthur L. 2006. Consent and Anonymization in Research Involving Biobanks. *EMBO reports* 7(7): 661-666.

Elger, Bernice. 2010. *Ethical Issues of Human Genetic Databases: A Challenge to Classical Health Research Ethics*? Farnham: Ashgate.

Eriksson, Stefan and Helgesson, Gert. 2005. Potential Harms, Anonymization, and the Right to Withdraw Consent to Biobank Research. *European Journal of Human Genetics* 13: 1071-1076.

Everett, Margaret. 2003. The Social Life of Genes: Privacy, Property and the New Genetics. *Social Science and Medicine* 56: 53-65.

--- 2007. The "I" in the Gene: Divided Property, Fragmented Personhood, and the Making of a Genetic Privacy Law. *American Ethnologist* 34 (2): 373-384.

Faden, Ruth R. and Beauchamp, Tom L. 1986. *A History and Theory of Informed Consent*. New York; Oxford: Oxford University Press.

Feldman, Robin. 2011. Whose Body is it Anyway? Human Cells and the Strange Effects of Property and Intellectual Property Law. *Stanford Law Review* 63: 1377-1402.

Felt, Ulrike, Bister, Milena D., Strassnig, Michael and Wagner, Ursula. 2009. Refusing the Information Paradigm: Informed Consent, Medical Research, and Patient Participation. *Health* 13 (1): 87-106.

Fortin, Sabrina, Pathmasiri, Saminda, Grintuch, Rhonda, Deschênes, Mylène. 2011. 'Access Arrangements' for Biobanks: A Fine Line between Facilitating and Hindering Collaboration. *Public Health Genomics* 14: 104-114.

Foster, Morris W., Bernsten, Deborah, Carter, Thomas H. 1998. A Model Agreement for Genetic Research in Socially Identifiable Populations. *American Journal of Human Genetics* 63(3): 696-702.

Friend, Stephen H. and Norman, Thea C. 2013. Metcalfe's Law and the Biology Information Commons. *Nature Biotechnology* 31 (4): 297-303.

George, Alexandra. 2004. Is 'Property' Necessary? On Owning the Human Body and Its Parts. *Res Publica* 10: 15-42.

Gerrand, Nicole. 1999. The Misuse of Kant in the Debate about a Market for Human Body Parts. *Journal of Applied Philosophy* 16 (1): 59-67.

Geuna, Aldo and Nesta, Lionel J.J. 2006. University Patenting and its Effects on Academic Research: The Emerging European Evidence. *Research Policy* 35: 790-807.

Gillett, Grant. 2007. The Use of Human Tissue. *Journal of Bioethical Inquiry* 4: 119-127.

Glantz, Leonard H., Roche, Patricia, and Annas, George J. 2008. Rules for Donations to Tissue Banks – What Next? *New England Journal of Medicine* 358 (3): 298-303.

--- 2010. Gift Giving to Biobanks. *American Journal of Bioethics* 10 (9): 33-34.

Gottweis, Herbert and Lauss, Georg. 2010. Biobank Governance in the Post-Genomic Age. *Personalized Medicine* 7 (2): 187-195.

--- 2012. Biobank Governance: Heterogenous Modes of Ordering and Democratization. *Journal of Community Genetics* 3: 61-72.

Gracia, Diego. 2012. The Many Faces of Autonomy. *Theoretical Medicine and Bioethics* 33: 57-64.

Graff, Gregory D., Phillips, Devon, Lei, Zhen, Oh, Sooyoung, Nottenburg, Carol and Pardey, Philip G. 2013. Not Quite a Myriad of Gene Patents. Nature Biotechnology 31 (5): 404-410.

Greely, Henry T. 2007. The Uneasy Ethical and Legal Underpinnings of Large-Scale Genomic Biobanks. *Annual Review of Genomics and Human Genetics* 8: 343-364.

--- 2010. To the Barricades! *American Journal of Bioethics* 10 (9): 1-2.

Gymrek, Melissa, McGuire, Amy L., Golan, David, Halperin, Eran, and Erlich, Yaniv. 2013. Identifying Personal Genomes by Surname Inference. *Science* 339: 321-324.

Haddow, Gillian, Laurie, Graeme, Cunningham-Burley, Sarah, Hunter, Kathryn G. 2007. Tackling Community Concerns About Commercialisation and Genetic Research: A Modest Interdisciplinary Proposal. *Social Science and Medicine* 64: 272-282.

Halewood, Peter. 1996. Law's Bodies: Disembodiment and the Structure of Liberal Property Rights. *Iowa Law Review* 81: 1331-1393.

Hallowell, Nina, Cooke, Sarah, Crawford, Gillian, Lucassen, Anneke, Parker, Michael, and Snowdon, Claire. 2010. An Investigation of Patients' Motivations for their Participation in Genetics-Related Research. *Journal of Medical Ethics* 36: 37-45.

Hansson, Mats G. 2009. Ethics and Biobanks. *British Journal of Cancer* 100: 8-12.

--- 2010. Do We Need a Wider View of Autonomy in Epidemiological Research? *British Medical Journal* 340: 1172-1174.

--- 2011. The Need to Downregulate: A Minimal Ethical Framework for Biobank Research. In *Methods in Biobanking*, edited by Joakim Dillner. New York: Springer, 39-59.

Hansson, Mats G., Dillner, Joakim, Bartram, Claus R., Carlson, Joyce A., and Helgesson, Gert. 2006. Should Donors Be Allowed to Give Broad Consent to Future Biobank Research? *The Lancet Oncology* 7: 266-269.

Hansson, Mats G., Van Ommen, Gert J., Chadwick, Ruth, Dillner, Joakim. 2013. Patients Would Benefit from Simplified Ethical Review and Consent Procedure. *The Lancet Oncology* http://dx.doi.org/10.1016/S1470-2045(13)70129-3 (accessed 14 June 2013).

Hardcastle, Rohan. 2009. *Law and the Human Body. Property Rights, Ownership and Control*. Oxford; Portland: Hart Publishing.

Harmon, Shawn H. E. 2009. Semantic, Pedantic, or Paradigm Shift? Recruitment, Retention and Property in Modern Population Biobanking. *European Journal of Health Law* 16: 27-43.

--- 2010. Yearworth v. North Bristol NHS Trust: A Property Case of Uncertain Significance? *Medicine, Healthcare and Philosophy* 13: 343-350.

Harris, James W. 1996a. *Property and Justice*. Oxford: Clarendon Press.

--- 1996b. Who Owns My Body. *Oxford Journal of Legal Studies* 16 (1): 55-84.

Harris, John. 2005. Scientific Research Is a Moral Duty. *Journal of Medical Ethics* 31: 242-248.

Harrison, Charlotte H. 2002. Neither Moore nor the Market: Alternative Models for Compensating Contributors of Human Tissue. *American Journal of Law and Medicine* 28: 77-105.

Hayden, Erika C. 2013. Geneticists Push for Global Data-Sharing. *Nature* 498: 16-17.

Häyry, Matti. 2005. The Tension between Self Governance and Absolute Inner Worth in Kant's Moral Philosophy. *Journal of Medical Ethics* 31: 645-647.

Häyry, Matti and Takala, Tuija. 2007. American Principles, European Values and the Mezzanine Rules of Ethical Genetic Databanking. In *The Ethics and Governance of Human Genetic Databases. European Perspectives*, edited by Matti Häyry, Ruth Chadwick, Vilhjálmur Árnason, and Gardar Árnason. Cambridge; New York: Cambridge University Press, 14-36.

Helgesson, Gert and Eriksson, Stefan. 2008. Against the Principle that the Individual Shall Have Priority over Science. *Journal of Medical Ethics* 34: 54-56.

--- 2011. The Moral Primacy of the Human Being: A Reply to Parker. *Journal of Medical Ethics* 37: 56-57.

Helgesson, Gert, Dillner, Joakim, Carlson, Joyce, Bartram, Claus R. and Hansson, Mats G. 2007. Ethical Framework for Previously Collected Biobank Samples. *Nature Biotechnology* 25 (9): 973-976.

Herrera, Christopher. 2003. Universal Compulsory Service in Medical Research. *Theoretical Medicine* 24: 215-231.

Herring, Jonathan and Chau, Pak-Lee. 2007. My Body, Your Body, Our Bodies. *Medical Law Review* 15: 34-61.

--- 2013. Interconnected, Inhabited and Insecure: Why Bodies Should Not Be Property. *Journal of Medical Ethics*. doi: 10.1136/medethics-2012-100904 (accessed 9 April 2013).

Herrmann, Beate. 2011. *Der menschliche Körper zwischen Vermarktung und Unverfügbarkeit. Grundlinien einer Ethik der Selbstverfügung*. Freiburg: Verlag Karl Alber.

Hewitt, Robert E. 2011. Biobanking: The Foundation of Personalized Medicine. *Current Opinion in Oncology* 23: 112-119.

Hoedemaekers, Rogeer, Gordijn, Bert and Pijnenburg, Martien. 2006. Does an Appeal to the Common Good Justify Individual Sacrifices for Genomic Research? *Theoretical Medicine and Bioethics* 27: 415-431.

--- 2007. Solidarity and Justice as Guiding Principles in Genomic Research. *Bioethics* 21 (6): 342-350.

Hofmann, Bjørn. 2004. Do Biobanks Promote Paternalism? On the Loss of Autonomy in the Quest for Individual Independence. In *Blood and Data: Ethical, Legal and Social Aspects of Human Genetic Databases*, edited by Gardar Árnason, Salvör Nordal and Vilhjálmur Árnason. Reykjavik: The Centre for Ethics and University of Iceland Press, 237-242.

--- 2008. Bypassing Consent for Research on Biological Material. *Nature Biotechnology* 26 (9): 979-980.

--- 2009. Broadening Consent – and Diluting Ethics? *Journal of Medical Ethics* 35: 125-129.

Holm, Søren. 2006. Who Should Control the Use of Human Embryonic Stem Cell Lines: A Defence of the Donors' Ability to Control. *Journal of Bioethical Inquiry* 3: 55-68.

--- 2011. Withdrawing from Research: A Rethink in the Context of Research Biobanks. *Health Care Analysis* 19: 269-281.

Holm, Søren, Hofmann, Bjørn, and Solbakk, Jan Helge. 2009. Conscription to Biobank Research? In *The Ethics of Research Biobanking*, edited by Jan Helge Solbakk, Søren Holm and Bjørn Hofmann. Dordrecht: Springer, 255-262.

Homer, Nils, Szelinger, Szalbocs, Redman, Margot, Duggan, David, Tembe, Waibhav, Muehling, Jill, Pearson, John V., Stephan, Dietrich A., Nelson, Stanley F., Craig, David W. 2008. Resolving Individuals Contributing Trace Amounts of DNA to Highly Complex Mixtures Using High-Density SNP Genotyping Microarrays. *PLOS Genetics* 4 (8): e1000167.

Honoré, Anthony M. 1987. Ownership. In *Making Law Bind. Essays Legal and Philosophical*, edited by Anthony M. Honoré. Oxford: Clarendon Press, 161-192.

Hoppe, Nils. 2009. *Bioequity – Property and the Human Body*. Farnham: Ashgate.

--- 2010. Cui bono? Eigentum am eigenen Körper in der internationalen juristischen Diskussion. *Berliner Debatte Initial* 21 (4): 19-27.

--- 2011. Risky Business: Re-Evaluating Participant Risk in Biobanking. In *Human Tissue Research. A European Perspective on the Ethical and Legal Challenges*, edited by Christian Lenk, Nils Hoppe, Katharina Beier, and Claudia Wiesemann. Oxford: Oxford University Press, 35-45.

Høyer, Klaus L. 2008. The Ethics of Research Biobanking: A Critical Review of the Literature. *Biotechnology and Genetic Engineering Reviews* 25: 429-452.

Hunter, Kathryn G. and Laurie, Graeme T. 2009. Involving Publics in Biobank Governance: Moving Beyond Existing Approaches. In *The Governance of Genetic Information. Who Decides?*, edited by Heather Widdows and Caroline Mullen. Cambridge; New York: Cambridge University Press, 151-177.

Indech, Barbara. 2000. The International Harmonization of Human Tissue Regulation: Regulatory Control Over Human Tissue Use and Tissue Banking in Select Countries and the Current State of International Harmonization Efforts. *Food and Drug Law Journal* 55: 343-372.

Irving, Louise and Harris, John. 2007. Biobanking. In *The Oxford Handbook of Bioethics*, edited by Bonnie Steinbock. Oxford: Oxford University Press, 240-257.

Janger, Edward J. 2005. Genetic Information, Privacy, and Insolvency. *Journal of Law, Medicine, and Ethics* 33 (1): 79-88.

Jonas, Hans. 1969. Philosophical Reflections on Experimenting with Human Subjects. *Daedalus* 98 (2): 219-247.

Kanellopoulou, Nadja K., Kaye, Jane, Whitley, Edgar A., Creese, Sadie, Lund, David, Hughes, Kay. 2011. Dynamic Consent – A Solution to a Perennial Problem? *British Medical Journal* 343: d6900 (accessed 12 April 2013).

Kanellopoulou, Nadja K. 2004. Gift or Duty? A Normative Discussion for Participation in Human Genetic Databases Research. In *Blood and Data: Ethical, Legal and Social Aspects of Human Genetic Databases*, edited by Gardar Árnason, Salvör Nordal and Vilhjálmur Árnason. Reykjavik: The Centre for Ethics and University of Iceland Press, 95-99.

Kant, Immanuel. 1991 [1797]. *The Metaphysics of Morals*. Introduction, translation, and notes by Mary Gregor. Cambridge; New York: Cambridge University Press.

--- 1997 [1762-1784]. *Lectures on Ethics*. Edited by Peter Heath and J.B. Schneewind. Cambridge: Cambridge University Press.

--- 1998 [1785]. *Groundwork of the Metaphysics of Morals*. Translated and edited by Mary Gregor. Cambridge; New York: Cambridge University Press.

Karlsen, Jan Reinert, De Faria, Paula L., Solbakk, Jan H. 2006. To Know the Value of Everything – A Critical Commentary on B Björkman and S O Hansson's "Bodily Rights and Property Rights". *Journal of Medical Ethics* 32: 215-219.

Karlsen, Jan Reinert and Strand, Roger. 2009. Annexation of Life: The Biopolitics of Industrial Biology. In *The Ethics of Research Biobanking*, edited by Jan Helge Solbakk, Søren Holm and Bjørn Hofmann. Dordrecht: Springer, 315-329.

Karlsen, Jan Reinert, Solbakk, Jan Helge, and Holm Søren. 2011. Ethical Endgames: Broad Consent for Narrow Interests; Open Consent for Closed Minds. *Cambridge Quarterly of Healthcare Ethics* 20: 572-583.

Kauffmann, Clemens. 2011. Gattungspolitik: Der Menschliche Körper als Globales Öffentliches Gut. In *Biopolitik im Liberalen Staat*, edited by Clemens Kauffmann and Hans-Jörg Sigwart. Baden-Baden: Nomos Verlagsgesellschaft, 135-162.

Kaye, Jane. 2011. From Single Biobanks to International Networks: Developing E-Governance. *Human Genetics* 130 (3): 377-382.

--- 2012. The Tension Between Data Sharing and the Protection of Privacy in Genomics Research. *Annual Review of Genomics and Human Genetics* 13: 415-431.

Kaye, Jane and Martin, Paul. 2000. Safeguards for Research Using Large Scale DNA Collections. *British Medical Journal* 321: 1146-1149.

Kaye, Jane, Helgason, Hordur Helgi, Nõmper, Ants, Sild, Tarmo, and Wendel, Lotta. 2004. Population Genetic Databases: A Comparative Analysis of the Law in Iceland, Sweden, Estonia and the UK. *Trames* 8 (1/2): 15-33.

Kaye, Jane, Boddington, Paula, De Vries, Jantina, Hawkins, Naomi, and Melham, Karen. 2010. Ethical Implications of the Use of Whole Genome Methods in Medical Research. *European Journal of Human Genetics* 18: 398-403.

Kaye, J., Curren, Liam, Anderson, Nick, Edwards, Kelly, Fullerton, Stephanie M., Kanellopoulou, Nadja, Lund, David, MacArthur, Daniel G., Mascalzoni, Deborah, Shepherd, James, Taylor, Patrick L., Terry, Sharon F. and Winter, Stefan F. 2012. From Patients to Partners: Participant-Centric Initiatives in Biomedical Research. *Nature Reviews Genetics* 13: 371-376.

Kegley, Jacquelyn Ann K. 2004. Challenges to Informed Consent. *EMBO reports* 5(9): 832-836.

Kihlbom, Ulrik. 2008. Autonomy and Negatively Informed Consent. *Journal of Medical Ethics* 34: 146-149.

Kirchhoffer, David G. and Dierickx, Kris. 2011. Human Dignity and Human Tissue: A Meaningful Ethical Relationship? *Journal of Medical Ethics* 37: 552-556.

Kissell, Judith L. 1998. Getting Beyond Classical Liberalism: The Human Body and the Property Paradigm. *Medicine, Healthcare and Philosophy* 1: 279-281.

Knoppers, Bartha M. 2005a. Biobanking: International Norms. *Journal of Law, Medicine and Ethics* 33 (1): 7-14.

--- 2005b. Of Genomics and Public Health: Building Public "Goods"? *Canadian Medical Association Journal* 173 (10): 1185-1186.

--- 2010. Consent to ‚Personal' Genomics and Privacy. *EMBO reports* 11 (6): 416-419.

Knoppers, Bartha M. and Chadwick, Ruth. 2005. Human Genetic Research: Emerging Trends in Ethics. *Nature Review Genetics* 6: 75-79.

Knoppers, Bartha M. and Sallée, Clémentine. 2005. Ethical Aspects of Genome Research and Banking. In *Handbook of Genome Research*, edited by Christoph W. Sensen. Weinheim: Wiley-Vch, 509-536.

Kohane, Isaac A. and Altman, Russ B. 2005. Health Information Altruists – A Potentially Critical Resource. *New England Journal of Medicine* 353 (19): 2074-2077.

Kosseim, Patricia and Jospe, Dara. 2011. Banking for the Future: "Informing" Consent in the Context of Biobanks. Paper submitted at the IV International Seminar on the UNESCO Universal Declaration on Bioethics and Human Rights http://www.priv.gc.ca/media/sp-d/2011/sp-d_20110121_pk_e.asp (accessed 4 June 2013).

Krajewska, Atina. 2009. Conceptual Quandaries about Genetic Data – A Comparative Perspective. *European Journal of Health Law* 16: 7-26.

Kristinsson, Sigurdur. 2007. Autonomy and Informed Consent: A Mistaken Association? *Medicine, Healthcare and Philosophy* 10: 253-264.

Kuehn, Bridget M. 2013. Groups Experiment with Digital Tools for Patient Consent. *Journal of the American Medical Association* 310 (7): 678-680.

Laberge, Claude. 2003. Genomics, Health and Society. In *Genomics, Health and Society: Emerging Issues for Public Policy*, edited by Bartha M. Knoppers and Charles R. Scriver. Ottawa: Policy Research Initiative, 11-21.

Larson, Eric B. 2013. Building Trust in the Power of "Big Data" Research to Serve the Public Good. *Journal of the American Medical Association* 309 (23): 2443-2444.

Laurie, Graeme. 2003. Privacy and Property? Multi-Level Strategies for Protecting Personal Interests in Genetic Material. In *Genomics, Health and Society: Emerging Issues for Public Policy*, edited by Bartha M. Knoppers and Charles R. Scriver. Ottawa: Policy Research Initative, 83-98.

--- 2004. *Genetic Privacy. A Challenge to Medico-Legal Norms*. Cambridge: Cambridge University Press.

Law, Iain. 2011. Respect for Autonomy: Its Demands and Limits in Biobanking. *Health Care Analysis* 19: 259-268.

Lenk, Christian. 2008. Gibt es das Recht auf Eigentum am eigenen Körper? Ein Beitrag zur Forschungsethik in der kantischen Tradition der Aufklärung. *Zeitschrift für medizinische Ethik* 54 (1): 13-22.

Lenk, Christian and Hoppe, Nils. 2009. Using Tissue and Material from the Human Body for Biomedical Research: Proposals for a Normative Model. In *Altruism Reconsidered: Exploring New Approaches to Property in Human Tissue*, edited by Michael Steinmann, Peter Sýkora and Urban Wiesing. Farnham: Ashgate, 133-141.

Lenk, Christian and Beier, Katharina. 2012. Is the Commercialization of Human Tissue and Body Material Forbidden in the Countries of the European Union? *Journal of Medical Ethics* 38: 342-346.

Levitt, Mairi. 2011. Relating to Participants: How Close Do Biobanks and Donors Really Want to Be? *Health Care Analysis* 19: 220-230.

Levitt, Mairi and Weldon, Sue. 2005. A Well Placed Trust?: Public Perceptions of the Governance of DNA Databases. *Critical Public Health* 15 (4): 311-321.

Locke, John. 2003 [1690]. *Two Treatises of Government and A Letter Concerning Toleration*. Edited by Ian Shapiro. New Haven; London: Yale University Press.

Lowrance, William W. and Collins, Francis S. 2007. Identifiability in Genomic Research. *Science* 317: 600-602.

Lunshof, Jeantine E., Chadwick, Ruth, Church, George M. 2008. Hippocrates Revisited? Old Ideals and New Realities. *Genomic Medicine* 2: 1-3.

Lunshof, Jeantine E., Chadwick, Ruth, Vorhaus, Daniel B., Church, George M. 2008. From Genetic Privacy to Open Consent. *Nature Reviews Genetics* 9: 406-411.

Lutz, Ralf. 2010. Mein Körper, Ich und seine Vermarktung – Zwischen Personalität und Kommerzialität. Moraltheologische Anmerkungen zur Selbstverfügung über den eigenen Körper. In *Wem gehört der menschliche Körper? Ethische, rechtliche und soziale Aspekte der Kommerzialisierung des menschlichen Körpers und seiner Teile*, edited by Thomas Potthast, Beate Herrmann and Uta Müller. Paderborn: Mentis, 37-60.

Macilotti, Matteo. 2013. Informed Consent and Research Biobanks: A Challenge in Three Dimensions. In *Comparative Issues in the Governance of Research Biobanks. Property, Privacy, Intellectual Property, and the Role of Technology*, edited by Giovanni Pascuzzi, Umberto Izzo and Matteo Macilotti. Berlin; Heidelberg: Springer, 143-161.

Macklin, Ruth. 2003. Dignity is a Useless Concept. *British Medical Journal* 327: 1419-1420.

Majumder, Mary A. 2005. Cyberbanks and Other Virtual Research Repositories. *Journal of Law, Medicine and Ethics* 33 (1): 31-39.

Malinowski, Michael J. 2005. Technology Transfer in BioBanking: Credits, Debits, and Population Health Futures. *Journal of Law, Medicine, and Ethics* 33 (1): 54-69.

Mandl, Kenneth D. and Kohane, Isaac S. 2008. Tectonic Shifts in the Health Information Economy. *New England Journal of Medicine* 358 (16): 1732-1737.

Manson, Neil C. and O'Neill, Onora. 2007. *Rethinking Informed Consent in Bioethics*. Cambridge; New York: Cambridge University Press.

Marshall, Patricia A., Thomasma, David C., and Daar, Abdallah S. 1996. Marketing Human Organs: The Autonomy Paradox. *Theoretical Medicine* 17: 1-18.

Mascalzoni, Deborah, Hicks, Andrew, Pramstaller, Peter, and Wjst, Matthias. 2008. Informed Consent in the Genomics Era. *PLOS Medicine* 5 (9): e192/1302-1305.

Maschke, Karen J. 2006. Alternative Consent Approaches for Biobank Research. *The Lancet Oncology* 7: 193-194.

Mason, J. Kenyon and Laurie, Graeme. 2001. Consent or Property? Dealing with the Body and its Parts in the Shadow of Bristol and Alder Hey. *Modern Law Review* 64: 710-729.

McConnell, Terrance. 2000. *Inalienable Rights. The Limits of Consent in Medicine and the Law*. Oxford; New York: Oxford University Press.

McGuire, Amy L. and Gibbs, Richard A. 2006. No Longer De-Identified. *Science* 312: 370-371.

McHale, Jean V. 2011. Accountability, Governance and Biobanks: The Ethics and Governance Committee as Guardian or as Toothless Tiger? *Health Care Analysis* 19: 231-246.

McLean, Sheila A. M. 2010. *Autonomy, Consent and the Law*. London; New York: Routledge-Cavendish.

Mello, Michelle M. and Wolf, Leslie E. 2010. The Havasupai Indian Tribe Case — Lessons for Research Involving Stored Biologic Samples. *New England Journal of Medicine* 363 (3): 204-207.

Meslin, Eric M. and Cho, Mildred K. 2010. Research Ethics in the Era of Personalized Medicine: Updating Science's Contract with Society. *Public Health Genomics* 13: 378-384.

Meslin, Eric M. and Garba, Ibrahim. 2011. Biobanking and Public Health: Is a Human Rights Approach the Tie that Binds? *Human Genetics* 130: 451-463.

Mieth, Dietmar. 2007. Das Verbot der Kommerzialisierung des menschlichen Körpers: Mehr als Tabu? – Ethische Aspekte. In *Kommerzialisierung des menschlichen Körpers*, edited by Jochen Taupitz. Berlin; Heidelberg: Springer, 141-151.

Mill, John Stuart. 2009 [1859]. *On Liberty*, and Other Essays. New York: Kaplan Publishing.

Mullen, Caroline. 2009. The Model of Trust. In *Altruism Reconsidered: Exploring New Approaches to Property in Human Tissue*, edited by Michael Steinmann, Peter Sýkora and Urban Wiesing. Farnham: Ashgate, 149-159.

Munzer, Stephen. 1994. An Uneasy Case Against Property Rights in Body Parts. *Social Philosophy and Policy* 11: 259-286.

Nelkin, Dorothy and Andrews, Lori. 1998. Homo Economicus. Commercialization of Body Tissue in the Age of Biotechnology. *The Hastings Center Report* 28 (5): 30-39.

Nissenbaum, Helen. 2010. *Privacy in Context. Technology, Policy, and the Integrity of Social Life*. Stanford: Stanford University Press.

Noiville, Christine. 2009. Preventing Conflicts of Interests in the Field of Human Biological Materials: the 'Contractual Model' as an Avantgarde. In *Altruism Reconsidered: Exploring New Approaches to Property in Human Tissue*, edited by Michael Steinmann, Peter Sýkora and Urban Wiesing. Farnham: Ashgate 143-148.

Nowotny, Helga, Pestre, Dominique, Schmidt-Aßmann, Eberhard, Schulze-Fielitz, Helmuth, Trute, Hans-Heinrich. 2005. *The Public Nature of Science under Assault. Politics, Markets, Science and the Law*. Berlin; Heidelberg: Springer.

Nozick, Robert. 1974. *Anarchy, State, and Utopia*. New York: Basic Books.

Nwabueze, Remigius N. 2007. *Biotechnology and the Challenge of Property. Property Rights in Dead Bodies, Body Parts, and Genetic Information*. Aldershot: Ashgate.

O'Brien, Stephen J. 2009. Stewardship of Human Biospecimens, DNA, Genotype, and Clinical Data in the GWAS Era. *Annual Review of Genomics and Human Genetics* 10: 193-209.

O'Neill, Onora. 2003. Some Limits of Informed Consent. *Journal of Medical Ethics* 29: 4-7.

--- 2004a. *Autonomy and Trust in Bioethics*. Cambridge: Cambridge University Press.

--- 2004b. Informed Consent and Public Health. *Philosophical Transactions of the Royal Society: Biological Sciences* 359: 1133-1136.

Ossorio, Pilar N. 2007. The Human Genome as Common Heritage: Common Sense or Legal Nonsense? *Journal of Law, Medicine and Ethics* 35 (3): 425-439.

--- 2012. Taking Aims Seriously: Repository Research and Limits on the Duty to Return Individual Research Findings. *Genetics in Medicine* 14: 461-466.

Otlowski, Margaret. 2007. Donor Perspectives on Issues Associated with Donation of Genetic Samples and Information: An Australian Viewpoint. *Journal of Bioethical Inquiry* 4: 135-150.

--- 2009. Developing an Appropriate Consent Model for Biobanks: In Defence of 'Broad' Consent. In *Principles and Practice in Biobank Governance*, edited by Jane Kaye and Mark Stranger. Farnham: Ashgate, 79-92.

Palmer, Larry I. 2005. Should Liability Play a Role in Social Control of Biobanks? *Journal of Law, Medicine, and Ethics* 33 (1): 70-78.

Pálsson, Gísli. 2007. The Rise and Fall of a Biobank: The Case of Iceland. In *Biobanks: Governance in Comparative Perspective*, edited by Herbert Gottweis and Alan Petersen. Abingdon; New York: Routledge, 41-55.

Parker, Colin. 2010. The Moral Primacy of the Human Being. *Journal of Medical Ethics* 36: 563-566.

Parry, Bronwyn and Gere, Cathy. 2006. Contested Bodies: Property Models and the Commodification of Human Biological Artefacts. *Science as Culture* 15 (2): 139-158.

Petersen, Alan. 2005. Securing our Genetic Health: Engendering Trust in UK Biobank. *Sociology of Health and Illness* 27 (2): 271-292.

--- 2007. 'Biobanks' "Engagements": Engendering Trust or Engineering Consent?' *Genomics, Society and Policy* 3 (1): 31-43.

Piccolo, Kaitlin M. 2008. In the Wake of Catalona: An Alternative Model to Safeguard Research Participants' Interests in Their Biological Materials. *The University of Pittsburgh Law Review* 69: 769- 788.

Porter, Gerard. 2004. The Wolf in Sheep's Clothing: Informed Consent Forms as Commercial Contracts. In *Blood and Data: Ethical, Legal and Social Aspects of Human Genetic Databases*, edited by Gardar Árnason, Salvör Nordal and Vilhjálmur Árnason. Reykjavik: The Centre for Ethics and University of Iceland Press, 85-93.

Price, David. 2010. *Human Tissue in Transplantation and Research. A Model Legal and Ethical Framework*. Cambridge, New York: Cambridge University Press.

Purtova, Nadezhda. 2011. Property in Personal Data: Second Life of an Old Idea in the Age of Cloud Computing, Chain Informatisation, and Ambient Intelligence. In *Computers, Privacy and Data Protection: An Element of Choice*, edited by Serge Gutwirth, Yves Poullet, Paul De Hert and Ronald Leenes. Dordrecht; Heidelberg: Springer, 39-64.

Quigley, Muireann. 2007. Property and the Body: Applying Honoré. *Journal of Medical Ethics* 33: 631-634.

Radin, Margaret J. 1987. Market-Inalienability. *Harvard Law Review* 100 (8): 1849-1937.

--- 1993. *Reinterpreting Property*. Chicago; London: University of Chicago Press.

--- 1996. *Contested Commodities*. Cambridge: Harvard University Press.

Ram, Natalie. 2009. Assigning Rights and Protecting Interests: Constructing Ethical and Effective Legal Rights in Human Tissue Research. *Harvard Journal of Law and Technology* 23: 119-177.

Rao, Radhika. 2000. Property, Privacy, and the Human Body. *Boston University Law Review* 80: 359-460.

--- 2007. Genes and Spleens: Property, Contract, or Privacy Rights in the Human Body? *Journal of Law, Medicine and Ethics* 35 (3): 371-382.

Rawls, John. 1993. *Political Liberalism*. New York: Columbia University Press.

Rehbock, Theda. 2011. Limits of Autonomy in Biomedical Ethics? Conceptual Clarifications. *Cambridge Quarterly of Healthcare Ethics* 20: 524–532.

Rhodes, Rosamund. 2005. Rethinking Research Ethics. *American Journal of Bioethics* 5 (1): 7-28.

Rich, Leigh E., Ashby, Michael A. and Méthot, Pierre-Olivier. 2012. Rethinking the Body and its Boundaries. *Journal of Bioethical Inquiry* 9: 1-6.

Riegman, Peter H.J., Morente, Manuel M., Betsou, Fay, De Blasio, Pasquale, Geary, Peter, and the Marble Arch International Working Group on Biobanking for Biomedical Research. 2008. Biobanking for Better Healthcare. *Molecular Oncology* 2: 213-222.

Roche, Patricia. 2010. The Property/Privacy Conundrum over Human Tissue. *HEC Forum* 22: 197–209.

Rodriguez, Laura L., Brooks, Lisa D., Greenberg, Judith H. and Green, Eric D. 2013. The Complexities of Genomic Identifiability. *Science* 339: 275-276.

Rommetveit, Kjetil. 2011. Tackling Epistemological Naivety: Large-Scale Information Systems and the Complexities of the Common Good. *Cambridge Quarterly of Healthcare Ethics* 20: 584–595.

Rössler, Beate. 2001. *Der Wert des Privaten*. Frankfurt am Main: Suhrkamp.

Rose, Hilary. 2001. The Commodification of Bioinformation: The Icelandic Health Database. London, Wellcome Trust. http://www.wellcome.ac.uk/stellent/groups/corporatesite/@msh_grants/documents/web_document/wtd003281.pdf (accessed 15 May 2013).

--- 2006. From Hype to Mothballs in Four Years: Troubles in the Development of Large-Scale DNA Biobanks in Europe. *Community Genetics* 9: 184-189.

Rose, Nikolas and Novas, Carlos. 2005. Biological Citizenship. In *Global Assemblages. Technology, Politics, and Ethics as Anthropological Problems*, edited by Aihwa Ong and Stephen J. Collier. Malden, MA: Blackwell Publishing, 439-463.

Rose, Nikolas. 1996. Governing "Advanced" Liberal Democracies. In *Foucault and Political Reason. Liberalism, Neo-Liberalism and Rationalities of Government*, edited by Andrew Barry, Thomas Osborne and Nikolas Rose. Chicago: The University of Chicago Press, 37-64.

Rosenfeld, Jeffrey and Mason, Christopher E. 2013. Pervasive Sequence Patents Cover the Entire Human Genome. *Genome Medicine* 5: 27.

Roth, Carsten. 2009. *Eigentum an Körperteilen. Rechtsfragen der Kommerzialisierung des menschlichen Körpers*. Berlin; Heidelberg: Springer.

Rothstein, Mark A. 2005. Expanding the Ethical Analysis of Biobanks. *Journal of Law, Medicine, and Ethics* 33 (1): 89-101.

Rynning, Elisabeth. 2009. Legal Challenges and Strategies in the Regulation of Research Biobanking. In *The Ethics of Research Biobanking*, edited by Jan Helge Solbakk, Søren Holm and Bjørn Hofmann. Dordrecht: Springer, 277-313.

Saha, Krishanu and Hurlbut, J. Benjamin. 2011. Treat Donors as Partners in Biobank Research. *Nature* 478: 312-313.

Sampat, Bhaven N. 2006. Universities and Intellectual Property: Shaping a New Patent Policy for Government Funded Academic Research. In *Shaping Science and Technology Policy: The Next Generation of Research*, edited by David H. Guston and Daniel Sarewitz. Madison: The University of Wisconsin Press, 55-76.

Sandel, Michael J. 2012. *What Money Can't Buy. The Moral Limits of Markets*. New York: Farrar, Straus and Giroux.

Sándor, Judit, Bárd, Petra, Tamburrini, Claudio, and Tännsjö, Torbjörn. 2012. The Case of Biobank with the Law. Between a Legal and Scientific Fiction. *Journal of Medical Ethics* 38: 347-350.

Santosuosso, Amedeo. 2002. The Right to Genetic Disobedience: The Icelandic Case. In *Ethics and Law in Biological Research*, edited by Cosimo Marco Mazzoni. The Hague: Kluwer Law International,163-172.

--- 2013. Should Privacy Be Abolished in Genetics and Biobanking? In *Comparative Issues in the Governance of Research Biobanks. Property, Privacy, Intellectual Property, and the Role of Technology*, edited by Giovanni Pascuzzi, Umberto Izzo and Matteo Macilotti. Berlin; Heidelberg: Springer, 105-130.

Savard, Jacqueline. 2013. Personalized Medicine: A Critique on the Future of Health Care. *Journal of Bioethical Inquiry* 10: 197-203.

Schadt, Eric E. 2012. The Changing Privacy Landscape in the Era of Big Data. *Molecular Systems Biology* 8: 612, doi:10.1038/msb.2012.47.

Schmidt, Charlie. 2006. Tissue Banks Trigger Worry About Ownership Issues. *Journal of the National Cancer Institute* 98 (17): 1174-1175.

Schmidt, Harald and Callier, Shawneequa. 2012. How Anonymous is 'Anonymous'? Some Suggestions Towards a Coherent Universal Coding System for Genetic Samples. *Journal of Medical Ethics* 38 (5): 304-309.

Schmietow, Bettina. 2012. Conceptualizing the Commons: Genetic Resource Management, Property Claims, and Global Innovation Ethics. *St Antony's International Review* 8 (1): 70-87.

Schneider, Ingrid. 2003. Biobanken im Spannungsfeld zwischen Gemeinwohl und partikularen Interessen. http://fes-stabsabteilung.de/docs/biobankenschneider.pdf (accessed 15 October 2012).

--- 2008. 'This Is Not a National Biobank…': The Politics of Local Biobanks in Germany. In *Biobanks: Governance in Comparative Perspective*, edited by Herbert Gottweis and Alan Petersen. Abingdon; New York: Routledge, 88-108.

--- 2010. Transnationale Normbildung und Governance von zirkulierenden Körpersubstanzen: Eine Taxonomie und Leitlinien. In *Wem gehört der menschliche*

Körper? Ethische, rechtliche und soziale Aspekte der Kommerzialisierung des menschlichen Körpers und seiner Teile, edited by Thomas Potthast, Beate Herrmann and Uta Müller. Paderborn: Mentis, 155-180.

Schnorrenberg, Hans Ekkehard. 2010. Zur Kommerzialisierung menschlicher Körpersubstanzen: Verstößt die Vereinbarung der Zahlung eines Entgelt an den Substanzspender gegen die Menschenwürde? In *Wem gehört der menschliche Körper? Ethische, rechtliche und soziale Aspekte der Kommerzialisierung des menschlichen Körpers und seiner Teile*, edited by Thomas Potthast, Beate Herrmann and Uta Müller. Paderborn: Mentis, 223-242.

Schweda, Mark and Schicktanz, Silke. 2009. The „Spare Parts Person"? Conceptions of the Human Body and Their Implications for Public Attitudes towards Organ Donation and Organ Sale. *Philosophy, Ethics and Humanities in Medicine* 4: 4, doi:10.1186/1747-5341-4-4.

Scott, Christopher Thomas, Caulfield, Timothy, Borgelt, Emily and Illes, Judy. 2012. Personal Medicine – The New Banking Crisis. *Nature Biotechnology* 30 (2): 141-147.

Sensen, Christoph W. 2005. The Future of Large-Scale Life Science Research. In *Handbook of Genome Research*, edited by Christoph W. Sensen. Weinheim: Wiley-Vch, 573-584.

Sethe, Sebastian. 2004. Cell Line Research with UK Biobank. Why the New British Biobank is Not Just Another Population Genetic Database. In *Blood and Data: Ethical, Legal and Social Aspects of Human Genetic Databases*, edited by Gardar Árnason, Salvör Nordal and Vilhjálmur Árnason. Reykjavik: The Centre for Ethics and University of Iceland Press, 313-319.

Sheehan, Mark. 2011. Can Broad Consent be Informed Consent? *Public Health Ethics* 4 (3): 226-235.

Shickle, Darren. 2006. The Consent Problem Within DNA Biobanks. *Studies in History and Philosophy of Biological and Biomedical Sciences* 37: 503-519.

Simm, Kadri. 2005. Benefit-Sharing: An Inquiry Regarding the Meaning and Limits of the Concept in Human Genetic Research. *Genomics, Society and Policy* 1 (2): 29-40.

--- 2011 . The Concepts of Common Good and Public Interest: From Plato to Biobanking. *The Cambridge Quarterly of Healthcare Ethics* 20: 554–562.

Simon, Jürgen and Robienski, Jürgen. 2010. Eigentum an humanem Material in Biobanken und dessen Nutzung. In *Wem gehört der menschliche Körper? Ethische, rechtliche und soziale Aspekte der Kommerzialisierung des menschlichen Körpers und seiner Teile*, edited by Thomas Potthast, Beate Herrmann and Uta Müller. Paderborn: Mentis, 299-323.

Singer, Joseph William. 2000. *Entitlement. The Paradoxes of Property*. New Haven; London: Yale University Press.

Skloot, Rebecca. 2010. *The Immortal Life of Henrietta Lacks*. New York: Crown Publishers.

Sommerville, Ann and English, Veronica. 1999. Genetic Privacy: Orthodoxy or Oxymoron? *Journal of Medical Ethics* 25: 144-150.

Spinello, Richard A. 2004. Property Rights in Genetic Information. *Ethics and Information Technology* 6: 29-42.

Stefanini, Elisa. 2010. The Need for Italian Biobank Regulation. *SCRIPTed* 7 (1): 71-82.

Steinmann, Michael. 2009a. Introduction. In *Altruism Reconsidered: Exploring New Approaches to Property in Human Tissue*, edited by Michael Steinmann, Peter Sýkora and Urban Wiesing. Farnham: Ashgate, 1-10.

--- 2009b. Under the Pretence of Autonomy: Contradictions in the Guidelines for Human Tissue Donation. *Medicine, Healthcare and Philosophy* 12: 281-289.

Steinsbekk, Kristin S. and Solberg, Berge. 2011. Biobanks – When is Re-Consent Necessary? *Public Health Ethics* 4(3): 236-250.

Steinsbekk, Kristin S., Solberg, Berge and Myskja, Bjørn K. 2009. From Idealism to Realism: Commercial Ventures in Publicly Funded Biobanks. In *New Challenges for Biobanks: Ethics, Law and Governance*, edited by Kris Dierickx and Pascal Borry. Antwerp; Oxford: Intersentia, 137-151.

Steinsbekk, Kristin S., Myskja, Bjørn K. and Solberg, Berge. 2013a. Broad Consent versus Dynamic Consent in Biobank Research: Is Passive Participation an Ethical Problem? *European Journal of Human Genetics*. doi: 10.1038/ejhg.2012.282.

Steinsbekk, Kristin S., Ursin, Lars Øystein, Skolbekken, John-Arne, and Solberg, Berge. 2013b. We're Not in it for the Money—Lay People's Moral Intuitions on Commercial Use of 'Their' Biobanks. *Medicine, Healthcare and Philosophy* 16: 151-162.

Sterckx, Sigrid and Van Assche, Kristof. 2011. The New Belgian Law on Biobanks: Some Comments from an Ethical Perspective. *Health Care Analysis* 19: 247-258.

Stewart, Cameron. 2007. The Human Body – The Land that Time Forgot. *Journal of Bioethical Inquiry* 4: 117-118.

Stiglitz, Joseph E. 1999. Knowledge as a Global Public Good. In *Global Public Goods: International Cooperation in the 21st Century*, edited by Inge Kaul, Isabelle Grunberg, and Marc A. Stern. Oxford; New York: Oxford University Press, 308-325.

Stirrat, Gordon and Gill, Robin. 2005. Autonomy in Medical Ethics After O'Neill. *Journal of Medical Ethics* 31: 127-130.

Stjernschantz Forsberg, Joanna, Hansson, Mats G. and Eriksson, Stefan. 2009. Changing Perspectives in Biobank Research: From Individual Rights to Concerns about Public Health Regarding the Return of Results. *European Journal of Human Genetics* 17: 1544-1549.

--- 2011. The Risks and Benefits of Re-Consent. *Science* 332: 306.

Stjernschantz Forsberg, Joanna, Hansson, Mats G. and Evers, Kathinka. 2013. International Guidelines on Biobank Research Leave Researchers in Ambiguity: Why Is This So? *European Journal of Epidemiology* 28: 449-451.

Sulston, John and Ferry, Georgina. 2002. *The Common Thread. A Story of Science, Politics, Ethics, and the Human Genome*. Washington: Joseph Henry Press.

Sunder Rajan, Kaushik. 2006. *Biocapital. The Constitution of Postgenomic Life*. Durham, NC and London: Duke University Press.

Suter, Sonia M. 2004. Disentangling Privacy from Property: Toward a Deeper Understanding of Genetic Privacy. *The George Washington Law Review* 72 (4): 737-814.

Sutrop, Margit. 2011. Changing Ethical Frameworks: From Individual Rights to the Common Good? *Cambridge Quarterly of Healthcare Ethics* 20: 533–545.

Sýkora, Peter. 2009. Altruism in Medical Donations Reconsidered: The Reciprocity Approach. In *Altruism Reconsidered: Exploring New Approaches to Property in Human Tissue*, edited by Michael Steinmann, Peter Sýkora and Urban Wiesing. Farnham: Ashgate, 13-49.

Tallacchini, Mariachiara. 2005. Rhetoric of Anonymity and Property Rights in Human Biological Materials. *Law and the Human Genome Review* 22: 153-175.

--- 2013. Human Tissues in the "Public Space": Beyond the Property/Privacy Dichotomy. In *Comparative Issues in the Governance of Research Biobanks. Property, Privacy, Intellectual Property, and the Role of Technology*, edited by Giovanni Pascuzzi, Umberto Izzo and Matteo Macilotti. Berlin; Heidelberg: Springer, 87-103.

Taupitz, Jochen and Weigel, Jukka. 2012. The Necessity of Broad Consent and Complementary Regulations for the Protection of Personal Data in Biobanks: What Can We Learn from the German Case? *Public Health Genomics* 15: 263–271.

Tavani, Herman T. 2004. Genomic Research and Data-Mining Technology: Implications for Personal Privacy and Informed Consent. *Ethics and Information Technology* 6: 15-28.

Taylor, James S. 2005. *Stakes and Kidneys: Why Markets in Human Body Parts are Morally Imperative*. Aldershot; Burlington, VT: Ashgate.

--- 2010. Introduction: The HEC Forum Special Issue on Privacy and Commodification. *HEC Forum* 22: 173-177.

Thorisson, Gudmundur A., Muilu, Juha, and Brookes, Anthony J. 2009. Genotype–Phenotype Databases: Challenges and Solutions for the Post-Genomic Era. *Nature Reviews Genetics* 10: 9-18.

Thorsteinsdóttir, Halla, Daar, Abdallah S., Smith, Richard D. and Singer, Peter A. 2003. Genomics – A Global Public Good? *The Lancet* 361: 891-892.

TIME Magazine. 2009. Ten Ideas Changing the World Right Now: Biobanks. http://content.time.com/time/specials/packages/article/0,28804,1884779_1884782_1884766,00.html (accessed 10 April 2012).

Titmuss, Richard M. 1997 [1970]. *The Gift Relationship: From Human Blood to Social Policy*. New York: The New Press.

Trinidad, Susan B., Fullerton, Stephanie M., Ludman, Evette J., Jarvik, Gail P., Larson, Eric B. and Burke, Wylie. 2011. Response—The Risks and Benefits of Re-Consent. *Science* 332: 306.

Tully, James. 1980. *A Discourse on Property. John Locke and his Adversaries*. Cambridge: Cambridge University Press.

Tutton, Richard. 2004. Person, Property and Gift: Exploring Languages of Tissue Donation to Biomedical Research. In *Genetic Databases. Socio-Ethical Issues in the Collection and Use of DNA*, edited by Richard Tutton and Oonagh Corrigan. London; New York: Routledge, 19-38.

--- 2009. Notes on Policy, Language and Human Tissue. In *Altruism Reconsidered: Exploring New Approaches to Property in Human Tissue*, edited by Michael Steinmann, Peter Sýkora and Urban Wiesing. Farnham: Ashgate, 51-61.

Ursin, Lars Øystein. 2010a. Das persönliche Genom. Abschied von Privatheit und Zustimmung in der Biobankforschung. *Berliner Debatte Initial* 21 (4): 64-76.

--- 2010b. Privacy and Property in the Biobank Context. *HEC Forum* 22: 211–224.

VanderWalde, Ari and Kurzban, Seth. 2011. Paying Human Subjects in Research: Where are We, How Did We Get Here, and Now What? *Journal of Law, Medicine and Ethics* 39 (3): 543-558.

Vayena, Effy and Tasioulas, John. 2013. The Ethics of Participant-Led Biomedical Research. *Nature Biotechnology* 31 (9): 786-787.

Wachbroit, Robert and Wasserman, David. 2005. Research Participation: Are We Subject to a Duty? *American Journal of Bioethics* 5 (1): 48-49.

Wagstaff, Anna. 2011. International Biobanking Regulations: The Promise and the Pitfalls. *Cancer World* http://www.cancerworld.org/Articles/Issues/42/May-June-2011/Cutting-Edge/469/International-biobanking-regulations-the-promise-and-the-pitfalls.html (accessed 15 May 2013).

Waldby, Catherine and Mitchell, Robert. 2006. *Tissue Economies. Blood, Organs, and Cell Lines in Late Capitalism*. Durham, NC; London: Duke University Press.

Waldby, Catherine. 2000. *The Visible Human Project. Informatic Bodies and Posthuman Medicine*. London; New York: Routledge.

Waldron, Jeremy. 1988. *The Right to Private Property*. Oxford: Clarendon Press.

Weir, Robert F. and Olick, Robert S. 2004. *The Stored Tissue Issue. Biomedical Research, Ethics, and Law in the Era of Genomic Medicine*. Oxford; New York: Oxford University Press.

Weldon, Sue. 2004a. 'Public Consent' or 'Scientific Citizenship'? What Counts as Public Participation in Population-Based DNA Collections? In *Genetic Databases. Socio-Ethical Issues in the Collection and Use of DNA*, edited by Richard Tutton and Oonagh Corrigan. London; New York: Routledge, 161-180.

--- 2004b. Public Engagement in Genetics: A Review of Current Practice in the UK. http://www.nowgen.org.uk/CubeCore/.uploads/documents/Review_of_Public_Engagement_Sue_Weldon.pdf (accessed 11 March 2013).

Wendel, Lotta. 2007. Third Parties' Interest in Population Genetic Databases: Some Comparative Notes Regarding the Law in Estonia, Iceland, Sweden and the UK. In *The Ethics and Governance of Human Genetic Databases. European Perspectives*, edited by Matti Häyry, Ruth Chadwick, Vilhjálmur Árnason, and Gardar Árnason. Cambridge; New York: Cambridge University Press, 108-119.

Widdows, Heather and Cordell, Sean. 2011a. The Ethics of Biobanking: Key Issues and Controversies. *Health Care Analysis* 19: 207-219.

--- 2011b. Why Communities and Their Goods Matter: Illustrated with the Example of Biobanks. *Public Health Ethics* 4 (1): 14-25.

Widdows, Heather. 2007. Reconceptualizing Genetics: Challenges to Traditional Medical Ethics. In *Ethics and Law of Intellectual Property: Current Problems in Politics, Science and Technology*, edited by Christian Lenk, Nils Hoppe, and Roberto Andorno. Aldershot: Ashgate, 159-173.

--- 2009. Constructing Communal Models of Governance: Collectives of Individuals or Distinct Ethical Loci? In *The Governance of Genetic Information. Who Decides?*, edited by Heather Widdows and Caroline Mullen. Cambridge; New York: Cambridge University Press, 75-98.

Wilkinson, Stephen. 2000. Commodification Arguments for the Legal Prohibition of Organ Sale. *Health Care Analysis* 8: 189-201.

Williams, Garrath and Schroeder, Doris. 2004. Human Genetic Banking: Altruism, Benefit and Consent. *New Genetics and Society* 23 (1): 89-103.

Williams, Garrath. 2005. Bioethics and Large-scale Biobanking: Individualistic Ethics and Collective Projects. *Genomics, Society and Policy* 1 (2): 50-66.

Williams-Jones, Bryn and Ozdemir, Vural. 2007. Enclosing the "Knowledge Commons": Patenting Genes for Disease Risk and Drug Response at the University-Industry Interface. In *Ethics and Law of Intellectual Property: Current Problems in Politics, Science and Technology*, edited by Christian Lenk, Nils Hoppe, and Roberto Andorno. Aldershot: Ashgate, 137-158.

Wilson, James. 2007. Is Respect for Autonomy Defensible? *Journal of Medical Ethics* 33: 353-356.

Winickoff, David E. 2003. Governing Population Genomics: Law, Bioethics, and Biopolitics in Three Case Studies. *Jurimetrics: The Journal of Law, Science, and Technology* 43: 187-228.

--- 2007. Partnership in U.K. Biobank: A Third Way for Genomic Property? *Journal of Law, Medicine, and Ethics* 35 (3): 440-456.

--- 2008. From Benefit Sharing to Power Sharing: Partnership Governance in Population Genomics Research. JSP/Center for the Study of Law and Society Faculty Working Papers, Jurisprudence and Social Policy Program, UC Berkeley. http://escholarship.org/uc/item/845393hh (accessed 10 June 2013).

Winickoff, David E. and Neumann, Larissa B. 2005. Towards a Social Contract for Genomics: Property and the Public in the 'Biotrust' Model. *Genomics, Society and Policy* 1 (3): 8-21.

Winickoff, David E. and Winickoff, Richard N. 2003. The Charitable Trust as a Model for Genomic Biobanks. *New England Journal of Medicine* 349 (12): 1180-1184.

Wolf, Susan M. et al. 2012. Managing Incidental Findings and Research Results in Genomic Research Involving Biobanks and Archived Data Sets. *Genetics in Medicine* 14: 361-384.

Womack, Chris and Gray, Neil M. 2009. Banking Human Tissue for Research: Vision to Reality. *Cell and Tissue Banking* 10 (3): 267–270.

Yassin, Rihab, Lockhart, Nicole, González de Riego, Mariana, Pitt, Karen, Thomas, Jeffrey W., Weiss, Linda, Compton, Caroline. 2010. Custodianship as an Ethical Framework for Biospecimen-Based Research. *Cancer Epidemiology, Biomarkers and Prevention* 19 (4): 1012-1015.

Yuille, Martin, Van Ommen, Gert-Jan, Bréchot, Christian, Cambon-Thomsen, Anne, Dagher, George, Landegren, Ulf, Litton, Jan-Eric, Pasterk, Markus, Peltonen, Leena, Taussig, Mike, Wichmann, H.-Erich and Zatloukal, Kurt. 2007. Biobanking for Europe. *Briefings in Bioinformatics* 9 (1): 14-24.

Zawati, Ma'n H. and Knoppers, Bartha M. 2012. International Normative Perspectives on the Return of Individual Research Results and Incidental Findings in Genomic Biobanks. *Genetics in Medicine* 14: 484-489.