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The Informed Consenters

Biobank Research and the Ethics of Recruitment
and Participation

Thesis for the degree of Philosophiae Doctor

Trondheim, November 2008

Norwegian University of Science and Technology
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NTNU

Norwegian University of Science and Technology

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ISBN 978-82-471-1281-6 (printed ver.)

ISBN 978-82-471-1282-3 (electronic ver.)

ISSN 1503-8181

Doctoral theses at NTNU, 2008:290

Printed by NTNU-trykk

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Acknowledgements

Many people have been involved in the making of this thesis. Bjørn Myskja started it all by encouraging me to work in the field of biobank ethics. John-Arne Skolbekken had the idea for the focus group study with HUNT participants which eventually grew into the *Consented* project. Our research group consisted of John-Arne Skolbekken, Borgunn Ytterhus, Erik Christensen, Berge Solberg and myself. The *Consented* project was funded by the National Programme in Functional Genomics in Norway (FUGE) through the Research Council of Norway and the Norwegian University of Science and Technology, which also funded my doctoral fellowship.

I would like to thank my main supervisor Berge Solberg for his constructive advice, and his patience in reminding me that without any practical implications, distinctions and arguments lose their meaning. John-Arne Skolbekken has been a most helpful co-supervisor and co-writer. I have learned a lot from working with Berge and John-Arne. Both of them have read and commented on the entire thesis manuscript.

I also learned a great deal by writing *The Informed Consenters* article with Klaus Høyer, and from our discussions at various times and places.

I would like to thank everyone who read and improved my manuscripts: Nancy Bazilchuk, Lene Bomann-Larsen, Jakob Elster, Bjørn Hofmann, Sophie Kasimow, Alasdair Maclean, Domhnall Mitchell, Marit Hovdal Moan, Bjørn Myskja, James Stacey Taylor, Jukka Varelius and Borgunn Ytterhus.

I would like to thank my colleagues at NTNU, and in particular Erik Christensen, Asle Kiran, Marit Hovdal Moan, Marit Solbjør and Monica Wegling, for keeping my spirits up while working on this thesis.

Last, but not least, I would like to thank my family for their kind encouragement.

Notes on the articles

The article **Not worth the paper it's written on? Informed consent and biobank research in a Norwegian context** was published in the journal *Critical Public Health*, vol. 15, no. 4 in December 2005. The article is written by John-Arne Skolbekken, Lars Øystein Ursin, Berge Solberg, Erik Christensen and Borgunn Ytterhus. JAS wrote the introduction of the article, and the following sections: “The HUNT biobank”, “Methods and material”, and “Findings from the focus groups”. LØU wrote the remaining sections, with input from BS. JAS, BS and LØU designed the focus group study. JAS moderated the groups with BY as co-moderator. BS, LØU and EC participated in the groups. All members of the group participated in the data analysis and in revisions of the manuscript.

The article **The Informed Consenters: Governing Biobanks in Scandinavia** was published in the book *Biobanks: Governance in a Comparative Perspective*, edited by Herbert Gottweis and Alan Petersen, on Routledge, in April 2008. The article is written by Lars Øystein Ursin, Klaus Høyer, and John-Arne Skolbekken. KH wrote the passages on biobank research and regulation in Sweden and Denmark, the empirical studies from Umeå, and the sections “Epidemiology in the Scandinavian welfare states” and “Regulating research”. LØU wrote the remaining sections, with input from KH. JAS contributed to the revisions of the manuscript.

The article **Personal Autonomy and Informed Consent** was in April 2008 accepted for publication in the journal *Medicine, Health Care and Philosophy*. The article is written by LØU. Berge Solberg, Bjørn Myskja, Alasdair Maclean, James Stacey Taylor, Jukka Varelius, Marit Hovdal Moan, Domhnall Mitchell and two anonymous reviewers from MHEP gave comments on earlier drafts of this article.

The article **Biobank Research and the Right to Privacy** was submitted to the journal *Theoretical Medicine and Bioethics* in February 2008. The article is written by LØU. Berge Solberg, Bjørn Myskja, Domhnall Mitchell and Sophie Kasimow contributed to revisions of the manuscript.

The article **When is normative recruitment to medical research legitimate?** was submitted to the *Journal of Applied Ethics* in April 2008. The article is written by Lars Øystein Ursin and Berge Solberg. BS wrote the sections “When normative recruitment is not justified“ and “Citizenship and the ethics of belonging”. LØU wrote the remaining sections. John-Arne Skolbekken and Nancy Bazilchuk contributed to revisions of the manuscript.

Introduction

Although tissue samples have been routinely collected for decades for clinical purposes, a broad discussion of ethical and legal aspects of biobanking only began in the 1990s. With the introduction of genetics, the potential of gaining knowledge from research on tissue samples increased, and was seen to substantially alter the nature of biobanking.¹ In the years from 2000 to 2003, the Nordic countries of Iceland, Finland, Sweden and Norway all implemented national acts on biobanks. These laws were aimed to fill a legislative gap created by the promises and perils of scientific development, which transformed “collections of tissue samples” into “genetic databases”.

Biobanks are set up for different purposes, and biobanks of different kinds contain different types of biological material. However, the focal point of both ethical and legal attention has been medical research biobanks, which are set up and designed to study the health effects of genetic predispositions, environmental exposure, and the interplay between genetic and environmental factors. Biobank material is thus comprised of genetic data and health data as well as health-related data in a broad sense provided by the participant in a questionnaire. Additional material can be obtained by linking biobank information to information contained in other registries, such as birth registries, cancer registries, family registries, and other medical and non-medical registries.

As biobanks contain information concerning both hereditary and environmental factors for a large number of individuals, they give researchers the ability to find factors that put people at risk for – or may allow them to avoid – diseases with complex causes of development. Biobank research is thus characterised by requiring a large number of participants, who take part mainly by providing information and information carriers– and by agreeing to the creation of, and further linkage to, information by the research institution. Because of the unknown nature of future

¹ See Hansson M. and Levin M. (eds.), 2003: *Biobanks as resources for health*, Research Program Ethics in Biomedicine.

biobank research projects, the participants cannot know what kinds of research projects they might be (asked to be) part of.

These characteristics of biobank research participation gave rise to new laws on biobanking, designed to address the legislative challenges that biobank research poses. The main challenge is whether the gold standard of regulating medical research participation by requiring researchers to obtain *specific* and *explicit* informed consent from participants also should apply to biobank research. The large numbers of participants and the unknown nature of future research projects make the use of specific and explicit consent cumbersome and costly. The expenses of administering this type of consent requirement was argued as having put an effective ban on biobank research, or at least to make it much less efficient. And, given the nature of biobank participation, a pertinent question became: Provided that participants have already decided to volunteer for biobank research, is it in anybody's interest to go through repeated rounds of providing consent for new projects? The exact justifications for informed consent requirements thus became an ethical question. This thesis attempts to address some of the ethical challenges concerning consent requirements for biobank research in general, as well as for medical research in general.²

The starting point of this thesis is the research project called *Consented to contribute to the common good?*³, which in 2004 and 2005 conducted focus group interviews with participants and research groups involved in the HUNT⁴ study. The starting point for the *Consented* project is described in the first article of this thesis. In the process leading up the Norwegian Biobanks Act, the safeguarding of ethically legitimate biobank research was mainly thought of in terms of finding the most appropriate requirements for informed consent. Little was known, however, about the opinions of participants and researchers regarding ethical questions about biobank research.

One aim of the *Consented* project was therefore to increase our knowledge by conducting a series of focus group interviews with the groups in question. Findings from these focus groups are presented in the three of the articles of this thesis. The findings in these articles provide an entry for a discussion of how research design and legislative requirements frame and

² Thus, several ethical questions concerning biobanking – such as issues of benefit-sharing, discrimination, risk focus and forensic use – are not directly addressed.

³ Hereafter referred to as the *Consented* project.

⁴ HUNT is an acronym for *Helseundersøkelsen i Nord-Trøndelag*, which translates as *The Nord-Trøndelag Health Study*.

fit the ethical questions pertaining to biobank research and biobank participation. HUNT constitutes the main case study in these discussions.

Part 1 of this thesis presents some of the key arguments from the articles found in part 2. As reflected in the metaethical and methodological discussion in the first chapter of this introduction, the ambition of this thesis is not to provide definite principles, requirements or justifications for sound biobank research. Its ambition is rather to contribute to an ongoing discussion of how to accurately describe, view and balance the conflicting, or just apparently conflicting, values and interests involved in biobank research.

Part 1 will also explore and expand on some of the relevant themes and perspectives that had to be left out or just briefly discussed in the articles. Arguments from all and a short synopsis of some of the articles are connected in the presentation of Chapters 2 to 4 in part 1 to form the parts of a general argument or a story. This story begins in Chapter 2 with a description of the standards for informed consent in medical research, and the way in which consent requirements are justified in bioethical literature, national laws and international conventions in terms of an idea of securing individual autonomy. It then moves on to a discussion of the complexity of promoting individual autonomy as a cultural ideal in the context of medical research. In Chapter 3, consent as a waiver for privacy rights is analysed in terms of notions such as relational privacy, principled autonomy and voluntariness. A recurrent theme is to show how different notions of ideals, rights and duties attributed to participants transform their relationship to biobank research. In Chapter 4, appeals to the common good and the legitimacy of normative recruitment are discussed in order to show how the ethics of this relationship also depends on study design.

Part 1 also leaves out important issues discussed in the articles. In *Not worth the paper it's written on? Informed consent and biobank research in a Norwegian context (NW)*, it is argued that trust should be made relevant to consent, by making consent a process rather than a contract. In *The Informed Consenters: Governing Biobanks in Scandinavia (IC)*, the importance of political, and not just ethical, issues for biobank participants are emphasised in relation to the findings of the *Consented* focus groups. In *Personal Autonomy and Informed Consent (PA)*, the justification for general versus specific consent is discussed. In *Biobank Research and the Right to Privacy (RP)*, aspects of privacy are seen in relation to making the Norwegian Patient Register identifiable by person. And in *When is normative recruitment to medical research legitimate? (NR)*, participation in medical research is discussed as a perfect versus an imperfect duty.

The question of participation in and recruitment to biobank research leads to rather fundamental issues of societal values, duties and rights. The aim of this thesis is thus firstly to assess how legitimate biobank research is safeguarded, and to discuss actual and potential

justifications of the safeguards installed. Secondly, it aims to identify the values we seek to promote and protect both in pursuing biobank research and in the legal regulation of this research and its recruitment of participants. And thirdly, it aims to analyse and clarify the concepts used in biobank ethics, and to propose and discuss the actual and potential framing of ethical aspects of biobank research.

Part 1

The justification of moral judgements

An important part of the *Consented* project design was to bring theoretical ethical reflection and an empirical study on biobank ethics together for their mutual benefit. The project group therefore consisted of both philosophers and social scientists. The aim of doing an interdisciplinary study of this kind was to enable reflection on the discourse concerning the ethics of biobank research with input from the researchers who conducted the actual scientific study and the persons who participated in it. The input from the participants was considered particularly important in the field of biobanking, since the focus on informed consent emphasizes the opinions of the participants.

The focus on informed consent was already questioned by HUNT researchers, as a consequence of the complications of the consent process in HUNT2 described in *NW*. This raised questions concerning the empirical and the ethical justifications of the different kinds of consent one could require (general versus specific, passive versus active, implicit versus explicit). On the one hand, strict consent requirements were viewed as an illegitimate individualization of the general ethical and political dilemmas involved in genetic biobank research. On the other hand, liberal consent requirements were viewed as a return to a paternalistic past which did not fit the potential perils of participation in biobank research in the era of genetics.

The opinions of the participants were regarded to be of great importance to an assessment of the very legitimacy of the different kinds of requirements to informed consent. In the *Consented* study design, the findings from the focus groups on ethical aspects of biobanking was thought to enrich the opinions and intuitions used – and perhaps taken for granted – in the governmental and academic debate. Maybe the concerns that academics and governmental bodies voiced on behalf of the participants were others than those to be found among participants themselves?

Empirical versus empty ethics

The focus group participants in the *Consentenced* project comprised of people who had given their consent to participate in the HUNT biobank, former participants who had withdrawn their consent to take part in the biobank, and researchers who were involved in or had an interest in HUNT. The five discussion themes of the focus groups were:

1. The use (and abuse) of the biobank material
2. Their own decision for giving consent/not giving consent, and the appropriateness of different kinds of consent
3. Duty vs. autonomy in biobank research participation
4. Ethical and practical consequences of doing genetic research vs. other kinds of medical research in HUNT
5. Commercialization of the biobank research

The focus group participants discussed (rather freely) questions concerning the use of general consent to biobank participation, the adequacy of a putative duty to take part, ethical consequences of commercial use of HUNT biobank material, and their general hopes and fears concerning the biobank research of HUNT.

The focus group study was designed by two ethicists (Berge Solberg and Lars Øystein Ursin) and a social scientist (John Arne Skolbekken). This meant that the study was organised in a *continuous* manner from the start, rather than in a *serial* manner – where the social scientists plan and do the empirical study before leaving the normative discussion of the findings to the ethicists, or in a *parallel* manner – where social scientists and ethicists work side by side without any interaction.⁵ The focus groups were designed by interdisciplinary cooperation with the specific intent of making results suitable for ethical discussions.

Gary Weaver and Linda Trevino discern three ways of combining empirical and normative research: the *parallel* approach, the *symbiotic* approach and the *integrative* approach.⁶ The *parallel* approach views empirical and ethical research as inquiries into separate kinds of issues,

⁵ See Molewijk, Bert et al., 2004: Empirical data and moral theory. A plea for integrated empirical ethics, in *Medicine, Health Care and Philosophy*, vol. 7, p. 62

⁶ See Weaver, Gary and Trevino, Linda, 1994: Normative and Empirical Business Ethics: Separation, Marriage of Convenience, or Marriage of necessity?, in *Business Ethics Quarterly*, vol. 4, no. 2

and as representing separate forms of inquiry. The *symbiotic* approach views the subject matter of social science and ethics as quite distinct, but is open for the possibility that interdisciplinary collaboration can be fruitful in the sense that descriptive findings can inform the normative discussions, and the normative questions can inform the empirical research questions. Finally, the *integrative* approach implies a hybridisation of empirical and ethical research into a new kind of discipline, where the distinctions between empirical and philosophical methods and descriptive and normative claims are challenged.

The *integrated empirical ethics* programme of Lieke van der Scheer and Guy Widdershoven may be used to illustrate the integrative approach. Commenting on the relation between morality and ethics, they state that:

The first ethical systems and their applications to politics consisted to a large extent in codes stipulating how people had been behaving and by the same token how people ought to behave. But, strangely, when it comes to morals, we have become used to think that theory ought to precede practice, that practice ought to be based on theory, and that this theory cannot be derived from practice. In integrated empirical ethics, this idea is rejected.⁷

It is hard to accept this as a critique of normative ethics. An important task of ethics is, as will be argued in this chapter, to provide accurate descriptions of normative opinions. But the core of normative ethics is precisely to aim to assess rather than just to codify current morality.⁸ This point is conceded by Sheer and Widdershoven, on the condition that the ethicists' critical

⁷ Van der Scheer, Lieke, and Widdershoven, Guy, 2004: Integrated empirical ethics: Loss of normativity?, in *Medicine, Health Care and Philosophy*, vol. 7, p.77

⁸ Another way of understanding the view of Scheer and Widdershoven, is that isolation of value inquiry from the messiness of the empirical reality prevents ethicists from having impact in society. As pointed out by Mairi Levitt, the traditional task of ethicists has been to “clarify the situation, apply principles/theory and formulate policy i.e. the right thing to do. But if ethicists' work is actually going to make a difference in health care then they do need to pay attention to what happens next and particularly to unintended consequences.” (Levitt, Mairi, 2004: Complementarity rather than integration, in *Medicine, Health Care and Philosophy*, vol. 7, p.81) See also Musschenga, A. W., 2005: Empirical Ethics, Context-Sensitivity, and Contextualism, in *Journal of Medicine and Philosophy*, vol. 30, p. 473

assessments are considered *contextually relevant*: “Ethical theory may well be at odds with everyday ethical reasoning and everyday moral practice. But our point is that such criticism is only relevant if the practitioners can learn from it.”⁹ This seems right. To relate norms and ethical principles to some kind of shared value is a condition of their meaning, and certainly a condition for the motivation to act from such principles.¹⁰

Bert Molewijk et al. also champion a version of integrated empirical ethics. They distinguish their approach from *critical applied ethicists* in several ways: While the critical applied ethicists make distinctions between prescriptive and descriptive sciences, moral theory and social practice, and the use of empirical findings as an object of study and as a means to improve moral theory, the integrated empirical ethics approach makes none of these distinctions. For integrated empirical ethics, the exercise of moral theory is part of a practice and a subject of study just like the empirical data.

Molewijk et al. draws on experiences from the project *Patient Autonomy and Empirical Ethics* in emphasising that

every moral theory is inherently based on “empirical background assumptions.” For example, any moral theory on patient autonomy presupposes a specific anthropology, in particular with respect to human agency. Different moral theories on patient autonomy are based on different ideas about the identity and rationality of humans. One cannot construct a normative theory on patient autonomy without referring to an interpretation of what human beings actually “are.” Empirical background assumptions are not static ideas; they may change due to historical and cultural developments.¹¹

⁹ Van der Scheer, Lieke, and Widdershoven, Guy, 2004: A response to Levitt and Molewijk, in *Medicine, Health Care and Philosophy*, vol. 7, p.89

¹⁰ We will return to this issue in discussing the “ad hominem” type of moral argument later in this chapter.

¹¹ Molewijk et al. op. cit. 2004, pp. 58-59

The work of Molewijk et al. and others¹² on how informed consent procedures actually work is aimed to bring out the explicit and implicit normativity involved in these procedures. This might change our idea of “identity and rationality in humans” which gives meaning to the advocacy of specific kinds of informed consent procedures. The work of empirical ethics might in this way be crucial to make certain background assumptions explicit, and to offer a “thicker description” of the adequacy of informed consent requirements. This helps to explain the need felt for empirical research in ethical assessments of consent requirements when these assessments are aimed to be used in evaluations of specific consent procedures and in the implementation of new requirements.

The focus groups study of the *Consentenced* project is a contribution to such a thick description, which aims to avoid what Oonagh Corrigan has termed *empty ethics*: “Arguments that focus on informed consent as an absolute moral principle result in a reductionist abstraction and an *empty ethics* that strips the principle of consent away from its social context. On the other hand, arguments that plead for the recognition of the limits of consent in certain contexts argue for a more paternalistic approach.”¹³ In *NW*, findings from the focus groups are used to turn the attention from elaborate consent requirements to an emphasis on consent as a process aimed to build trust. In this way, an upheaval of the dichotomy between the use of active and specific consent (seen to promote autonomy), and the use of passive and general (seen to promote paternalism) was aimed for. This is in line with Corrigan’s conclusion from her discussion of her findings: “More recent discussions on informed consent have focused on the need to see

¹² There is a vast literature on this topic. See for instance Siminoff, Caputo and Burant, 2004: The promise of empirical research in the study of informed consent theory and practice, in *HEC Forum*, 16(1): 53-71 and Musschenga, A.W., 1999: Empirical Science and Ethical Theory: The Case of Informed Consent, in: A.W. Musschenga and W. van der Steen (eds.), *Reasoning in Ethics and Law: The Role of Theory, Principles and Facts*. Ashgate: Aldershot, pp. 183–203. For recent studies on informed consent in a Scandinavian context, see for instance Gustafsson Stolt, U et al., 2005: Information and informed consent in a longitudinal screening involving children: a questionnaire survey, in *European Journal of Human Genetics*, vol. 13, pp. 376-383, and Helgesson, G; Ludvigsson, J; Gustafsson Stolt, U, 2005: How to handle informed consent in longitudinal studies when participants have a limited understanding of the study, in *Journal of Medical Ethics*, vol. 31:11, pp. 670-3

¹³ Corrigan, Oonagh, 2003: Empty ethics: the problem with informed consent, in *Sociology of Health & Illness*, vol. 25 (7) , p. 787

informed consent as an on-going process rather than as a discrete act of choice that takes place in a given moment of time.”¹⁴ Consent as a process emphasizes the interactive aspect which might be away of weakening the autonomy/paternalism dichotomy induced by consent as a form.¹⁵

In the *Consented* project, and in the articles of this thesis, findings from the focus groups were used to give a better description of the ethical challenges of biobank ethics. Empirical findings have in this way informed the normative discussions in this thesis. But the approach of this thesis is clearly not the one of integrated empirical ethics. Rather, it is a variant of critically applied ethics in Molewijk’s sense. That is to say, rather than moving from ethical analyses of the advantages and disadvantages of different kinds of informed consent requirements as such (“empty ethics”), to blending value and empirical inquiry in studying the normativity present in the actual workings of consent procedures in biobank research (“empirical ethics”), the approach of this thesis is to use the thick description at hand to as an abductions means to take one step in the other direction, in order to identify, analyse and discuss the concepts used in the justification of informed consent in the first place.

As pointed out by Mairi Levitt, integrated empirical ethics approaches seems in the end to amount to nothing more than “that social scientists should make their ‘oughts’ implicit”.¹⁶ Normative and analytical ethics, on the other hand, just seems to lose the possibility to do ethics apart from the morality of a specific context. To accept such a limited scope for normative analysis amounts to a bold claim of the context-dependence of ethical judgements. This claim will be discussed later in this chapter.

The normative status of the focus group findings

An important question concerning the use of empirical results in this thesis is: If the empirical findings of the *Consented* project are used to inform the normative and conceptual discussions in the thesis, what is the findings’ normative status?

There are several possible answers to this question. One is to say that the opinions of the participants in the *Consented* project are of *instrumental* rather than of normative importance, because they voice the concerns of the persons who the HUNT study rely on to volunteer as participants. As such, they contribute to increase our knowledge of how to build relationships of

¹⁴ Ibid., pp. 787-8

¹⁵ See chapter 3 for a further discussion of this issue.

¹⁶ Levitt, op. cit. 2004, p. 82

trust, and thereby improve the participation rate in HUNT3. Their opinions is therefore of importance to HUNT researchers, regardless of whether we approve of them or not.

The opinions of the participants could also, as mentioned above, be of special importance to legislators, in as much as the participants' opinions allow the legislators to learn more about the common sense of justice in a public research project, which is thought to involve entering citizens' private zone.

In this chapter, it will be argued, in general terms, that the participants' opinions are of bioethical importance in the sense that they give moral reasons with basically the same status as the one given in this thesis. This implies, conversely, that the opinions of the participants are not of any *special* significance – except, perhaps, in the sense of coming from persons having a special and relevant kind of experience. The experience aspect of the statements of HUNT participants is, as mentioned above, of great descriptive importance in order to build relationships of trust, and of ambiguous normative importance in order to secure legitimate biobank research: if lawyers and ethicists view something as a privacy problem when participants do not, the opinions of the participants might be argued to be definite – or just naïve.

The opinions of the participants are central to important aspects of the issues discussed in this thesis, where for instance the scope of the self-governance of the participants is in focus. To ask the participants' opinion on consent requirements is different from asking whether one should do research on cloning. The first question concerns the line dividing the public and the private – that is, the nature of integrity and the relation between the citizens and the state. The second question concerns what anyone should be allowed to do. In the first case, the normative implications of a description of the opinions of the participants become significant in a special way, because it concerns the scope of self-governance.

In this thesis, the focus group material is used to challenge established ethical truths, like the importance ascribed to informed consent on behalf of the participants. The opinions of HUNT participants will be cited recurrently in this thesis, not as arbiters of the normative questions, but rather as illustrations of the interaction between accepted *norms* and promoted *values*.

For example: In *IC* the minor importance given to consent requirements by biobank participants in Scandinavia is described. It is then suggested, on the one hand, that the opinions of participants is of special value, in being unspoilt by overexposure to the ethical judgements and arguments of those who discuss these issues for a living, and which thereby might have conflicting interests in these matters. Thus the legitimacy of using broad consent would have a firm basis in the *norms* accepted by the participants. On the other hand, it is suggested that the

participants' opinions of are of rather limited value, in as much as the participants are too defensive in promoting the importance of exercising their personal autonomy. Thus a promotion of the autonomy of the participants and the consequent requirement of specific consent by legislators would have a firm basis if the *value* of personal autonomy is endorsed.

This thesis is based on the *symbiotic* rather than the *integrative* approach of Weaver and Trevino. In part 1 as well as in part 2 of this thesis, the findings of the focus groups are argued to have normative consequences, but only because they constitute or take part in constituting well-founded ethical views. Thus, identifying the criteria for judging an ethical view to be well-founded is the main aim of this chapter. The vital question concerning the relationship between – or the status of – ‘is’ and ‘ought’ in this thesis is not merely a question of discussing the relation between empirical findings and normative conclusions. Rather, it is a matter of analysing the way in which duties and rights are grounded in norms and principles that are motivated by, and grounded in, a set of values.

In this chapter, the issue of identifying the criteria for judging an ethical view to be well-founded will be discussed by exploring the role and status of reasons and intuitions, principles and values – in moral judgement in general, and in judgements on bioethical issues like biobanking, in particular. A *transitional* position is stated, which implies that general, moral judgements, and moral reasoning both in general and in this thesis, are to be assessed in terms of the values and principles they can be interpreted to represent, and from different notions of the good. This transitional perspective, and the interplay of values and norms, the good and the right, will reappear in the subsequent chapters, in the descriptions and discussions of issues concerning biobank ethics.

Rightful intuitions

Biobank research and biotechnological advances both have the potential to change essential aspects of how we conceive of ourselves as human beings, and pose new ethical dilemmas as to how we should act in relation to the promises and realities offered by medical research. The transformation of biobanking from being an uncontroversial activity to being ethically problematical with the introduction of genetics is a case in point. The novelty of bioethical dilemmas – in subject matter and perhaps even in kind – might lead us to ask how we can make sound judgements concerning the new options confronting us. Biotechnological innovations are aimed to enable us to mend or amend ourselves. This easily elicits strong emotional reactions. Perhaps our intuition then provides the only source of reliable judgement if we are faced with seemingly well-argued proposals we nevertheless find ultimately transgressive? Or perhaps our

intuitions lead us astray in being biased towards some status quo, which hampers progress and prosperity?

These kinds of questions might lead us to ask: What generally is the basis of our moral opinions? If I oppose the use of stem cells for therapeutic cloning, is my opinion justified by saying that I find it morally disgusting? Or should I in addition be prepared to justify my disgust in terms of an explanation, which perhaps should involve general moral principles? The task of bioethicists would in the latter case be to bring out the explanations and principles that lie hidden in the feeling of disgust. The bioethicist is, in that case, acting as a medium rather than a guru: His or her task is to bring out how shared feelings and intuitions connect with relevant reasons and principles that give the feelings their *moral* force.

Ethics is about the right and the good: How we should act and how we should live. We judge acts to be morally right or wrong, good or bad, and thereby as permissible or impermissible. To start with, we can point out two different ways of arriving at a moral judgement, namely by moral reasoning and by moral intuition. In *moral reasoning* we intentionally provide arguments for our judgements that can be presented to others. The arguments are debatable and open to objections. For example, moral reasoning might proceed by evaluating whether a given act complies with virtues or principles we think should be respected by everybody. *Moral intuition*, on the other hand, is neither intentional nor argumentative. Moral intuition gives rise to spontaneous judgements that are to be accepted or rejected at face value. Moral intuition and reasoning alike can provide judgements both concerning acts and principles.

Moral intuition is distinguished from intuitions and feelings that lack the normative aspect. I might for instance find eating snake-meat repulsive, without finding it impermissible and immoral. I won't say that nobody should do it - I just think that I would never do it. For an emotion like disgust to be morally relevant, it needs to express the judgement that the act that we find disgusting is also universally impermissible, or at least for everyone in the relevant group.

The spontaneity of both feelings and intuitions makes it easy to conflate them. Indeed, the very possibility of moral sensibility does seem to presuppose moral sentiments. These sentiments can be and are cultivated and educated¹⁷, however, making it illuminating to view moral intuition as analogous to mathematical or linguistic intuition¹⁸.

¹⁷ See Pizarro, D. and Bloom, P. 2003: The Intelligence of the Moral Intuitions: Comment on Haidt, in *Psychological Review*, vol. 110, no1, pp. 193-196.

¹⁸ Compare Williams, Bernard, 1985/2006: *Ethics and the Limits of Philosophy*, Routledge, ch. 6.

Now, one general way to relate and weigh different intuitions, opinions and principles, would be to simply counterbalance the elements according to the relative weight we think they have in a particular issue or situation. Our belief in some general principle might for instance give us a vague, but not a strong, intuition concerning how to act in a specific kind of situation. In this way, moral beliefs and judgements might gain justification – even if they go against the application of a general endorsed principle in a specific case. For instance, even if we think that all our actions should in principle be judged morally by their maximization of good consequences for the greatest number of people, we might still act according to our intuition that killing someone in order to save two others is impermissible – even if we do not see this as an instantiation of some higher principle that trumps the one we started out with. As both moral judgements and principles can seem intuitively correct, however, this kind of counterbalancing might be more about balancing intuitions against each other rather than balancing intuitions against reasoned judgement.

To show the reliability of the moral judgement of intuitions, two general objections must be met. The first one is: Given that intuitions are often not universally shared – how do we single out the reliable ones? For, if moral emotions are just unreliable indications that something might be wrong – and even if they are to be trusted, they have to be rephrased as rational moral arguments in order to be of any worth – then they should be disregarded, because they are in the end morally irrelevant. The second general objection is a variation of the first: We know that intuitions have been appealed to in the past, for instance in invoking the transgression of nature involved in interracial relationships¹⁹, in order to argue for moral opinions we today hold as prejudiced rather than insightful and wise. So how do we know that our current intuitions are expressions of wisdom rather than prejudice?

It is important to qualify this objection by pointing out that it rests on an inductive argument: To link the fact that intuitions have been used inappropriately in some cases does not show that they are inappropriate in all cases.²⁰ But we nevertheless need to show the difference between the appropriate uses of intuition and the inappropriate ones.

For Leon Kass, moral sentiments can be expressions of wisdom that are not in need of rational explication to be justified, because sometimes we “intuit and feel, immediately and

¹⁹ See Turner, Leigh, 2004: Is repugnance wise?, in *Nature*, vol. 22, no. 3, p. 269.

²⁰ See Streiffer, Robert, 2003: In Defence of the Moral Relevance of Species Boundaries, in *The American Journal of Bioethics*, vol. 3, no. 3, p. 38.

without argument, the violation of things that we rightfully hold dear.”²¹ However, to say that we “rightfully” hold such intuitions is a futile attempt to have it both ways: To say that these intuitions do not need justification, but that further justification nevertheless can be given. But Kass must hold that further justification in fact cannot be given – just further explanation. Otherwise, the intuitions are not justified by themselves, but by the justification that shows we *rightfully* hold them.

Shelly Kagan has discussed the possibility of establishing the legitimacy of moral intuitions by making an analogy to the trustworthiness of our empirical observations. The reliability of empirical observations depends on our ability to construct a theory that accounts for the observations, and to identify a mechanism that shows how the physical domain comes to contain the facts reported by our observations.

Likewise, the reliability of moral intuitions depends on our ability to construct a theory that accounts for the intuitions, and to identify a mechanism that shows how the moral domain comes to contain the facts reported by our intuitions: “Absent a story about the mechanics of moral intuitions – the workings of the moral sense – any confidence that intuition is indeed to be trusted at all, even when there is agreement, may seem strained or premature.”²² The burden of proof is thus firmly placed on the advocates of moral intuitions. And given how the intuitive moral judgments of different people often differ in the same case, Shelley thinks that an analogy with empirical observations is futile from the outset as a strategy to establish intuitions as reliable.²³

Intuitions as an impediment to morality

Rather than identifying a mechanism that safeguards our intuitions, Peter Singer identifies a mechanism to show the basis of their unreliability. Singer says the status we give moral reasoning and intuition implies a fundamental choice between two opposing metaethical views. According to the first view, “our moral intuitions and judgements are and always will be emotionally based intuitive responses, and reason can do no more than build the best possible case for a decision

²¹ Ibid.

²² Kagan, Shelly, 2001: Thinking about cases, in *Social Philosophy and Policy*, 18:2, pp. 52-3.

²³ It is worth noting the argument of unconditioned legitimacy of moral intuitions per se, cf. Streiffer, op. cit. 2003

already made on nonrational grounds.”²⁴ The second is that our moral judgements should have a “rational basis”, which perhaps, in turn, will make us develop certain “rational intuitions”.

In advocating the second view, Singer draws upon recent psychological and neurological research on moral decision making, the most important being the neurological experiments of Joshua Greene and his colleagues concerning so-called *trolley problems*²⁵. The classic problem of “trolleyology”²⁶ is that you have a choice between throwing a switch that will let a runaway trolley hit and kill one person standing on a side track – or standing by and watch the trolley hit and kill five people working further down on the main track. Most people confronted with this dilemma respond that the right thing to do is to throw the switch²⁷. In another version of the trolley problem, you stand on a footbridge above the track. Your choice now is either to let the trolley hit the five people, as before, or to push a very large stranger off the bridge, killing him but saving the five others. Confronted with this change of scene, most people respond that the right thing to do is not to push the stranger²⁸.

For Singer, there is no ethically significant difference between the two cases. Both are about making one person die in order to save five. The difference in people’s intuitions concerning these two cases is therefore all the more puzzling for the ethicist. Singer now argues that the difference in intuitions in the trolley examples is explained by evolutionary psychology rather than by moral philosophy. This is where the experiments of Greene enter the picture. Green and his colleagues measured activity in areas of the brain associated with either emotion or cognition and found that pondering the second dilemma triggers activity in the area associated with emotions to a greater extent than when pondering the first dilemma²⁹. Additionally, those

²⁴ Singer, Peter, 2005: Ethics and Intuitions, in *The Journal of Ethics* (2005) 9, p. 351.

²⁵ Originally discussed by Philippa Foot in The problem of abortion and the doctrine of the Double Effect, in *Oxford Review* 5, 1967, and by J. J. Thompson in Killing, Letting Die, and the Trolley Problem, in *The Monist* 59, 1976.

²⁶ Pinker, Steven, 2008: The Moral Instinct, in *The New York Times*, January 13.

²⁷ For instance, most of the 200 000 people who have participated in this web-based test: <http://wjh1.wjh.harvard.edu/~moral/index.html>, discussed by Marc Hauser in *Moral Minds*, Ecco, 2006.

²⁸ Ibid.

²⁹ Greene, Joshua, 2001: An fMRI Investigation of Emotional Engagement in Moral Judgment, in *Science*, vol. 293. no. 5537, pp. 2105 – 2108.

who actually opted to push the stranger off the bridge in the second dilemma pondered the question for a longer time than those who opposed pushing him.

Singer reads the findings of Greene from an evolutionary view of moral intuitions, where these intuitions were moulded as a part of the evolutionary history of mankind. From this perspective, an explanation of the difference between people's intuitions in the two dilemmas can be found: The second dilemma elicits emotional responses concerning which actions are permissible when you are in close contact with people. The exposure to similar cases up through our evolutionary history has equipped us with these emotions. The throwing of the switch in the first dilemma, however, does not to the same extent resemble situations we have encountered in our evolutionary past. This explains the difference in response to the two dilemmas.

Given this explanation, Singer goes on to ask where this leaves our moral intuitions generally. His opinion is that research into the psychology of moral reasoning shows that our intuitions go against each other, as in the two dilemmas, and therefore clearly lack a rational basis. As our moral intuitions are not to be trusted, the aim of ethics should therefore be to provide a rational basis for morality:

There is little point in constructing a moral theory designed to match considered moral judgements that themselves stem from our evolved responses to the situations in which we and our ancestors lived during the period of our evolution as social mammals, primates, and finally, human beings. We should, with our current powers of reasoning and our rapidly changing circumstances, be able to do better than that.³⁰

The justification of moral judgement is not to be had from moral intuitions. On the contrary: We should try to change and correct our intuitions in order to make them fit the morally relevant differences in cases presented to us in a rapidly changing environment, as is the case for judgements with a rational basis. Moral intuitions stem from feelings: The permissibility of an action is decided by the presence or absence of disgust. But since the feeling of disgust might be an echo of our environmental past rather than appropriate to the present situation, its presence does not amount to the impermissibility of the relevant way of acting. Neither does its absence make for the permissibility or duty to act in a certain manner. For Singer, moral intuitions simply do not have any justificatory status in moral judgement. The role of moral

³⁰ Singer, *ibid.*, p. 348.

intuition is just to be a preliminary judgement that might give us a hint as to what's right or wrong, but that always awaits reasoned evaluation in order to be legitimate.

Intuitions as enveloped reasons

Singer firmly judges the moral quality of acts in terms of their outcome. Consequently, there is no significant moral difference between throwing the switch and pushing the stranger: The outcome of both acts is the same, namely that one person is sacrificed in order to save five others. So, the fact that pushing the stranger amounts to using him as a mere means, or the fact that you actually actively bring about the death of a person, is thus not judged to be crucial in the moral judgement in these situations. It is simply the fact that the lives of four people are saved by these ways of acting that makes them both morally laudable.

An exclusive disjunction between judging acts on the basis of their moral consequences versus their intrinsic moral qualities presents Mary Midgley a false dilemma for moral judgement. The problem with making judgements based on consequences is that it is often hard to know what the consequences are going to be. This makes the situation of choice between clear-cut sets of consequences, as alluded to by the utilitarian, often rather illusory in real life situations. And the problem with judging based on intrinsic qualities is that these qualities might be simple to state, but often hard to argue for: "Many people are inclined to dismiss intrinsic objections as emotional, subjective, something that can't really be justified or argued about at all."³¹

The construed conflict between feelings and reason is especially unfortunate in bioethics, Midgley holds, since judgement based on intrinsic qualities in terms of emotional responses is easily associated with backward-looking conservatism, while reasoned judgement based on consequences is associated with forward-looking liberalism. Midgley thinks that the sharp division between feelings and reason that gives rise to this kind of stereotyping is misguided, because in reality "feelings always incorporate thoughts – often ones that are not yet fully articulated – and reasons are always found in response to particular sorts of feelings."³²

In her view, feelings are enveloped or compressed reasons which, if unpacked, will show how intuitive moral judgement is based on reasons expressed in a condensed form. To have opposing views on what is "natural" in an ethically significant way, for instance, is to have views

³¹ Midgley, Mary, 2000: Biotechnology and Monstrosity, in *Hastings Center Report*, vol. 30, no. 5, p. 7.

³² *Ibid.*, p. 8.

that “can be spelled out, made clearer, and (...) in principle (...) be decided in rational terms.”³³ Midgley warns against a conception of ethics as simply irrational, which is based on given judgements that cannot be argued against, and that are respected because of their political influence or religious significance. Conversely, she thinks that reasons always have some kind of emotional backing that makes us able to trust them and act by them. If someone who judges something to be very wrong did not have the slightest feeling of disgust, we would begin to doubt if they really understood the *point* of their own moral judgement.

Leon Kass argues for the same view in holding that concerning some crucial ethical issues, our moral emotions alone can provide us with adequate judgement:

Can anyone really give an argument fully adequate to the horror which is (...) raping and murdering another human being? Would anybody’s failure to give full rational justification for his or her revulsion at these practices make that revulsion ethically suspect? Not at all. On the contrary, we are suspicious of those who think they can rationalize away our horror, say, by trying to explain the enormity of incest with arguments only about the genetic risks of inbreeding.³⁴

Moral intuitions have a vital role not just in the process of attaining legitimate moral principles, but more importantly as the direct expression of “things we hold dear”, to use Kass’s expression. In the same vein, Bernard Williams holds that sometimes the attempt to justify our actions might be not just unnecessary, but also immoral: The moral intuition that I should help my wife from drowning rather than a stranger is not to be (more) justified by my subsuming it under a general principle which says something like “one should always help family members before helping others”. My attempt at subsuming this though will rather reveal a weakness of moral character, according to Williams – it will be “one thought too many.”³⁵

Midgley suggests that feelings of moral disgust might manifest fundamental conceptions of who we are and what our ideals should be. To object to genetic engineering by saying that it “is unnatural is not just to say that it is unfamiliar. It is unnatural in the quite plain sense that it calls on us to alter radically our whole conception of nature.”³⁶ To understand the emotional

³³ Ibid, p. 9.

³⁴ Kass, Leon, 1997: The Wisdom of Repugnance, in *The New Republic*, 2. June, p. 17.

³⁵ Williams, Bernard, 1981: *Moral Luck*, Cambridge UP, p. 18.

³⁶ Ibid., p. 12.

responses to genetic engineering is to spell out the relevant parts of such a conception of nature. Intrinsic objections to certain acts likewise show how they upset our conceptions of how things are and should be, and thereby introduce an imbalance that will lead to unfortunate consequences. For example, we might view people who commit acts deemed intrinsically wrong as having invited the negative consequences associated with their acts, so that they thereby “get what they are asking for”³⁷. To institute slavery, to take a rather simple example, is intrinsically wrong in that it is disrespectful of human rights, and because disrespect is introduced into a social situation, it invites the subsequent commission of acts done out of disrespect in return. In order to understand these basic conceptions, they have to be spelled out.

While Midgley thinks that moral emotions will lead us to bioethical insights even in novel cases, Singer thinks that they should be regarded with suspicion, even in familiar cases. For Midgley, the burden of proof is on those who argue against moral emotions, while for Singer (and Kagan) it is the other way around. For Midgley, moral emotion “necessarily accompanies”³⁸ a serious moral judgement, while for Singer moral judgement rests on reasoning and perhaps “rational intuition”³⁹.

One way to read Midgley is to see her as advocating the position that moral intuitions are enveloped reasons, waiting to be made explicit. As these reasons concern deep conceptions of nature that we generally share and take for granted, they present themselves as emotions, and to come clear about them might be a complicated task. Nevertheless, it is a task that in principle can be accomplished. Such a reading of Midgley’s position would mean that despite taking the opposite position regarding the *role* and the *prima facie status* of moral emotions, Midgley and Singer nevertheless agree concerning the *fundamental status* of moral emotions. This can be seen if we ask what, in their views, distinguishes a feeling that expresses a legitimate moral concern (rape is disgusting), from a feeling that expresses an illegitimate moral concern (interracial marriage is disgusting), or even a feeling of no moral concern at all (eating snails is disgusting).

The criteria for a feeling that expresses a legitimate moral concern would then for both of them be an evaluation of the arguments made for the emotional moral judgement. The status of moral emotions is thus to be assessed in terms of their implicit reasoning. If you offer an emotional moral judgement without being able to back it by (Midgley) or cash it into (Singer)

³⁷ Ibid., p. 8.

³⁸ Ibid., p. 9.

³⁹ Singer, 2005, p. 351.

legitimate reasons, it would be hard both for Midgley and Singer to justify the judgement as being legitimately moral.

Qualitative distinctions

Singer appeals to Kant in asserting that morality has to be based on pure reason in order to be more than an illusion.⁴⁰ For Midgley, feelings are not alien to or an impediment to morality. Midgley seems, however, not just to hold that feelings not only give *meaning* to morality, but moreover that the *justification* of morality is irreducible to pure reason. In order to examine whether it is possible to defend such a position, we should examine whether moral intuitions are indispensable to moral justification.

Charles Taylor describes intuitive moral judgements as having a dual nature in this way:

Our moral reactions (...) have two facets, as it were. On one side, they are almost like instincts, comparable to our love of sweet things, or our aversion to nauseous substances, or our fear of falling; on the other, they seem to involve claims, implicit or explicit, about the nature and status of human beings. From this second side, a moral reaction is an assent to, an affirmation of, a given ontology of the human.⁴¹

If we treat moral reactions just like other likes and dislikes, at best to be merely empirically explicable (perhaps as a part of our evolutionary heritage), Taylor says we miss the crucial distinction between weak and strong evaluations that separates moral reactions from others. While non-moral reactions express “weak evaluations” of the phenomenon in question, a moral reaction also endorses a weak evaluation as the correct one. Such a “strong evaluation” “marks the object as one *meriting* this reaction; in the other the connection between the two is just a brute fact”, Taylor says⁴². The intuitive moral reactions of Kass and Williams thus have to be approved by a strong evaluation in Taylor’s sense in order to express legitimate moral judgements.

Strong evaluations presuppose some standards by which we judge our reactions. These demonstrate that we have some idea of how we are to live and act. Such ideals enable us to make what Taylor calls “qualitative distinctions” between the moral goods we should strive for, and the

⁴⁰ Ibid., p. 351.

⁴¹ Taylor, Charles, 1989: *Sources of the self*, p. 5.

⁴² Ibid., p. 6.

perverted goods we should avoid. Contrary to the liberalist dictum, an idea of the good must always precede the right, for instance in the form of “hypergoods” – such as the liberalist values of autonomy and tolerance. According to Taylor, reductive moral theories such as utilitarianism deny us the ability to make explicit the very qualitative distinctions that give meaning to acting by their principles.

Since moral principles and concepts in this way inherently can be associated with notions of the good, a moral outlook is incompletely described just in terms of such principles and concepts. For Taylor, any moral outlook is most accurately described by a phenomenological “best account” of how our notions of the good make sense of our principles:

My perspective is defined by the moral intuitions I have, by what I am morally moved by. If I abstract from this, I become incapable of understanding any moral argument at all. You will only convince me by changing my reading of my moral experience, and in particular my reading of my life story, of the transitions I have lived through – or perhaps refused to live through.⁴³

Our moral intuitions stand in need of our endorsement of them in the form of strong evaluations, by our holding them up against our moral ideals. The “rational intuitions” of Singer might be an example of such a strong evaluation – but only if interpreted as intuitions asserting “hypergoods” rather than objective principles.

We can now revisit the trolley case. Singer and I might both hold that killing an innocent person is wrong, but he might say that an exception has to be made for pushing him off a bridge in order to save five others. The standard procedure of a reductive moral theory would in this case be to disapprove of this exception by showing that it does not satisfy certain criteria for making it fall under an approved set of principles. The problem with this way of framing moral discussion is, however, that it captures the challenges of moral argument in a poor way. As pointed out by Taylor, it is very rare that the relevant basic values are not shared even between people holding conflicting moral opinions⁴⁴.

The challenge is thus not to show the adequacy of basic moral principles, and how they apply, but rather to make a convincing case for judging a specific dilemma in a certain way.

⁴³ Ibid., p. 73.

⁴⁴ Taylor, Charles, 1995: *Explanation and Practical Reasoning*, in *Philosophical Arguments*, Harvard UP.

Accordingly, the task of the bioethicist, confronted with novel ethical dilemmas, is to identify the values expressed in intuitions and opinions from any source in a way that can be brought to bear on the relevant issue. The adequacy of intuitions and principles must be critically discussed. For example: Does the high level of abstraction of the trolley cases give strength or a weakness to the moral judgements we reach? As remarked by Levitt: “Ethicists often proceed by constructing their own examples to highlight the issue they want to discuss. For example, people tied to railway lines only one of whom can be saved and the decision to be based on only a few facts about them. Ethicists are not used to making sense out of the messy situations that come up in real life.”⁴⁵ The aim of bioethical discussion and justification is in the end to give the best possible account of the issues, and to justify the moral judgements of such an account.

Non-foundationalism

In this way, a notion of the good is a transcendental condition for making moral theories instruct human agency.⁴⁶ To act according to a notion of the good, and not just from a principle, is indeed a prerequisite for being a person we can fully relate to. Some intuitions define us, and we think that if we don’t adhere to them, we somehow more or less fundamentally change the way we identify ourselves as persons and as a culture. These intuitions mark the end of the domain of individual liberty, and we may say that cloning, abortion, or public nudity, as three examples, are all affronts to human dignity, and are not things for which an individual ought to opt.

We have seen that the status of moral intuitions can be held to be an impediment to sound moral judgement (Singer), or preliminary moral judgements (Midgley?), or final moral judgements (Kass). To an “intuitionist”, the justification of an emotional moral judgement will result from a strong evaluation in terms of coherence with our shared moral intuitions. The “rationalist” will instead try to justify an emotional moral judgement by showing how the judgement adheres to certain rational criteria. The moral relevance of these criteria, however, is not given, but stands in need of justification if challenged.

Then, according to Michael Hauskeller, the rationalist will have to explain “why his or her account of what is morally relevant is more adequate than alternative accounts. This, however, can only be done by reference to widely shared moral intuitions, i.e. to the way people actually feel about it. Those intuitions in fact provide the only possible justification for *any* theory of what

⁴⁵ Levitt, op. cit., p. 82

⁴⁶ See Brinkmann, Svend, 2004: The Topology of Moral Ecology, in *Theory & Psychology*, vol. 14/1.

is morally relevant.”⁴⁷ Neither moral feelings nor principles are thus normatively authoritative as such. In order to be morally justified, both intuitions and principles stand in need of strong evaluations in the context of the situation at hand.

To act from universal moral principles always have to be justified by the interpretation and assessment of the person acting on the principles. Moral judgements are essentially *subjective*, as pointed out by Andrew Gleeson:

The source of the authority of the cases does not lie in the inadequacy of the principles – it lies in the nature of morality as a phenomenon in which the agent cannot palm off the responsibility of his or her decisions. (...) in contrast with something like rules of etiquette, or legal and administrative rules, the very idea of following a moral rule (even if the rule accurately tracks moral properties) is problematic.⁴⁸

The justification of our moral concerns is in this way not provided by a reduction to pure intuitions or principles. “Thus the relevant question is not: Are those concerns rational [or intuitional] and therefore legitimate?; but rather: Do they make sense to us in the light of the complex of interrelated beliefs and feelings that define our specific way of living in, and looking at, the world?”⁴⁹ Such a non-reductive meta-ethical perspective can be called *non-foundationalist*, in that it denies that intuitions essentially consist of reasons that await being spelled out, or vice versa. This view might be given a contextual twist, as Molewijk et al. does in their description of the integrated empirical ethics approach (IEE):

In IEE, researchers do not believe in or strive for universal and absolute foundations of morality (either in social practice or in moral theory). On the contrary, IEE is primarily concerned with the contextual relevance of moral theory for the morality of specific social practices. Morality, and its evolution, is inherently connected with particular contexts during particular periods. Morality cannot be separated from its source without significant changes in its content. This implies that in the case of IEE one should not automatically assume that moral principles or social practices have universal meanings. It

⁴⁷ Hauskeller, Michael, 2006: Moral Disgust, in *Ethical Perspectives*, 13, no. 4, p. 579.

⁴⁸ Gleeson, Andrew, 2007: Moral Particularism Reconfigured, in *Philosophical Investigations*, 30:4, p. 373

⁴⁹ *Ibid.*, p. 585.

also means that the validity of (the normative conclusions of) research in IEE will always be limited to a specific social practice.⁵⁰

Contrary to the approach of Molewijk et al. non-foundationalism does not imply that normative ethics should be immersed in empirical studies of context-dependent morality which limits itself to claims regarding this particular context. The task of the ethicist is not to show how moral judgements only can be given relative to a specific case, or can be given final justification in terms of intuitions or principles without context, but rather to show in the most convincing way how shared values should inform our judgement when we are confronted with specific cases. As noted by Albert Musschenga: “If ethics indeed intends not only to prescribe actions, but also to actually guide actions, a turn to empirical ethics is inevitable. The main challenge for empirical ethics is how to further the context-sensitivity of ethics without making ethics uncritical.”⁵¹ Thus the question of context is not just a question of the nature of moral judgements, but also about the use made of these judgements, and the tasks of the ethicist.

Practical reasoning and moral justification

This meta-ethical perspective calls for an understanding of moral reasoning as *comparative* and *transitional* rather than absolute and conclusive. This aspect might be called *narrative*⁵² or *particularist*⁵³, in denying that the essence of reason is nothing but overt or hidden principles⁵⁴. It goes against an inadequate *legalisation* of ethics, which weakens rather than strengthens moral sensitivity if taken to be codifying *moral* – and not just *legal* – answers to moral questions. This perspective is of special importance to bioethics, which emerged as a field in which ethical

⁵⁰ Molewijk et al. op. cit. 2004, p. 58

⁵¹ Musschenga, op. cit. 2005, p. 486

⁵² See McCarty, Joan, 2003: Principlism or narrative ethics: must we choose between them?, in *Journal of Medical Ethics*, 29, pp. 65-71.

⁵³ Little, Margaret, 2001: Wittgensteinian Lessons on Moral Particularism, in Carl Elliot (ed.): *Slow cures and bad philosophers*, Duke UP.

⁵⁴ Thus not in the sense of denying the relevance of moral theory for ethical assessments of morality, see Molewijk et al., op. cit. 2004, p. 57. The problem for the particularist here, however, is not just that principlist ethics lacks accounts of their own legitimacy, but that there simply is so much left, in particular cases, to decide on and interpret given general principles: For instance, how “harm” is avoided, or “respect” is shown.

principles are sought to be identified and operationalised as directly relevant both for legislation and specific medical dilemmas. In the context of research ethics, an interesting question then is whether the principle of informed consent to participate in medical research presents a rare instance of consensual ethical truth, or rather a legalistic quick fix? Or, to be a bit more nuanced: Provides informed consent a handy legal solution and common framework for interdisciplinary discussions – which nevertheless might dim the moral and political aspects of concrete cases and contexts?

Moral reasoning is by this perspective a way to solve normative conflicts by giving convincing accounts of the issue at hand, rather than as a way to arrive at principles. In moral controversy, the aim of moral reasoning is therefore not to look for principles or criteria external to the opposing notions of the good, which should settle the issue at hand decisively. As the right must be connected with some kind of good in order to make sense, relevant notions of the good should be identified and interpreted. Ethics should aim for a discussion of conflicting views by making illustrative comparisons to clarify and perhaps change them, rather than aiming for definite justifications. Ethics is accordingly about *reasoning*, but also importantly about *showing* how one way of looking at issues is better than another.

Taylor makes a distinction between two models of practical reason, the “apodictic” and the “ad hominem”.⁵⁵ The ideal of the apodictic model is to justify a moral judgement by showing facts and principles that everyone has to accept. The ad hominem model is specifically directed at the holders of a view that is opposite the one that we support. The ad hominem argument proceeds by an “appeal to what the opponent is already committed to, or at least cannot lucidly repudiate”⁵⁶, and then tries to show that his specific opinions rest on exceptions to views and values we both share.

This importance of the ad hominem way of arguing is reflected in the psychological research on moral judgement conducted by Jonathan Haidt. His social intuitionist hypothesis suggests that intuitions play a more vital role in actual ethical discussions than is commonly acknowledged: “Moral reasoning may have little persuasive power in conflict situations, but (...) if one can get the other person to see the issue in a new way, perhaps by reframing a problem to trigger new intuitions, then one can influence others with one’s words.”⁵⁷ In this way, the

⁵⁵ Taylor, Charles, 1995, op.cit. pp. 35-6.

⁵⁶ Ibid., p. 53.

⁵⁷ Haidt, Jonathan, 2001: The Emotional Dog and Its Rational Tail: A Social Intuitionist Approach to Moral Judgement, in *Psychological Review*, vol. 108, no. 4.

distinction between ethical reasoning and rhetoric is blurred rather than absolute when it comes to moral argument and the identification of shared values.

For instance: Kass thinks that having to explain why the examples he provides are horrible and that the acts committed must be condemned means that you lack moral sensibility, much like having to explain why a simple joke is funny shows that you lack a sense of humour. But even if he cannot make you feel the horror of cloning, he could try to convince you that cloning is an affront to human dignity. Kass should then argue *ad hominem*. He should try to convince you that your notion of human nature is inferior to his, or that it actually entails the banning of cloning on an interpretation superior to the one you're using.

In a discussion of four models of practical reasoning, Onora O'Neill starts out with two teleological conceptions. The *first* one is the conception that practical reason aims at the realisation of the objectively good. Unless a convincing case for the objectively good is provided, however, this conception is not persuasive. The *second* approach is then to say that practical reason aims at the realisation of subjective ends. Practical reasoning is thus purely instrumental, as its proponents assign no role for reason in identifying the good: "They may show that omelette makers cannot reasonably refuse to break eggs, but they cannot show whether making omelettes is reasonable."⁵⁸ In this way, individual preferences are given no particular authority.

The last two conceptions O'Neill discusses are action based. This means that they assess the normative value of actions in terms of qualities of the actions as such, rather than in terms of an act being instrumental in attaining objective or subjective ends. The *third* conception of practical reasoning "takes as its premise those features of our lives which we cannot 'go behind' or assume away without undercutting our very sense of self, community or identity."⁵⁹ This conception resonates well with the view of practical reasoning advocated in this chapter. O'Neill now argues that the weakness of this view is the ethno-/egocentrism and thus the arbitrariness of the ethical commitments thought to provide the bedrock of moral justification.

The *fourth* conception of practical reasoning, and the one endorsed by O'Neill, adheres to the Kantian requirement that all others must in principle be able to follow our moral judgements and justifications in thought and action. This requirement effectively avoids the ethno-/egocentrism of the previous conception, in explicitly demanding of any moral reasoning that it should be understandable for anybody, not just for insiders. This provides moral judgements with

⁵⁸ O'Neill, Onora, 2000: *Bounds of Justice*, Cambridge UP, p.16.

⁵⁹ *Ibid.*, p. 20.

the universal authority of reason, rather than the local/individual authority of tradition and idiosyncrasy.

Now, the weakness of O'Neill's view is that it does not get us very far. In fact, it leads us back to Singer's claim that the justification and motivation of moral judgements must be totally separated. While Singer proposes to justify moral judgements using utilitarian criteria, O'Neill proposes vindication by the Kantian criterion of universality. Even if O'Neill is optimistic about the guidance we can derive from such a criterion, it seems to radically underdetermine moral judgements in specific cases. The reason for this is that criteria for the good collapses into the criteria for the right, confusing a clear view of the ends that give meaning to our acts.

It is important here to see, as pointed out by Christopher Cordner, the different roles of the good and the right, and the corresponding difference between general moral significance and general moral principles. One might argue that not to respect others is contrary to our notion of the good, for example – even if it has to be done in order to act right sometimes (I have to lie to you – or push you off a bridge – in order to save someone else). This is what makes moral dilemmas real: The right does not always accord with the good. Even if I was right in lying to you, I am to blame, because I did something contrary to our notion of the good.⁶⁰ The general moral principle of not lying, not once, might be seen as an expression of the unconditional worth of an individual, and gains moral significance in this way. A moral principle thus might be interpreted as expressing the *hypergood* of human dignity by giving an instruction as to the right way to act in order to respect it, while this hypergood provides the real moral weight for the principle.⁶¹

Reasons and intuitions in bioethics

The status of the opinions of the focus group participants in the *Consented* project might be viewed rather differently, depending upon which of the following two views of the nature of the good we endorse.⁶² In the *first*, we see the moral good as basically somehow widely known, even if different groups of people don't agree on its content. This view makes bioethics into a Socratic

⁶⁰ See Cordner, Christopher, 2007: Three Contemporary Perspectives on Moral Philosophy, in *Philosophical Investigations*, 30:1, pp. 71-2.

⁶¹ Ibid., p. 67.

⁶² Compare Hellesnes, Jon, 1995: Etikk-satsing?, in Carleheden, Mikael & Margareta Bertilsson (ed.): *Det goda livet. Etik i det (post)moderna sambället*, Brutus Östlings Bokförlag Symposion.

enterprise of digging out the knowledge of the moral good already ensconced in peoples' shared sentiments and beliefs. The moral good lies hidden in these sentiments and beliefs: If identified correctly they will be recognised and justified by their affinity to our original intuitions. The task of bioethics is accordingly to figure out how our general intuitive moral principles are to be applied in specific and novel kinds of cases; or conversely to find the general moral principles which implicitly induce intuitive moral sentiments and beliefs in us. Bioethics should operationalise these intuitions of what's right and wrong into laws and guidelines concerning the use of biotechnology. The important thing then is not to lose sight of these intuitions on the way, and not to be led away from the important moral insights we already possess.

In the *second* view, the moral good is basically unknown. This makes the enterprise of bioethics a matter of finding or constructing the right way to go about the questions raised by biotechnology - in a Baconian entrepreneurial manner. As the possibility of invoking a superior sensibility concerning moral intuitions is perhaps better left unused, the bioethicist will proceed from arguments and general principles that guide us to the moral *good* – or at least to the *right* ways of handling the possible uses of biotechnology. From this perspective, our intuitions are unreliable and redundant (except in the form of “rational intuitions”) in guiding us to the justifiably good and right. We need someone to find out about this, and trust bioethicists to be experienced in producing and assessing the kinds of arguments and principles we seek and await in order to know how to handle biotechnology in a good way.

To view bioethics as a kind of “Socratic” enterprise might be said to be Midgley's position, while Singer can be said to promote a more “Baconian” perspective. In the transitional perspective advocated here, the bioethicist is confronted with an ethical field where moral judgements based on intuitions, opinions, principles and arguments cannot and need not be decisively justified. The task of the bioethicist is thus not one of justification but of clarification (pointing out parameters, interrelations and implications of certain views) and of arguing for substantive positions (arguing for the superiority of certain views in terms of their promotion of certain values). The perspectives of principles are very helpful tools for those ends, but are not to be confused with the ends themselves, however. With these methodological and meta-ethical remarks in mind, we now turn to a presentation of the articles in this thesis and the research questions that distinguish and unite them.

The promotion of personal autonomy

The discussion of findings from the HUNT focus groups in *NR* concentrates on the controversy over the appropriateness and legitimacy of consent types against the background of the prevailing trust among participants in research carried out by publicly funded institutions in Norway – in contrast to the mistrust in commercial international pharmaceutical companies. The aspects of trust and distrust were found to play a major role for our focus group participants, while consent issues – in stark opposition to current biobank legislation – were thought to be of significantly minor importance. An analysis of this difference in emphasis between participants and the government led to an analysis of the relationship between research institutions and research participants in general, and the justifications of informed consent requirements in particular.

The use of general or broad consent, in which the participants consent to take part in future biobank research projects of unknown nature – unless they choose to opt out, seems to be tailor-made for making everybody happy in this situation: Legislators get their consent, and the researchers just needs to get it one time, and the participants just need to give it one time. Thus time and money can be used for the research which made the whole enterprise meaningful in the first place. The opposition to the use of general consent is, in this perspective, all the more interesting. A reason for such opposition is given in *PA*, namely that the use of general consent does not secure the autonomy of the participants.

In this chapter, the question posed is *how* and *why*, rather than *if*, informed consent requirements in biobank recruitment can be viewed as a promotion of the individual autonomy of potential participants. The aim is thus to take one step back, and try to describe and assess some grounds for and consequences of the promotion of autonomy as a cultural ideal in this context.

The autonomy turn

It is often said that the worst atrocities committed against our fellow human beings have been committed in the name of the community rather than the individual. And it is the nature of

medical research that a large group of people could collectively benefit from research conducted on a smaller group of individuals. At the same time, these experiments could severely harm the research subjects. One way to protect research subjects' interests with respect to their well-being is to apply the Hippocratic principle of non-maleficence to medical *research* as well, through the Helsinki Declaration of 1964, which states in §5 that for medical research to be judged legitimate, the interests of the individual should always take precedence over the interests of society.

In international declarations and guidelines, national law, medical practice, and bioethical literature, this perceived conflict of interest between the individual and society has found its resolution in obtaining the legitimate consent of participants in medical research. The coercion, brutality and disrespect towards research subjects in Nazi experiments led the Nuremberg Code of 1947 to declare the principle of *voluntary* consent as given by the research subject as “absolutely essential” for all kinds of medical research. Later revelations of abuse and deception of research subjects both in Europe and in North America led to an increased focus on the need for consent by participants in medical research. In the Nuremberg Code, voluntary consent requires a participant's explicit consent to take part in a study. This presupposes that the participant is able to assess the research design and to make a competent and informed decision as to whether to participate or not. The voluntary consent acts as a safeguard for research subjects in medical research against any abuse and deception.

Traditional medical ethics, with its roots in the Hippocratic Oath, was initially focused on the physician's duties. As medical ethics was transformed into bioethics in the 1970s, however, the main issue became patient rights.⁶³ During the last few decades, moreover, this major change in the relationship between the patient and the doctor has been accentuated. The ideal of autonomy has gained ground in health care, as well as in society at large. To enable people to govern their own lives according to their own values has been a primary justification in the development of modern society. As summarised by Bruce Jennings: “Joining with other parallel cultural forces since the early 1970's, bioethics has participated in the social construction of the autonomous person – a thin self who leads a rich life. And the quotidian work of bioethics is to devise an ethical system that will respect and protect this self.”⁶⁴

⁶³ See Wolpe, Paul Root, 1998: The Triumph of Autonomy in American Bioethics, in Raymond DeVries and Jaradan Subedi (eds.): *Bioethics and Society*, Prentice-Hall, pp. 38-9.

⁶⁴ Jennings, Bruce, 1998: Autonomy and difference, in Raymond DeVries and Jaradan Subedi (eds.): *Bioethics and Society*, Prentice-Hall, p. 260.

The concept of consent has developed correspondingly.⁶⁵ For example, the Helsinki Declaration emphasised the informational aspect of consent. Thus, while the “voluntary consent” of the Nuremberg Code promoted non-maleficence, the “informed consent” of the Declaration also promoted autonomy as a safeguard against undue paternalism in health care.⁶⁶ The relatively recent requirement for informed consent in medical research can be said to have been assigned two quite distinct justifications in terms of autonomy: On the one hand, it safeguards the well-being of participants by promoting the instrumental use of their autonomy, and on the other hand it foregrounds autonomy as a right in itself. Autonomy might be thought of as both a means and an end for participants, in enabling the justification of consent requirements both as a way of avoiding harm and of promoting autonomy as such.

Consenting to biobank participation

Informed consent justified by personal autonomy would be a *necessary* condition for the ethical legitimacy of biobank research if this research was understood to interfere with decisions that *have to* be taken autonomously by participants. Appeals could be made both to the intrinsic and the instrumental value of autonomy. A possible position that appeals to the *inherent* value of autonomy would imply that making a relevant decision is essential in respecting participants, regardless of the consequences. To be enrolled in or to join a biobank research project without giving autonomous consent would then mean to renounce one’s inherent worth in this situation. The interest of citizens to autonomously take their own decisions regarding potential participation in biobank research is recognised in liberal society. This interest is nevertheless not

⁶⁵ See for example White, B. C. and Zimbelman, Joel, 1998: Abandoning Informed Consent: An Idea Whose Time Has Not Yet Come, in *Journal of Medicine and Philosophy*, vol. 23, no. 5, p. 478, and Burgess, Michael, 2007: Proposing modesty for informed consent, in *Social science and medicine*, 65:11.

⁶⁶ The very term “*informed* consent” is rightly criticised for being tautological and misleading. Consent is a relational term: To give one’s consent is necessarily to consent to something. Therefore the term informed consent gives the false impression that there is a definite amount of information that makes consent informed – as opposed to “*uninformed* consent” (which is a contradiction in terms). See Maclean, Alasdair: 2004, “The doctrine of informed consent: does it exist and has it crossed the Atlantic?”, in *Legal Studies*, 24(3), pp. 386-413 and Manson, Neil and O’Neill, Onora: 2007, *Rethinking Informed Consent in Bioethics*, Cambridge UP, p. 89. We will in this thesis nevertheless use the term informed consent by way of convention.

granted as an unqualified right. The interests of the individual, society and researchers must all be balanced, and the law should state principles by which such a balance can be achieved. Research using information from diagnostic and therapeutic biobanks and health registers that is not based on consent could be legitimate if the scientific goals and benefits clearly exceed the inconvenience for the individual. From the principle of justice, biobank research for the benefit of and involving non-autonomous individuals, such as children, should also be possible to conduct in a legitimate way even if informed consent is impossible to obtain.

A position that appeals to the *instrumental* value of autonomy would be to hold that allowing one's genotypic and phenotypic information to be the subject of genetic epidemiology is unwanted or potentially harmful in a way that only the individual can assess.⁶⁷ Thus, unless society allows harmful research to proceed, informed consent can only adequately function to protect the well-being of research participants if we assume and allow that biobank participation might harm some individuals, but not others. And, unless potential participants are free to join biobank research that puts their well-being at risk, the purpose of their informed consent obviously cannot be to safeguard their well-being by way of their instrumental autonomy.

Informed consent is not a *sufficient* condition for ethically acceptable biobank research. Society limits the kinds of research a person can consent to participate in. Society conversely limits the kinds of biobank research that may legitimately be pursued on the basis of consent. These limits are imposed by legal frameworks, various levels of government, and research ethics committees. The government should ensure that no citizen is invited to participate in studies that are of poor quality, unduly harmful or ethically questionable. In this way, neither biobank researchers nor participants are granted unrestricted individual autonomy.⁶⁸ As pointed out by O'Neill, the libertarian view that any agreement "between consenting adults" is morally legitimate overlooks the fact that informed consent is the "tip of the ethical iceberg" (O'Neill, 2003, p. 5).

Limits to the exercise of the autonomy of the participants are based on several concerns, one of which is the well-being of participants. Consequently, the well-being of participants is supposedly addressed before any informed consent is sought: Nobody should be asked to consent to participate in research that has an unfavourable risk-benefit ratio. To think that

⁶⁷ See Helgesson, Gert and Johansson, Linus: 2005, 'The right to withdraw consent on biobank samples', in *Medicine, Health Care and Philosophy*, vol. 8, p. 318

⁶⁸ See Garrard, E. and Dawson, A.: 2005, 'What is the role of the research ethics committee? Paternalism, inducements, and harm in research ethics', in *Journal of Medical Ethics*, vol. 31, p. 421 and Manson and O'Neill 2007, ch. 4

concern for the well-being of research participants is a justification for requiring informed consent is thus to mistake levels of concern: The protection of the well-being of research participants is normally addressed at the collective – not at the individual – level.

In this way, concern for the well-being of participants is in practice not a primary justification for informed consent in biobank research. If the well-being of the individual is not at stake, the consent of the participant might be required because the research interferes with his private sphere. It then has to be shown that such a relevant right to privacy is justified. The consent of the participant might also be required because the decisions of an individual should be respected. Any and all decisions of an individual obviously do not have to be respected, so the reason why they should be respected in this context has to be demonstrated. The consent of the individual might also be shown to be required as a part of the basic political autonomy of citizens in a liberal society.

Informed consent can, as will be argued in the next section, be viewed as a way to make participants endorse and identify with a research project and its aims. In this way authenticity, rather than autonomy, justifies informed consent requirements. Information becomes as important as consent. Informed consent requirements are partly justifiable in a number of ways⁶⁹: To show the proper respect for participants and to treat them with dignity, to avoid harm and promote well-being, to empower participants, to establish a contractual relation and avoid liability, to distribute responsibility for the research being done, to waive rights to privacy, integrity or autonomy, to promote personal, moral and political autonomy, to give information, to build trust, as just a few examples.⁷⁰

The Helsinki Declaration emphasises three aspects in handling a possible conflict between the interests of researchers and participants: Participants should be well-informed before entering the study, researchers are always responsible for the well-being of the participant, and participants are always at liberty to refuse participation or to withdraw from the study. That is, a participant should autonomously decide to take part, but should not be allowed to consent to research which compromises her well-being, and is free to decline participation without reflection. Informed consent is asymmetrical in this context: To consent to participation non-autonomously makes the consent invalid, but to refuse participation non-autonomously is valid.

⁶⁹ Dworkin (op. cit. 1988, p. 103), lists “privacy, self-determination, loyalty, autonomy, freedom, integrity, dignity, and benefits. Individuals have the right to be treated as persons, as masters of their own body, as responsible for their own decisions, as makers of choices.”

⁷⁰ See *IC* and chapter 3 for a further discussion of these issues.

The Helsinki Declaration thus safeguards the autonomy and well-being of all participants, and the liberty of all potential participants.

Biobank research typically consists of assessing the impact of genetic and environmental factors on health at a group level. Given the appropriate safety measures, the potential for harming participants in any way should be negligible. Unlike screening programs, biobank research feedback for participants is provided at a group level, if at all. Once enrolled in the biobank, a participant's research interest *as an individual* thus disappears. Participation in biobank research in this scenario is very low risk for an individual. In this way, the protection of the autonomy of participants in biobank research constitutes a limit case that could bring forward the specific value of participant's autonomy in medical research. The most notable reasons for people to choose *not* to take part in medical research are avoided: Exposure to harm, loss of privacy, and controversial means, aims or funding of research. In this way, the instrumental value of autonomy in giving individuals the ability to avoid research participation for independent reasons is not in focus, while the intrinsic value of autonomy, the reasons to promote the autonomy of participants *per se*, as it were, is accentuated.

Conflicting conceptions of consent

The shift towards protecting the research participant against undue paternalism and not just harm from the voluntary consent of the Nuremberg Code of 1947 to the informed consent of the Helsinki Declaration of 1964 is even more apparent in the Belmont Report of 1979. The Belmont report states in section B1 that respect for persons is a basic ethical principle of vital significance to research ethics. The report explains the notion of respect for persons thus:

“Respect for persons incorporates at least two ethical convictions: first, that individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are entitled to protection. The principle of respect for persons thus divides into two separate moral requirements: the requirement to acknowledge autonomy and the requirement to protect those with diminished autonomy. An autonomous person is an individual capable of deliberation about personal goals and of acting under the direction of such deliberation.”⁷¹

⁷¹ The Belmont Report, 1979, Ethical Principles and Guidelines for the Protection of Human Subjects of Research, The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, sec. B1.

In section C1 the requirements set by the principle of respect for persons in medical research is given: “Respect for persons requires that subjects, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them. This opportunity is provided when adequate standards for informed consent are satisfied.”⁷²

In *IC* it is argued that autonomy in the individualistic sense has indeed become an important part of the justification of informed consent requirements for biobank research in Scandinavia.⁷³ In *IC*, it is suggested that the emphasis on autonomy in medical research should be seen as part of a general emphasis on individual liberty, non-paternalism and empowerment in modern social democracies of Scandinavia. Legislative efforts in Scandinavia stand in contrast to a background of the history of eugenics, unethical medical experiments during and after the WWII, a history of paternalistic thinking in health care, and are positioned in relation to research ethics documents such as the Nuremberg Code and the Helsinki Declaration. Thus, contemporary biobanking is contrasted with a past in which both science and government are viewed as lacking any respect for autonomy, which makes it important to signal anti-paternalism in current legislative initiatives.

Once this political field is framed as a matter of ethics, the themes come to reflect well-known ethical issues. For example, does genetics potentially open the door to genetic discrimination against individuals and groups, might this imply a disruption of our ideals of solidarity, and should the autonomy of the individual be sacrificed for the sake of societal ends? It becomes necessary for an act on biobanks to explicitly embody the ideal of a diversified and inclusive society. Public authorities are responsible agents for the welfare of the individual in a very intimate sense. Interestingly, however, the obligation of the individual to contribute to the maintenance of a research-based healthcare system is set aside by the legislative work of the Scandinavian countries in emphasising the rights of the individual.

Scandinavian law accomplishes this through requirements for informed consent. The consent procedure is, however, not just about delegating decision-making power. The *consenter* has to be *informed*. This implies figuring out what the population needs to know – and accordingly, most of the battles surrounding consent requirements revolve around determining what to write on the information and invitation sheets.

⁷² *Ibid.*, sec. C1

⁷³ This section and the one below offers a synopsis of *IC*.

The tool to protect the individual from harm turns out to be a tool that also can be used to avoid research perverted by motives alien to the common good of the society. To make the consent informed, research designs have to be publicly accessible, and thus shield participants from harmful research, and society from unethical research. Every participant should know and approve of the research he or she takes part in – if not, they are free to leave. To recruit and keep voluntary research participants, researchers have to build trust. In this way, the informed consent requirement can be claimed to serve three different purposes: to protect participants from pressure to take part in harmful research, to protect researchers from pressure to do research with questionable motives, and to ensure that biobank research is open to public scrutiny, control and debate.

As described in *IC*, Scandinavian biobank participants count on the state to establish the necessary incentives and control systems for securing ethically sound biobank research. Their worry is that the incentives could change, and that research could be placed out of reach of the systems designed to control them. From this perspective, it is the appointed public institutions that should be trusted to exclude harmful and unnecessary research projects – not individual donors. But from the researcher’s perspective, there is a conflict between the imperative to utilise biobank research material, and the restrictions put on research by consent and other requirements.

A paradox of the situation, touched upon earlier in this chapter, is that the law is looked upon to empower participants, while the thinking of the participants interviewed is that they expect authorities to take responsibility. Political attempts to integrate the individual into evaluating research are confusing to participants. To be positioned to evaluate the soundness of the research is seen as inadequate.

Educational consent

In view of the ambiguities of regulations enacted in respective countries, complaints from researchers and health professionals, and the mismatch between the problems and solutions articulated by legislators and the concerns articulated by the donating public, the *IC* makes an attempt to rethink the logic of biobank regulation. The question is raised: What is actually regulated by the laws and circulars on biobanking, and why?

A standard answer would be that biobank laws regulate researchers’ access to human tissue through consent requirements. From this perspective, consent should ensure the negative freedom of participants, in order to protect them from harm. Another possible answer is, however, that biobank laws are more about regulating the state/citizen relationship than about

regulating research. The political agenda might present solutions that neither reflect the worries of researchers nor participants, because the motivation for regulation has more to do with finding ways of ensuring trust, positive attitudes and legitimacy than with tightening rules for biobank research. The handling of stored tissue by public authorities is important because it indicates the care exercised by the liberal welfare state towards its citizens. In order for research to make use of biobank information in a legitimate way, the individuals taking part must waive their right to privacy, and exercise their self-determination by giving an informed consent.

Looking at the legislation in Scandinavia, it appears that it is not enough to support research by coincidence: you must want to support research. If you participate, you approve of the research; otherwise, you should decline participation. The overwhelming majority of participants in Scandinavian countries are thus individually and actively linked to biobank research. The consequence of setting individuals free is thus to link them closer to the research and to make them internalise research aims. They have to enact the values embedded in research participation.

How are notions of identity, privacy and control consequently shaped? Based on the exploration of the similarities above, it is argued in *IC* that the regulatory efforts in the field of biobanking exemplifies a paradoxical enactment of citizenship: An ideal of individual autonomy is fused with a notion of the education of the masses; a search for the uncontaminated and independent citizen as arbiter of moral judgement is fused with strong efforts to enrol this 'subject' in public health policymaking. Participants are involved in the responsibility for research that makes use of their biobank contributions – otherwise they should have opted out.

In a sense, the informed consent process becomes an education process. To consent without reading the consent form is not a 'proper' informed consent: Neither researchers nor participants have fulfilled their duties. In this way, to argue that studies show that participants do not find informed consent important is beside the point. Informed consent is an end in itself – it is part of the required practice for a meeting of citizens and science. Through consent procedures, biobanking becomes a mass education project. A suitable Millian narrative could be: Due to prevailing paternalistic ideas, and the average level of education, citizens have been treated like children by the public health service of the past. Nowadays they might be treated like youths – but in the end they will be treated like adults: entrepreneurs for their own health, both in private prevention of disease and in consulting the health service. In this way, personal autonomy *is* a major justification for informed consent requirements – if not for participants, then at least for policy makers.

The significance of personal autonomy

This brings us to a major question of this thesis: If informed consent requirements are grounded in the protection and promotion of the autonomy of biobank participants – what does this mean? What is thereby protected and promoted? Why is it important to secure the autonomy of participants, and what is the relationship between autonomy and freedom, well-being and privacy? Could it be that the autonomy of research participants, if we take a closer look, really in the end just turns out to be just another name for freedom of choice, voluntariness or privacy? Or perhaps autonomy in the end just turns out to be of instrumental value, so that informed consent justified by an asserted intrinsic value of individual autonomy is nothing but a chimera?

The answer to such questions, and indeed the meaning of the questions themselves, will of course vary according to the different conceptions of autonomy introduced in this thesis. To begin the discussion of these questions, we will use a concept of autonomy metaphorically linked to the etymological root of the concept in the ancient expression of “auto-nomos”, the self-governance of the city states of Greece. This metaphor suggests that people should, like countries, have the chance to develop a stable system of government, which is able to make long-term decisions that allow the country to prosper. Furthermore, the natural resources of the country should be acknowledged and appreciated, and its unique culture should be protected and promoted. In this analogy, people have to waive their rights to privacy and autonomy for their participation in medical research to be legitimate. In other words, their informed consent is needed.

Personal or individual autonomy in this sense is seen as vital to authenticity, moral responsibility, integrity and character. Personal autonomy is different from moral autonomy, which might still be enjoyed by the person imprisoned for his ethical beliefs, and from political autonomy, which might still be enjoyed by a person who is personally non-autonomous. Moral and political autonomy are, nevertheless, vital in making personal autonomy possible, as well as forming important aspects of personal autonomy itself. Thomas May points out the importance of distinguishing between moral and political autonomy, precisely because the acts protected by liberal rights should not be confused with a moral obligation to act this way – and vice versa.⁷⁴

⁷⁴ See May, Thomas: 2005, ‘The concept of Autonomy in Bioethics – An Unwarranted Fall from Grace’, in James Stacey Taylor (ed.): *Personal Autonomy*, Cambridge UP

The autonomy of the individual can be viewed as having aspects of independence, authenticity and control.⁷⁵ It can moreover be viewed as a *predicate*, a *norm* or an *ideal*⁷⁶: The autonomy of the individual accordingly is to be respectively observed, respected and cultivated. Jonathan Glover suggests that our intuitive preference for autonomy can be illustrated by the revulsion “many people have at the thought of Brave New World”⁷⁷, an environment where people are perfectly happy even though they have relinquished their autonomy. The implication here is that most people would not trade autonomy for happiness, which by extension suggests that there is more to autonomy than the instrumental value it has in helping us to achieve happiness.⁷⁸ As James Rachels and William Ruddick put it: “Without liberty, a person cannot have a life.”⁷⁹ Without liberty one would merely be alive – one would not lead a *life*. But does this mean that autonomy is of *inherent* value in granting us dignity as individuals; that the experience of the liberty associated with autonomy has *intrinsic* value to us; or that autonomy instead is *constitutive* of ourselves as persons?⁸⁰

⁷⁵ See Kristinsson, S. and Árnason, W. 2007: Informed consent and genetic database research, in Matti Häyry et al. (eds.) *The Ethics and Governance of Human Genetic Databases*, Cambridge UP, pp. 209-10.

⁷⁶ Joel Feinberg makes a fourfold distinction in meanings of autonomy: Autonomy as *capacity* vs. *actual condition* – a distinction to which we shall return; and as *ideal of character* vs. *sovereign authority*. The latter distinction, we will argue, should point to the difference between moral and political autonomy, rather than model a moral ideal of autonomy on a political right to autonomy. See Feinberg, Joel: 1989, ‘Autonomy’, in John Christman: *The Inner Citadel*, Oxford UP

⁷⁷ Glover, Jonathan: 1977, *Causing Death and Saving Lives*, Penguin Books, p. 81

⁷⁸ See also Young, Robert: 1982, ‘The Value of Autonomy’, in *The Philosophical Quarterly*, vol. 32, no. 126, pp. 36-7

⁷⁹ Rachels, J. and Ruddick, W.: 1989, ‘Lives and liberty’, in John Christman: *The Inner Citadel*, Oxford UP, p. 226

⁸⁰ Autonomy can at a basic level be taken to have *instrumental* value, as well as *intrinsic* or *inherent* value. Roughly speaking, something is judged to be of instrumental value by its good consequences and of inherent or intrinsic value if it is good as such. Inherent and intrinsic value again differ in the way that while some objects can be regarded as inherently valuable, subjective experiences can be regarded as intrinsically valuable. To illustrate these distinctions, we could argue against paternalism and say that we should respect the (sometimes foolish) decisions of our fellow citizens – for otherwise we will inflict far more harm than if we do not respect their

Jukka Varelius opts for the last alternative when he argues that the opposite of being a not-so-happy autonomous person is not a happy heteronomous person, but a person who is incapable of experiencing well-being whatsoever.⁸¹ It seems, however, that autonomy is not a necessary condition for personhood in the relevant sense⁸², since we ascribe well-being to non-autonomous human beings – such as infants, for example. The concept of *awareness* of oneself and the world, bereft of total manipulation, seems much closer to being a vital ingredient of well-being. Of course, to be able to *choose* well-being instead of autonomy does, in a trivial sense, presuppose some kind of autonomy, but this establishes autonomy as constitutive of well-being only in a circular way.

decisions. On the one hand, this can be taken to mean that respecting people's autonomy is of instrumental value in making them learn from their mistakes. On the other hand, it can be taken to mean that to have one's autonomy respected is of intrinsic value to people; perhaps because they believe that their dignity (to be respected as individuals) is offended if their autonomy, being an inherent value, is not respected. If autonomy is *constitutive* of ourselves as individuals, it is a necessary condition for us to hold anything as valuable at all. Autonomy is likewise of vital *instrumental* value to deliberative democracy, which requires citizens able to make up their own minds and express their views as part of the political process. Autonomy is of *intrinsic* value to human dignity, if viewed as part of a realisation of ourselves as ideally self-directed and independent-minded.

⁸¹ See Varelius, Jukka: 2006, 'The Value of Autonomy in Medical Ethics', in *Medicine, Health Care and Philosophy*, vol. 9

⁸² This sense is to be distinguished from the sense of autonomy as constitutive of moral personhood. Kant, for instance, argues that in respecting the capacity each of us has to establish and rationally justify our own moral goals, we respect such goals as ends in themselves, and do not simply treat them as a means to something else. The autonomy of everyone is to be respected as *constitutive* of personhood and morality. Nevertheless, Dawson and Garrard point out that a constitutive role of autonomy does not necessarily make autonomy a primary principle of medical ethics. They argue that without our capacity for suffering, morality would be "unrecognisably different", which seems to point an equal status for the principle of non-maleficence. See Dawson, A. and Garrard, E.: 2006, 'In defence of moral imperialism: four equal and universal prima facie principles', in *Journal of Medical Ethics*, vol. 32 and Gillon, R.: 2003, 'Ethics needs principles – four can encompass the rest – and respect for autonomy should be the "first among equals"', in *JME*, vol. 29, pp. 307-312

It seems more useful and accurate to see personal autonomy as having *aspects* of constitutive, instrumental, intrinsic, and inherent value to us in relation to well-being: Sometimes autonomy is constitutive of well-being, sometimes it is instrumental to well-being, sometimes we choose autonomy on its own merit, and sometimes it is vital to being treated with respect. Thomas Hurka illustrates the idea of the intrinsic value of the freedom associated with autonomy when he suggests that we would value having ten options instead of just one, even if after careful consideration the one option turns out to be the best one in any case.⁸³ On the other hand, the value of autonomy in Hurka's example can just as well be negative – if the process of decision-making is experienced as a waste of time. Nevertheless, if the autonomous choice in this case has any value, it is not an instrumental one, since it does not change the outcome. And if we somehow benefited or profited in any way from the single option, then it follows that autonomy is not a necessary condition for well-being – even if we were to be denied further choices.

Autonomy seems, however, to be of intrinsic or inherent value at the global rather than the local level. It is important that others respect us as autonomous beings, even if one cannot or does not exercise one's autonomy in any situation or relation. This is emphasised by Dworkin: "What does have intrinsic value is not having choices but being recognised as the kind of creature who is capable of making choices."⁸⁴ To conceive of oneself as the navigator of one's own life project means that autonomy has an inherent value⁸⁵.

Like the value of liberty, personal autonomy is a good that seems characteristically of *both* intrinsic and instrumental value. We pursue autonomy both for its own sake, and for the sake of being in the position of attaining what is good and avoiding what is bad. Seen in this light, autonomy is a distinct part of both our character and our well-being. Personal autonomy is not a precondition of being found worthy of respect as a person, since we grant human dignity to children and to temporarily or permanently non-autonomous adults.⁸⁶ Still, to deny adults some or any kind of autonomy might imply a lack of respect and recognition. Some kind of self-governance is a defining component of being a subject.

⁸³ Hurka, Thomas: 1987, 'Why value autonomy?', in *Social Theory and Practice*, vol. 13, no. 3

⁸⁴ Dworkin, Gerald: 1988, *The Theory and Practice of Autonomy*, Cambridge UP, p. 80

⁸⁵ Compare Claudia Mills' concept of "narrative authenticity" in Mills, Claudia: 1998, 'Choice and Circumstance', in *Ethics*, vol. 109, p. 164

⁸⁶ Dignity is here simply used as a term for being respected as a person. For a discussion of different senses of the concept of dignity, see Beyleveld, B., and Brownsword, R.: 2001, *Human Dignity in Bioethics and Biolaw*, Oxford UP

The instrumental value of autonomy, on the other hand, makes it a kind of good that attains value through the use that is made of it. As Russell Hardin remarks in this respect: “The value of autonomy must be contingent: we value it in our circumstances. (...) we cannot sensibly view it as the core value of our moral theory unless we are content with a hollow core.”⁸⁷ In much the same way as monetary value, the value of autonomy lies in relation to other goods: autonomy is the means at getting at these. This aspect of autonomy makes it complicated to weigh against goods that simultaneously lend value to autonomy.

Personal autonomy also seems vital for being a moral agent. It seems to be both a necessary and a sufficient condition for moral responsibility. It seems clear that a person not governing her own acts cannot be held morally responsible for them, just as her governing her own acts seems to justify us holding her morally responsible for them. Marina Oshana thinks this view is mistaken, because we fail to distinguish between two levels of autonomy at play here: “There is a tendency to conflate the *global* state of *being autonomous* with the *local* condition of *acting autonomously or exhibiting autonomy with respect to some act or decision*.”⁸⁸ The global or general condition of being autonomous should be distinguished from the local or specific decisions an autonomous person makes.

Global autonomy is not a necessary condition for making a person morally responsible for her acts. Even a slave or a small child will be held morally responsible for some of their acts, even though we do not grant them global autonomy. Local autonomy likewise is not a necessary condition for moral responsibility: A person could be morally culpable for unthinkingly committing an unethical act, instead of choosing her acts autonomously.

Oshana also argues that neither local nor global autonomy is sufficient for holding persons responsible for their acts. Autonomy is the ability to stand back from your acts and aims in order to assess and alter them if you want to. Does this ability suffice to ascribe moral responsibility to autonomous persons? Or is it the case that a person who understands the prevailing moral principles, but still disregards them without replacing them, nevertheless can be regarded as autonomous? Oshana would say that such a person exemplifies the fact that autonomy and moral responsibility require different competencies. She argues that a sociopath could be self-governing even though she recognises but repudiates central moral norms.¹

⁸⁷ Hardin, Russell: 1989, ‘Autonomy, Identity, and Welfare’, in John Christman (ed.): *The Inner Citadel: Essays on Individual Autonomy*, Oxford UP

⁸⁸ Oshana, Marina: 2002, ‘The Misguided Marriage of Responsibility and Autonomy’, in *The Journal of Ethics*, 6, pp. 261-80, p. 279

According to Oshana, we would ascribe autonomy to such a person, even though she would not be held morally responsible for her behaviour. However, Oshana's claim that the competence needed for being locally or globally autonomous might totally exclude recognition of the ethical aspect seems mistaken. We would rather say that the sociopath is autonomous in just a restricted sense. Receptivity to morality is an aspect of autonomy.⁸⁹

Autonomy versus well-being

Personal autonomy can be viewed as a purely neutral and *procedural* concept, which simply denotes the absence of any factors such as manipulation, coercion and irrationality in any decision-making process. Consequently, based on a purely procedural account of autonomy, it is possible to autonomously agree to conditions that will substantially restrict one's choices and have a marked influence on one's own situation – and still retain one's autonomy despite this. According to a *substantivist* account of autonomy, this implies a contradiction in terms: it is not possible to subject oneself to the will of others without compromising or fully negating one's autonomy.

In *PA* it is argued that a procedural conception of autonomy confuses autonomy with freedom of choice. For the substantivist, autonomy is about actually steering the course of one's life, while freedom is about doing whatever you like.⁹⁰ The substantivist account of autonomy implies that a person is autonomous if she has the capacity to take charge of her acts and aims, is in a condition to do so, and actually exercises this capacity. Whether a person's acts and motives are autonomous is to be judged by intersubjectively assessable conditions, rather than subjective assessments of authenticity.

⁸⁹ For an elaborate analysis of the importance and consequences of this intuition, see Wolf, Susan: *Sanity and the Metaphysics of Responsibility*, in John Christman: *The Inner Citadel*, 1989, Oxford UP), even though autonomous acts are not necessarily moral ones (This point constitutes a critique of the Kantian conception of autonomy from Sidgwick, see Guyer, Paul: 2003, 'Kant on the Theory and Practice of Autonomy', in Ellen F. Paul et al. (eds.): *Autonomy*, Cambridge UP, p. 78, and Oshana, Marina: 2006, *Personal Autonomy in Society*, Ashgate, p. 13). As noted by Joel Feinberg: " 'autonomy', if we construct the ideal carefully, might designate a necessary element in any full ideal of human character. But since it can coexist so comfortably with striking moral flaws, it cannot be the whole ideal." Feinberg, op. cit. 1989, p. 44

In a substantivist account, informed consent requirements in medical research may bring about a conflict between the interest that participants have in personal autonomy with the interest they have in liberty. Informed consent justified by the value of the autonomy of participants excludes both the use of general consent and the inclusion of research participants who fail to act in a way that adequately preserves their autonomy. Both general consent and inclusion of non-autonomous participants should rather be sought to be justified out of respect for their liberty and well-being.

To be cured restores one's well-being, but might also restore the autonomy of a patient. Respecting a patient's right to refuse a course of treatment on the grounds that not to do so would be to deny her autonomy might in the long run undermine that very same capacity for autonomy. This shows that respecting personal autonomy involves substantial as well as procedural judgements. The proceduralist would then demand respect for an autonomous decision, even if it undermines long-term autonomy, while the substantivist would opt for securing the person's long-term ability to make autonomous decisions. This difference in opinions reveals very distinct views of what it means to be autonomous, and how we are to respect the autonomy of a person.

Personal autonomy is neither necessary nor sufficient for an individual's well-being. A person might forgo her autonomy and allow her actions to be directed by more capable minds and hands, in order to enhance her well-being. Nor does living an autonomous life mean that you are living a fulfilling life. A statement to the effect that autonomy is vital to a life of self-realisation can be characterised either as an example of circular reasoning or as a debatable piece of anthropology. To argue that individual autonomy is indispensable for dignity and well-being is to forward an ideal rather than to provide an analysis of the relation between these concepts.

If we hold autonomy to be a vital component of a good life, autonomous living easily becomes a moral imperative. To overstate the significance of autonomy for human well-being might be detrimental both to autonomy and well-being, however, in the sense that it could have a negative impact on well-being itself and on our understanding of what conditions are necessary for the autonomy of others and ourselves - as when someone chooses suboptimal therapy in refusing to leave a medical decision to her physician, or when potential participants choose not to take part in a biobank research project that is needed to develop desirable therapies.

Varelius argues that, in the context of medicine, saying that the autonomy of a patient has intrinsic value to her implies that it is also acceptable for her to choose to take actions that are harmful to her. Since some instrumental rationality is required in definitions of autonomy, however, the patient cannot decide to act in ways that are harmful to her and still retain her

autonomy as this is conventionally understood. And insofar as decisions made by health personnel aim to yield the best possible result for the patient, the only reason for respecting a possible wish by the patient not to be treated, or to be treated differently, would be if the health personnel had a mistaken assessment of the optimal way to promote the patient's best interests.⁹¹ Varelius concludes that "the patient's autonomy should be valued only when, and to the extent that, it enhances their wellbeing. In other words, the primary value here is wellbeing, not autonomy."⁹²

Varelius says if we argue that autonomy is of intrinsic value, we do not get to the heart of the matter. The question of whether the patient should have the last word concerning her medical treatment depends on a subjective or intersubjective conception of well-being, not on whether autonomy is of purely instrumental value. Respecting someone's autonomous decision to be treated in a less than optimal way will result in harm being done to her health and thereby bring about an overall deterioration of the conditions of her autonomy.⁹³

In this way we could argue that not to respect a patient's autonomous decision could also be said to represent the best way of respecting and preserving her autonomy. Both choices aim to respect the autonomy of the individual involved, even if imposing treatment implies soft paternalism⁹⁴. To respect the autonomy of the patient consequently appears to justify both lines of action.⁹⁵ The salient point for Varelius, then, is whether a patient's *well-being* ultimately has to be assessed by the person herself, or by intersubjective criteria.

⁹¹ This line of argument is not directly susceptible to accusations of paternalism, if we accept that what is at stake here is nothing less than finding the optimal means to secure the subjective interests of the patient: providing the means to enable her to reach her aims.

⁹² Varelius, Jukka: 2006, 'Autonomy, Wellbeing, and the Case of the Refusing Patient', in *Medicine, Health Care and Philosophy*, vol. 9. See also Varelius op. cit. 2006

⁹³ Varelius, Jukka: 2005, 'Health and Autonomy', in *Medicine, Health Care and Philosophy*, 8: pp. 221-30

⁹⁴ For the distinction between hard and soft paternalism, see Feinberg, Joel: 1986, *Harm to Self*, Oxford UP

⁹⁵ Dworkin agrees with this when he remarks that "the body *is* me", (Dworkin, Gerald: 1988, *The Theory and Practice of Autonomy*, Cambridge UP, p. 133), a phrase which on the one hand implies that I have a special *right* to autonomy when it comes to the body, but on the other hand implies that I might have a special *duty* or obligation towards autonomy when it comes to the

Unfortunately, the line of argument adopted by Varelius does, however, beg the question of whether autonomy has intrinsic value – for if it has intrinsic value it would be instrumentally rational to pursue autonomy on its own merits, whereas if it does not it would not. Varelius’s thinking, however, rightly requires and emphasises that any claims to respect autonomous decisions have to be justified. This might be done by stating clearly how autonomous decisions related to an individual justification in a specific case and context have instrumental value, or how or why they represent an intrinsic good that ought to be respected. A general way of aiming to achieve the latter is by linking the value of autonomy with a right to privacy.⁹⁶

Positive and negative liberty

Autonomy can be a moral *ideal* in both a negative and a positive sense. The value of autonomy in the negative sense is that it enables freedom from social forces and oppression. As a key ideal of the modern era, this reflexive stance must in the end be balanced by a notion of the good, in order to avoid a total inability to act. The value of autonomy in the positive sense is to be seen as constituting part of a positive approach to life, in which choice and deliberation are essential components, irrespective of their consequences for optimising the life of the autonomous person. Autonomy in this sense is constitutive of a certain aspect of well-being.

To value autonomy highly does not, however, necessarily mean that one has to commit to the principle of acting (or having a *right* to act) autonomously in all situations in life. To try to arrange your life in such a way so that you have the ability to make autonomous decisions does not mean that you should always use – or even want to use – that ability. To strive for authenticity is not necessarily the same as consistently striving for autonomy; you might instead strive to make participation in group projects and decisions an important part of your identity – and as an exercise of your *positive liberty*.

A way to meet this challenge is to make the concept of autonomy denote more than just a way of protecting individuals against undue interference – and make it comprise of the moral and cultural idealization of a value which transcends the worth of the virtues it helps to enable, such as integrity, responsibility and privacy. Autonomy is valued as a goal in rearing children, education, and public attitude campaigns. This shows the close but ambiguous relationship between autonomy and paternalism: On the one hand, (soft) paternalism might aim to promote

body: To protect my body is to protect my autonomy, something which in turn might justify medical paternalism were I to oppose necessary and beneficial treatment for my body.

⁹⁶ In *RP* and in chapter 3 this particular issue is discussed.

autonomy; on the other hand, (hard) paternalism obstructs autonomy. As Jennifer Nedelsky has noted, “the most promising model, symbol, or metaphor for autonomy is not property, but childrearing”.⁹⁷

As argued later in *PA*, to require specified informed consent *is* to require the autonomous decision of any participant joining a research project. However, when is the autonomous decision to participate required, when is it not, and what kind of autonomy is implied? A question motivating the discussion of this chapter has been how, why and whether safeguards created through informed consent requirements are in the interest of the individual, if these requirements have an unclear justification and if they hamper fruitful biobank research?⁹⁸ Why should potential participants be able to veto their own participation and participants be autonomous, even when the well-being of participants is the responsibility of researchers?

If we believe that the individual is the infallible authority on what will be in his interest, this would provide us with a general reason to require informed consent. But, my idea of how I should be treated for my disease might not promote my interests at all, if I am confused in any way.⁹⁹ I might have a firm grip on my goals even if I am confused about the means to get there. To interfere with the means to make me reach my aims is different from interfering with my aims.

To view matters in this way seems to be rather contradictory in promoting the autonomy of the participant by paternalistic means. The concept of personal autonomy is, after all, the antithesis of the concept of paternalism. As argued in the *PA* article, personal autonomy is a relational concept: It signifies a certain relation to others - namely the absence of paternalism – rather than an individually attributable property. The intimate connection between autonomy and paternalism, however, creates the paradoxical nature of modern liberal post-WWII Western

⁹⁷ Nedelsky, Jennifer: 1989, ‘Reconceiving Autonomy: Sources, Thoughts and Possibilities’, in *Yale Journal of Law and Feminism*

⁹⁸ This question is different from the question of whether participants should feel morally, if not legally, obliged to participate in biobank research. That question is discussed in *NR*.

⁹⁹ Of course, the situation could also arise that the patient has interests which for her are more important than her health, which means that medical beneficence and patient autonomy might be at odds with each other. In this case, an appeal to give priority to the long-term (bodily conditioned) autonomy of the patient interferes with her aims (i. e. to restore her health), and not just the means to reach the aims. *See* White and Zimbelman, *op. cit.* 1998, p. 490.

culture: The valuing of the right before the good, the tradition of liberation, the imposition of autonomy, the exclusion of intolerance.

We saw an example of this in the analysis of justifying informed consent procedures by appealing to personal autonomy in *IC*. The field of bioethics in general is also illustrative in this respect, as pointed out by Bruce Jennings:

Bioethics has grown out and is unimaginable without the moral triumph of the open society: that is, a society respectful of individual rights and interests; dedicated to a moral style of reasonable moderation, compromise, and mutual accommodation; and optimistic about the possibility of creating and sustaining a system of individual privacy, freedom of choice, equality of opportunity, and ordered liberty under law. The open society tolerates pluralism and difference, to be sure, but only to bide the time. Ultimately, it believes in moral progress, ecumenicalism, and enlightened cultural convergence.¹⁰⁰

The twin concepts of autonomy and paternalism are mirrored in the distinction between negative and positive liberty. In the tradition of Isaiah Berlin, negative liberty signifies some sense of absence of external constraints, while positive liberty signifies some sense of self-control.¹⁰¹ Now, Charles Taylor argues in the essay *What is wrong with negative liberty?* that a purely negative concept of liberty leaves out the meaning of freedom in enabling us to reach our ends. And, as I might be mistaken in my real preferences, or letting a minor preference hamper my pursuit of a major one, internal obstacles can clearly obstruct my freedom, according to Taylor, just as well as external ones. Consequently, a first step is necessary towards a positive notion of liberty as the “ability to fulfil my purposes”¹⁰². This step implies that my freedom might depend on others liberating me from my inner obstacles in the form of misapprehensions or akrasia.

Taylor continues: “Whether we must also take the second step, to a view of freedom which sees it as realisable or fully realisable only within a certain form of society; and whether in taking this step one is necessarily committed to justifying the excesses of totalitarian oppression in the name of freedom, these are questions which must now be addressed.”¹⁰³ For Taylor, the

¹⁰⁰ Jennings, op. cit. 1998, p. 259.

¹⁰¹ See Berlin, Isaiah 1969: Two concepts of Liberty, in *Four Essays on Liberty*, Oxford UP.

¹⁰² Taylor, Charles 1985: What is wrong with negative liberty?, in *Philosophical Papers 2*, Cambridge UP, p. 229.

¹⁰³ Ibid.

notion of individual freedom must be able to be comprised both of freedom as an opportunity concept and an exercise concept. Positive freedom – freedom as an exercise concept – opens the way to the possibility of talking about “making oneself internally unfree” and “forcing others to be free”.

Autonomy versus freedom

This thesis places a strong emphasis on the relational aspects of autonomy and privacy. The connection between individual interests and rights on the one hand, and moral, civic and legal interests and duties on the other, is likewise a recurrent issue. Taylor’s view here might thus seem to fit in nicely. But the opposite is the case. A running theme of the thesis is rather that attempts to make autonomy – or freedom – comprise of the good, rather than being goods, is to conflate norms and ideals. As Berlin remarked on the concept of freedom: “It is one thing to say that I may be coerced for my own good which I am too blind to see (...) It is another thing to say that if it is my good, then I am not being coerced.”¹⁰⁴ To advocate liberty as a basic liberal ideal does not mean that it will never be in conflict with other important values. In order to get to the root of the values at stake, it seems better to attempt to bring out these conflicts by sharpening our concepts, rather than to overturning them by making more comprehensive concepts.

In *PA* it is argued that a conflation of notions of autonomy and freedom leads to a misleading justification of broad consent. Aspects of the paradoxes that result from the promotion of participant autonomy are described in *IC*. An attempt to synthesise autonomy and paternalism in a concept of positive liberty does not seem to be fruitful in this context. A decisive point regarding the tenability of a positive concept of liberty is whether the notion of internal bars to an agent’s freedom makes sense. If I am alone in the world, is it possible to say that I am not free to do something? Or am I merely unable to do things? The latter is implied by a concept of freedom, such as the *social responsibility view* of Kristján Kristjánsson, where my freedom can be restricted only by holding *somebody else* morally responsible for doing so.¹⁰⁵

Thus, according to Kristjánsson, the concept of freedom is irreflexible. Its aptness is illustrated by the example of Odysseus requesting to be tied to the mast: “If we deny the irreflexivity of freedom-constraining, we are forced to say that Odysseus had somehow plotted against his own future self, constraining its freedom, when the simpler and more reasonable thing

¹⁰⁴ Berlin, Isaiah 1969, p. 134.

¹⁰⁵ Kristjánsson, Kristján 1996: *Social freedom*, Cambridge UP.

to say is that the other sailors constrained his freedom, as he had ordered them to.”¹⁰⁶ In *PA*, the same example is used to show that Odysseus likewise is non-autonomous.

Concerning the relation between freedom and autonomy, Kristjánsson claims that freedom is not a condition for autonomy, and vice versa. In arguing for this view, he starts out by making a useful distinction between autonomy and autarchy, in which “the autonomous person actualises that which the autarchic person only has potentially. He is not only capable of reasoning, he reasons; not only capable of choosing, he chooses.”¹⁰⁷ This distinction brings out the complexity and ambiguousness of promoting personal autonomy, either in the sense of a substantial ideal, or as a matter of principle in the form of autarchy, or freedom. An example would be between insisting on participant’s autonomous decisions in asking for an informed consent, in contrast to assuming their autarchy as a norm.

Kristjánsson then goes on, unfortunately, to say that freedom is not a necessary condition for autonomy, because he takes autonomy simply to be an individual virtue, and that “unlike social freedom, autonomy is not an interpersonal relation.”¹⁰⁸ This view makes him say that a prisoner locked up in his prison cell might still be autonomous, if nothing prevents him from making reasoned choices. He is just prevented from acting on his choices. But this seems counter-intuitive. As argued earlier in this chapter, autonomy is about being self-governed in the social world, not just in the confinements of one’s mind.¹⁰⁹

Summary

This chapter emphasises the central position of individual autonomy in modern culture in general, and in giving justification for informed consent requirements in particular. It is argued, however, that the use of informed consent based on individual autonomy can neither provide a necessary nor a sufficient condition for legitimate recruitment for biobank research. The use of informed consent is described as having several possible justifications, but these either seem to fall back on the exercise of autonomy (as in waiving rights or avoiding liability), the responsibility of a research ethics committee (as in avoiding an unfavourable risk-benefit ratio), or just to be instrumental (as in showing respect or building trust). It is pointed out that in the case of requiring specific consent in biobank participation, if the risk element is perceived to be low, the

¹⁰⁶ Ibid., p. 106.

¹⁰⁷ Ibid., p. 127.

¹⁰⁸ Ibid., p. 136.

¹⁰⁹ For additional discussion of autonomy as a relational concept, see *PA*.

importance of autonomy must be high. In this context, the emphasis on specific informed consent, where the cost of requiring it is so high, thus underscores the high cultural value placed on individual autonomy. Individual autonomy is argued to be of both intrinsic and instrumental value, and thus to be important to well-being as such, and not just for instrumental reasons. The paradoxical paternalism of promoting personal autonomy is described, before the chapter concludes by describing and discussing ways of interpreting the status of autonomy as a good in relation to concepts of freedom.

The following chapter presents another way of looking at the justification for informed consent. The nature of the main risk involved in biobank participation, namely the potential of harm to the informational privacy of the participant, is discussed. This leads us to discuss other justifications of requiring informed consent for biobank participation than the promotion of individual autonomy as a cultural ideal.

Waiving rights to privacy

Since participation in a biobank is restricted to the use of tissue already procured by medical treatment, or minimally invasive procedures such as giving a blood sample, bodily harm is not a primary concern in this context. The primary concern is rather that biobank research involves collecting sensitive health information about participants and updating this through linkages to other medical and non-medical registers. In biobank research, the primary concern thus is that there needs to be protection against infringements of the *privacy* of research subjects.¹¹⁰

In the previous chapter, the interest of the participant in informational privacy was moderated, in order to bring out clearly the aspect of autonomy promotion. In this chapter, however, the interest – or maybe the right – of biobank participants in privacy will be scrutinised. The discussion of this chapter will show the interplay of views on autonomy and privacy on the one hand, and the justification of consent on the other. A crucial question will be to identify the rights to privacy involved in the context of biobanking, in order to be clear about how different kinds of research should involve the use of different kinds of consent.

The assumption of rights

A main aim of this thesis is to discuss, firstly, why and how biobank participants are to be respected, and, secondly, if, why and how citizens are faced with ethical, civic or legal duties to participate. The discussion of why and how biobank participants are to be respected deals with a certain assumption about an individual, namely that a person should – in some sense or another – have control over herself because she *owns* herself. Such an assumption harks back to the thinking of the principle of respect for the individual in terms of rights rather than of laws, as described by Charles Taylor: “The notion of a right, also called a ‘subjective right’, as this developed in the Western legal tradition, is that of a legal privilege which is seen as a quasi-possession of the agent

¹¹⁰ The notion of “harm” is used in a wide sense in this thesis, and comprises of both physical harm and infringements of integrity. In *NR*, it even extends to negative consequences of exposure to risk-information.

to whom it is attributed. (...) Law is what I must obey. (...) By contrast, a subjective right is something which the possessor can and ought to act on to put it into effect.”¹¹¹

The perspective of rights – or even “natural rights” – was discussed in the previous chapter on the basis of a picture in which every individual is the possessor of her body and information about herself. On the one hand, such a picture downplays the interpersonal aspect of moral obligations: If I am asked to provide blood samples for a biobank research project, I can make a decision all by myself, since I happen to *own* the blood in my veins. On the other hand, this picture emphasises the interpersonal aspect by making it the duty of the individual to govern her involvements with others –and vice versa: Since I own my blood, rather than it just being a part of my existence, I am supposed to control the uses to which it might be put. This way of answering the question of *why* biobank participants are to be respected leads to a discussion of *how* they are to be respected in terms of the aptness of different notions of ownership and control.

Another way of answering this question is in terms of a picture of a community of rational agents, in which the manipulation and coercion of any person would deny her rationality, and as such is incompatible with such a community. In this picture, which is described and discussed further in this chapter, individual control is linked to moral impartiality rather than to personal property. On the one hand, this picture emphasises the fact that every person should be respected as self-governing: If I am asked to provide blood samples for a biobank research project, I might make a good decision on my own, since I am an individual able to make reasonable choices. On the other hand, this picture downplays the personal – or private – aspect of governing oneself, by linking respect for an individual to the exercise of rationality in the sense of impartial decision-making.

Principled autonomy

The perspective of Onora O’Neill on the assumption of rights is to emphasise that duties precede rights.¹¹² She argues that you cannot claim anyone’s rights, without stating who has the duty to fulfil these rights. For instance, in order to claim the right to (better) healthcare, there might be a real sense that one ought to take part in sound health research, unless there are good reasons not to. O’Neill argues that the importance placed on autonomy in the bioethical debate, and the use of informed consent in medical practice, might “encourage ethically questionable forms of

¹¹¹ Taylor, Charles, 1989: *Sources of the self*, p. 11.

¹¹² See O’Neill, Onora, 2002: *Autonomy and Trust in Bioethics*, Cambridge UP.

individualism and self-expression, and may heighten rather than reduce public mistrust in medicine, science and biotechnology.”¹¹³ O’Neill thinks a better approach to securing sound ethical standards and the rights of the individual is to focus on obligations, because “(...) a right that nobody is required to respect is simply not a right.”¹¹⁴ Rights and obligations are two sides of the same coin. Rights without corresponding obligations are illusions at worst, ideals at best. To focus on obligations also brings out the relational nature of individual rights. It sheds light on how our autonomy is embedded in social settings and institutions, and on how these can enable and disable the exercise of our autonomy.

O’Neill bases her account of autonomy on the Kantian notion of the concept. Kant defined the notion of autonomy as *ethical*, in addition to and distinct from its *political* origins.¹¹⁵ The Kantian notion of autonomy is based on obligations, O’Neill points out, and for her it negates the notion of individual autonomy: “For Kant autonomy is *not relational, not graduated, not a form of self-expression*; it is a matter of acting on certain sorts of principles, and specifically on principles of obligation.”¹¹⁶ O’Neill calls this Kantian notion *principled* autonomy, which links autonomy to an adherence to principles instead of an attainment of independence.

According to O’Neill, principled autonomy connects to a kind of self-legislation – to oblige oneself to be led by ethical reasoning. O’Neill quotes Allen Wood, suggesting that this will lead us to a dilemma: If we are somehow obligated by ourselves, does such an obligation amount to much? Is it logically possible to obligate oneself to anything? This seems to be just an illusion, on par with the invention of a game where I am the only one who ever knows the rules. Or is it a description of the ideal of authenticity – our moral obligation to be true to ourselves? If we, on the other hand, say that this self-legislation is an obligation towards principles of reason that are somehow independent, does this not oblige us to accept the prevailing rationality, rather than my own will?

This dilemma will be avoided, however, if autonomy is neither a private obligation nor a commitment to common thinking, but rather the fundamental principle of reason itself. We are reasoning if we make it possible for others to follow us – in thought and in action. In that case, autonomy is the principle by which it is possible to give reasons at all. In O’Neill’s view, the fundamental requirements of an account of reason are “the necessary conditions that anyone

¹¹³ O’Neill, 2002, p. 73.

¹¹⁴ Ibid., p. 78.

¹¹⁵ See Schneewind, J., 1998: *The Invention of Autonomy*, Cambridge UP, esp. ch. 22 and 23.

¹¹⁶ O’Neill op. cit., pp. 83-84.

who seeks to reason with others must adopt. As Kant sees it, principled autonomy is no more – but also no less – than a formulation of these basic requirements of all reasoning. (...) we *must* act on principles others *can* follow. So there is no gap between reason and principled autonomy, and specifically no gap between practical reason and principled autonomy in willing.”¹¹⁷

Principled autonomy, then, requires us to act on principles that can be understood and acted on by anybody – in principle. Individual autonomy is a necessary, but not a sufficient, condition for principled autonomy. The notion of freedom involved here is freedom to act, independent of irrational influences. For Kant, causal independence – freedom from controlling impulses and plain coercion – is a more prominent condition for autonomy than social independence and self-expression. Principled autonomy requires mutual, and not just individual, understanding of the principles by which we guide our actions.

Universal moral principles and principles of reasoning are the essence of O’Neill’s conception of autonomy. Realised principled autonomy implies a common understanding between researcher and participants, and thereby promotes involvement and non-maleficence in medical research. Demanding independence rather than reasons might have the paradoxical consequence of weakening rather than strengthening the ability of the individual to autonomously pursue her own interests.

O’Neill’s concept of autonomy separates it from privacy. Principled autonomy is not about securing a private sphere of free choice, but about partaking in non-coercive intersubjective practises, and giving reasons in discussions. This means that justifying informed consent requirements out of respect for autonomy implies that participants should neither be coerced, nor unable to give cogent reasons consenting or declining participation. O’Neill claims that justifying informed consent requirements in terms of individual autonomy aims to secure both the well-being and the reflective choice of participants, but that in failing to connect autonomy with moral reason, it neither secures well-being nor reflection. Current informed consent practices based on individual autonomy just promote any choice, not specifically the ones that demand and defend the moral interests of the individual.¹¹⁸

Justifying consent by principled autonomy

Giving consent to become a patient or research participant (where others decide what happens to you) based on principled autonomy is thus about preventing coercion and abuse, rather than

¹¹⁷ Ibid., p. 92.

¹¹⁸ Ibid., p. 38.

about promoting individualistic autonomy. Autonomy should be seen to be a matter of adherence to moral principles, which is grounded in the autonomous recognition of these by the people concerned, and their mutual *trust* in each other to adhere to these principles. While autonomy as self-expression puts the emphasis on independent decision-making with reference to the (rights of the) individual, principled autonomy puts the emphasis on finding and acting from commonly accessible and assessable reasons. To justify informed consent requirements as the promotion of autonomy-based trust consequently seems to fit the principlistic conception better than the individualistic one. Informed consent justified by principled autonomy thus makes for legitimate biobank research recruitment in meeting both the demand of participants by promoting trust, and the demand of the Helsinki Declaration by securing informed and voluntary participation.

The adequacy of justifying informed consent under a Kantian conception of autonomy is also argued for in *Autonomy and informed consent: A mistaken association?*¹¹⁹ by Sigurdur Kristinsson. Kristinsson takes the aforementioned *Belmont Report* as his point of departure. As mentioned in chapter 2, the report states that informed consent is required in order to respect persons by respecting them as autonomous beings, understood as individuals “capable of deliberation about personal goals and of acting under the direction of such deliberation”.¹²⁰ Kristinsson now questions the moral justificatory power of the Belmontian concept of autonomy in general, and in relation to informed consent in particular.

Why should respect for people’s “deliberation about personal goals” be of basic moral significance, rather than just a fashionable idea, Kristinsson wonders. An attempt to link it with Kant’s Formula of Humanity¹²¹ will fail to capture Kant’s intention, if humanity is thought to be something more than the mere ability of rational agency. And, if autonomy is rightly understood as the Kantian *duty to oneself to be rational*, autonomy as the justification of elaborate informed

¹¹⁹ Kristinsson, Sigurdur, 2007: *Autonomy and informed consent: A mistaken association?* in *Medicine, Health Care and Philosophy* vol. 10, p. 253-264.

¹²⁰ The Belmont Report, 1979, *Ethical Principles and Guidelines for the Protection of Human Subjects of Research*, The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, sec. B1.

¹²¹ The formula of humanity as an end in itself is the version of the categorical imperative that says that you should act in such a way that you always treat humanity, whether in your own person or in the person of any other, never simply as a means, but always at the same time as an end.

consent procedures designed to secure the *personal* – but not necessarily rational - deliberation of *others* disappears. Kristinsson joins O’Neill in holding that justifying informed consent by Kantian autonomy means that “the ultimate point of informed consent policy is not to increase the incidence of personal deliberation but rather to decrease the incidence of manipulation, deception and coercion.”¹²²

In *NW* we find that a Kantian way of understanding and justifying informed consent requirements provides an accurate description of the views of our focus group participants in several important respects. Participants are concerned about the promotion of justice and the common good rather than a deliberation on personal ends. They are concerned about the making of trustworthy institutions for biobank research, rather than elaborate informed consent procedures. Most participants thought that ensuring that joining biobank research is purposeful and safe should be handled at the governmental rather than the individual level. That is, vital to the justification of informed consent procedures is respecting participants by excluding manipulation, deception and coercion, and to build a relationship of trust.

To argue that the justification of informed consent should be viewed in terms of avoiding harm, rather than as promoting the personal autonomy of the individual, means that its main function is to waive specific rights of the individual. This means that the norms grounding these rights, rather than the exercise of individual autonomy, are the real basis for the normative significance of informed consent requirements, as argued by Manson and O’Neill: “Consent (...) can be used to waive important norms, rules and standards, and so has considerable ethical importance. But since its use always presupposes whichever norms are to be waived, it cannot be basic to ethics, or bioethics.”¹²³ This view emphasises the relationship between the negative obligations of researchers not to manipulate participants or violate their bodily integrity, and the rights which corresponds to these duties.

Autonomy, perfection and neutrality

Another aspect at play here is whether the justification of informed consent requirements as a promotion of individual autonomy is compatible with the basic principle of liberalism, namely that of securing the equality of all citizens by letting the right precede the good. A *neutralist*

¹²² Kristinsson, *op. cit.*, p. 257. *See also* Kristinsson, S. and Árnason, V. 2007: Informed consent and genetic database research, in Matti Häyry et al. (eds.) *The Ethics and Governance of Human Genetic Databases*, Cambridge UP, p. 211.

¹²³ Manson and O’Neill, *op. cit.* 2007, p. 149

understanding of this principle would be that the state always should act in ways that are neutral between rival conceptions of the good, rather than to promote any(one's) particular and controversial conception of the good. The question is whether the emphasis on individual autonomy indeed can be given such a neutral justification, or if it is the promotion of the substantial conception of the good that is controversial.

The Millian justification for advancing the autonomy of biobank participants touched upon above seems to violate such a principle of neutrality. Rather than to respect a participant's right to handle his or her involvement with medical research as he or she wishes, it seems to impose an ideal of personal autonomy that involves an obligation to approve of the relevant research. Kristinsson argues that the promotion of individual autonomy not only fails to fulfil the ambition of identifying how participants in medical research should be respected as individuals, but that the promotion of individual autonomy in a liberal society is *in opposition to* respecting participants as individuals. The reason for this is that individualistic autonomy is a substantive moral ideal that is not compatible with the liberal principle of neutrality, according to which state regulations such as informed consent requirements "should be acceptable to all citizens, regardless of their comprehensive conceptions of the good"¹²⁴ Therefore, Kristinsson concludes, in order to respect individuals and the liberal principle of neutrality, a Kantian rather than a Belmontian conception of autonomy is called for.

To respect individuals and to treat them as equals does not necessarily mean treating them without favouring any particular notion of the good, however. It can also be argued that it should take the form of treating them according to the notion of the good that is thought to be superior. Liberal states often carry out attitude campaigns and economic incentives, numerous non-coercive but also non-neutral state policies in the form of public education. This aspect of the liberal state can be brought in accordance with the principle of neutrality if we distinguish a narrow neutrality principle from a comprehensive one.¹²⁵ In opposition to the comprehensive principle, which holds that state neutrality should extend both to the basic framework and the

¹²⁴ Ibid., p. 258. A procedural conception of personal autonomy, in which a person who has chosen to be led by others might still be deemed autonomous, will face a dilemma: Either it has substantive elements enough to justify informed consent as a means to secure Belmontian deliberation about personal goals, or it will lack these elements and collapse into a Kantian justification of informed consent.

¹²⁵ See Wall, Steven and Klosko, George (eds.), 2003: *Perfectionism and Neutrality*, Rowman & Littlefield Publishers, p. 6.

specific policies of the state, the narrow principle holds that neutrality is restricted to the constitutional structure of the state. According to a narrow conception, the state can legitimately promote an ideal of individual autonomy in non-coercive ways, even if such an ideal is controversial.

A central question of this thesis, in the most general sense, is the relationship between the state and its citizens in a liberal society. Research participants and policy makers all agree that this relationship should not be based on blind trust and/or unrestricted rights to intervention and access to information about citizens, as this would open the door to totalitarianism and the loss of citizens' freedom from paternalism and domination. The notion of principled autonomy does not promote blind trust, but it might nevertheless be susceptible to being regarded as a conceptual variant of positive liberty; "as soon as the autonomous self of the individual begins to be equated with the rational self as such (shared by all rational agents), a slide into paternalism begins."¹²⁶ A *liberal perfectionist* like Mill would argue that the promotion of a citizen's *personal* autonomy is essential to a liberal state. For the liberal perfectionist, respecting citizens as individuals is comprised of enabling the individual to deliberate on personal goals. It is not just to respect citizens through the shared obligations of principled autonomy, and to restrict state policies by the principle of neutrality.

In the Kantian conception of autonomy promoted by Kristinsson and O'Neill, an act is justified by the ability to back it with coherent rational and moral principles. In the Millian conception of autonomy, the moral obligation is *comprised of* the promotion of people's ability to develop and express their own character. The principlist emphasis on moral justification thus misses an important aspect, and makes it restrict itself to analysing the role of rationality in ascriptions of autonomy.¹²⁷ And the formal character of principled autonomy hands us a concept of autonomy that tends to presuppose rather than bring forth the way personal autonomy has certain substantial empirical conditions.¹²⁸

To insist that respecting people's autonomy is a general premise for morality and that respecting other persons as moral agents is well and good for the liberal perfectionist. But it still leaves an assessment of non-Kantian views and descriptions on the value of autonomy and ways

¹²⁶ Kristjánsson, op. cit., p. 142.

¹²⁷ Compare Hill, Thomas: *The Importance of Autonomy*, in *Autonomy and Self-Respect*, Cambridge UP 1991.

¹²⁸ See Guyer, Paul: *Kant on the Theory and Practice of Autonomy*, in Ellen F. Paul et al. (eds.): *Autonomy*, Cambridge UP, 2003.

of respecting other people – both people able to act autonomously as well as people unable to do so – in the best way in specific cases. The thin description of autonomy provided by principled autonomy does a good job of capturing the thinking of focus group participants concerning the liberty in taking personal responsibility for biobank research. A thicker description and justification of the way in which biobank research also is perceived by participants and policymakers alike to deal with the *private matters* of the citizens is still needed, however.

Biobanking and relational privacy

Participation in biobank research is a matter of providing information and allowing the researchers to build on this information, rather than allowing experiments to be done to your body. Biobank research is, in the words of Manson and O’Neill, *intrusive* rather than *invasive*.¹²⁹ This feature of biobank research makes the potential for physical harm negligible. Biobank researchers’ main interest in phenomena at the group level, and not at the individual level, moreover makes the potential for indirect harm to participants seem negligible.

The information collected about an individual in a biobank is, however, widely held to be *private* in some sense. It is not just gathered from those individuals: the idea is that it continues to belong to them. It is somehow *still part of their person*. The information contained in and by health registries and tissue samples in therapeutic and diagnostic biobanks, together with the information obtained when participants fill in a questionnaire and have their blood samples taken, are all taken to be information that somehow falls under the jurisdiction of the individual.¹³⁰ The collecting and collating of this kind of information is seen as something about which the individual should have a right to be informed, and which he or she can deny access to or otherwise control.

John Stuart Mill argued that the liberty of the individual is not only of instrumental, but also of intrinsic value, because everyone has the right to be sovereign in his or her own private

¹²⁹ Manson, Neil and O’Neill, Onora: 2007, *Rethinking Informed Consent in Bioethics*, Cambridge UP, p. 22

¹³⁰ Privacy is discussed in a quite general sense in this chapter and in *RP*. Attempts to show that there is a special ethical significance to privacy in connection with genetics is convincingly rebutted in Manson and O’Neill, *ibid.*, and in Nordal, Salvör 2007: Privacy, in Matti Häyry et al. (eds.) *The Ethics and Governance of Human Genetic Databases*, Cambridge UP

sphere.¹³¹ Mill thus establishes the intrinsic value of autonomy by an appeal to the concept of privacy. This harks back to the metaphor of people being self-legislative states that have home rule, and with borders that should be respected. Disrespect for an individual's privacy harms his or her autonomy, and is caused by illegitimate intrusion into the private sphere where individuals are sovereign.

In *RP* the relationship between autonomy and privacy is discussed in the context of the liberal society generally, and in biobank research specifically.¹³² In a liberal society, an individual's rights to autonomy and privacy also extend to biobank information. In article 8 of the European Convention on Human Rights, for instance, it is stated in paragraph 1 that "Everyone has the right to respect for his private and family life, his home and his correspondence."¹³³ In paragraph 2 this is, however, qualified rather strongly: "There shall be no interference by a public authority

¹³¹ Mill advances several kinds of argument in favour of promoting both the instrumental and the intrinsic value of individual liberty. (In this context we translate his discussion of "liberty" to be a discussion of "autonomy".) On the one hand, Mill says, society should aim to aid and stimulate its citizens to become autonomous individuals for instrumental reasons. Ideally, the choices made by the individual should be based on knowledge, free discussion and reflection. This ideal must be pursued, both for the good of the individuals and the State, for "a State which dwarfs its men, in order that they may be more docile instruments in its hands even for beneficial purposes – will find that with small men no great thing can ever be accomplished." (Mill, John Stuart: 1977, 'On Liberty', in *Collected Works of John Stuart Mill*, vol. XVIII, University of Toronto Press ch. V, p. 310) On the other hand, society has a duty to safeguard the intrinsic value of the autonomy of its citizens. "Over himself, over his own body and mind, the individual is sovereign" Mill writes. (Ibid., p. 224) Accordingly, persons should ideally be autonomous in their private sphere. And conversely, for Mill the possibility of individual privacy is essential to the realisation of autonomy. People should be left alone to be able to exercise and cultivate their autonomy. The right to privacy is also important for social autonomy: To illegitimately obtain and distribute private information hampers the ability people have to govern their relations to others, and consequently shows a lack of respect for their autonomy. Respecting the privacy of persons is thus justified by respecting their right to be autonomous. (See Lawrence, Gostin: 1997, 'Health Care Information and the Protection of Personal Privacy: Ethical and Legal Considerations', in *Annals of Internal Medicine*, vol. 127, issue 8, part 2, pp. 683-690)

¹³² This section offers a synopsis of *RP*.

¹³³ The European Convention on Human Rights, available at <http://conventions.coe.int>

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.”¹³⁴

The right to privacy is according to the Convention to be balanced against both the interests of the economic well-being of the country and the protection of health and morals. This leads us to ask how the right to privacy then supposed to be balanced against other interest. What kind of value is privacy thought to have? In the reasons for judgement given by the European Court of Human Rights in the case *Z v. Finland*, informational privacy in health care is argued to be of instrumental value:

The protection of personal data, not least medical data, is of fundamental importance to a person's enjoyment of his or her right to respect for private and family life as guaranteed by Article 8 of the Convention (art. 8). Respecting the confidentiality of health data is a vital principle in the legal systems of all the Contracting Parties to the Convention. It is crucial not only to respect the sense of privacy of a patient but also to preserve his or her confidence in the medical profession and in the health services in general. Without such protection, those in need of medical assistance may be deterred from revealing such information of a personal and intimate nature as may be necessary in order to receive appropriate treatment and, even, from seeking such assistance, thereby endangering their own health and, in the case of transmissible diseases, that of the community.¹³⁵

In the reasons for judgement given by the European Court of Human Rights in the case *Pretty v. Great Britain*, privacy is argued to be of intrinsic value in linking it to the concept of personal autonomy:

The concept of “private life” is a broad term not susceptible to exhaustive definition. It covers the physical and psychological integrity of a person. (...) Elements such as, for example, gender identification, name and sexual orientation and sexual life fall within the personal sphere protected by Article 8. (...) Article 8 also protects a right to personal

¹³⁴ Ibid.

¹³⁵ European Court of Human Rights, *Z v. Finland*, 1997-I, paragraph 95, available at <http://www.echr.coe.int/echr/>

development, and the right to establish and develop relationships with other human beings and the outside world (...) the Court considers that the notion of personal autonomy is an important principle underlying the interpretation of its guarantees.¹³⁶

It is clearly hard to point out what is matter of privacy. Here, labelling something “private” simply seems to add another layer of metaphor to those autonomous choices we should be able to make concerning relations with others, as Lloyd Weinreb has pointed out: “Strictly speaking, autonomy is not so much a right but rather is the condition of having any rights at all. Because it is possible at the limit, however, to deny personal autonomy, it is not seriously incorrect to speak of autonomy as a right. In the same way, one may speak of a right to a private domain, or to privacy, in the sense that, as a person, one has (a right to) a “space” in which he is autonomous. But the right thus identified does not specify at all the shape or dimensions of the space or what it contains. It adds nothing, except by way of metaphor, to a reference to autonomy itself.”¹³⁷ Weinreb’s observation can be illustrated by pointing to the standard grounding of the interest in or right to privacy, namely in terms of self-determination or well-being, which echoes the standard justifications of the interest in autonomy.

In *RP* it is argued that the most adequate perspective on the private matters relevant to biobanking is a *relational* one - rather than the Millian conception of the individual as sovereign over his own body and mind. To get this right we should distinguish between autonomy as home rule versus autonomy as self-governance. We do not grant each person the right to make autonomous choices because there are certain decisions that are inherently private matters. Which matters are regarded as private will vary depending on the specific social relation and cultural opinion.

One way of looking at the right to privacy is to argue that the closer you come to a person, the greater the burden of responsibility is on you to do so legitimately. In the world of medical research, this could be achieved through an agreement or principle along these lines: the nearer the permitted contact, the clearer and more explicit informed consent must be. This makes respect and legitimacy key approaches in establishing the required type of informed consent.

¹³⁶ European Court of Human Rights, *Pretty v. Great Britain*, 2002-IV, paragraph 61, available at <http://www.echr.coe.int/echr/>

¹³⁷Weinreb, Lloyd L.: 2000, ‘The Right to Privacy’, in Ellen F. Paul, Fred D (eds.) *The Right to Privacy*, p. 34

Autonomy may be regarded as a right, which taken together with the right to privacy, helps to constitute our understanding of what an individual is and secures her or his claim to be respected. The private realm of the individual might be a metaphor for personal autonomy, or more precisely for individual liberty. But an individual is not a territory. Rights to privacy are a social product, just as much as property rights are also made possible by society. Thus, it seems more useful to say instead that autonomy is valued because it is thought to be a good thing that people can freely and actively govern their acts and aims, whether these are “private matters” or not. Autonomy is more than just a way of protecting individuals against undue interference – it is the moral and cultural idealisation of a value that transcends the worth of the virtues it helps to enable, such as integrity, responsibility and privacy.

In promoting and attempting to uphold the privacy interests of those who take part in biobank research, it is argued in *RP* that that their interests should be related to the specific context of the provision and reception of health care with which participation in biobank research is connected. Rather than granting participants an exclusive right to or ownership of their health information, which must be waived in order to make biobank research possible, health information should be viewed as part of the doctor-patient relationship and in light of the moral rights and duties that accompany any involvement in a research-based system of health services.

Information about a person can be misused by companies, employers, or public authorities in order to control, deceive or harm. In a medical research setting, such abuse of power could take the following form: The participants of an epidemiological research project dutifully answer questions about their smoking habits, only to find out years later that this information is used to restrict their rights to free treatment for smoking-related diseases.

What makes the relevant information private here, however, is not its special relation to you, but the special relation it creates between you and someone else. By opening a bank account I enter into an understanding with my bank when it comes to my financial transactions. This information is private, meaning that the bank is obliged not to share this information with others, except under certain circumstances that I am aware of. The staff at the bank is furthermore obligated to handle this information respectfully – they should not read my bank transcript aloud as lunch entertainment, for instance. Any information should be handled securely by the bank and by me – we both have a responsibility not to let information fall into the hands of others, because of the potentially harmful consequences.

The reason why some sorts of information are more private than others is thus that they can have a negative impact on one’s relations to other people, and not that such information is in

itself inherently part of an “inviolable personality” and thus under the jurisdiction of the individual in every instance. The reason why we would want to avoid total surveillance is that we would want to avoid total social control. We do not want to be exposed either literally or metaphorically, because it harms our ability to enter into different kinds of relationships with different people.

Instead of trying to single out what does and what doesn't belong to our core self and what is therefore essentially private, a relational perspective sees privacy as something that depends on the relationships we enter. In this way, privacy does not have the status of an absolute right, but achieves value and is protected through various social relations. Privacy can be said to be more than an interest and less than a right, in the way that the keepers of privacy have an obligation to treat it as an absolute right within the relationship. The Hippocratic Oath can readily be understood this way: “All that may come to my knowledge in the exercise of my profession or in daily commerce with men that ought not to be spread around, I will keep secret and will never reveal.” This promise of secrecy exemplifies privacy in a way that exemplifies its relationship to confidentiality.

One of the problems of grounding a right to informational privacy is to identify which information is private *without circularity*, and on what grounds. How would, for instance, the view that I *own* my personal information work in terms of how I acquire such ownership, and what kinds of information does my ownership include and exclude? To single out certain kinds of information – for instance health information – as intrinsically private seems misguided, as the meaning of any piece of information is dependent on context. This general aspect of communication is emphasised by Manson and O'Neill: “Communication is a normative affair that presupposes a rich framework of *shared* norms, and shared background commitments (practical and cognitive), as well as the requisite *inferential* competences. (...) Acts of informing are typically inferentially *fertile*: telling someone one thing typically licences them to make many inferences.”¹³⁸

As remarked by Salvör Nordal, privacy has traditionally been conceived of empowering the individual to regain control of the private sphere threatened by intrusions made possible by new technology. Today, however, “information technology has blurred the line between the public and the private, making it important to protect not only sensitive or private information, but public information as well. The way to tackle this problem is not to undermine privacy, but to think about it in a new fashion. It requires, among other things, trustworthy institutions, which in

¹³⁸Manson and O'Neill, op. cit. 2007, pp. 65-66

turn need a strong public sphere.”¹³⁹ Today, a great deal of information about an individual is held by private and public institutions, and, as in the case of biobanking, even *created by* the institutions. It is consequently very complicated for individuals to keep track of and control their “personal” information in this sense. This makes the ethics of privacy consist not just of individual control (or the waiving of it by the use of consent), but also importantly to consist of safe handling and adequate use of the information.

In order to promote the specific privacy interests of participants in biobank research, it is important to locate and value these interests in their proper contexts. This context might be ambiguous. In the HUNT case, however, it is perceived by participants and researchers as a relationship between participants in a universal health care system that offers medical treatment based on research. The right to receive medical care could then be argued to correspond to a duty to take part in the maintenance of the system. In such a relation of mutual obligations, the relevant health information is private in the sense that the information should be handled with respect, it should not be passed on, and it should be ensured that its usage does not adversely affect or otherwise compromise participants in the system.

Authorisation and voluntariness

The perspectives of principled autonomy and relational privacy both emphasise the voluntariness of participants and the genuine trustworthiness of the institutions. In the case of biobank research, the unknown nature of future research projects and the significance of the findings for participants have, for instance, led the HUNT biobank to make a kind of general consent with continuously updated information of the on-going research projects available to participants. In this way the dichotomy between specific and general consent is transcended through the introduction of the dimension of *time*: Consent becomes a continuous, rather than a one-time, decision. This kind of consent could be called *processual*, or – as argued by Sigurdur Kristinsson and Vilhjálmur Árnason – an *authorisation*.¹⁴⁰

¹³⁹Nordal, Salvör 2007: Privacy, in Matti Häyry et al. (eds.) *The Ethics and Governance of Human Genetic Databases*, Cambridge UP, p. 189.

¹⁴⁰ Kristinsson, S. and Árnason, V. 2007: Informed consent and genetic database research, in Matti Häyry et al. (eds.) *The Ethics and Governance of Human Genetic Databases*, Cambridge UP. See also Arnason, V. 2004: Coding and consent: Moral challenges of the database project in Iceland, in *Bioethics*, 18:1.

According to Kristinsson and Árnason, an authorisation will, in a system of trustworthy and transparent institutions, safeguard participants from manipulation, and make voluntary participation possible. They argue that to require specific consent would be ineffective, burdensome, and even present a privacy risk, while general consent fails to meet the moral motivations for consent.¹⁴¹ Kristinsson and Árnason argue that the safeguarding of the voluntariness of biobank participants is a major moral motivation for informed consent requirements. The problem is, however, that “in contexts where relevant outcomes are foreseeable without being commonly known, potential subjects need to be informed in order for their participation to be voluntary. In contexts where possible relevant outcomes are poorly understood by even the researchers themselves, it is hard to see how participation can be voluntary.”¹⁴²

For Kristinsson and Árnason, both intentionality and control are conditions for voluntariness. Concerning intentionality, they state that: “Voluntary participation in research must be based on the subject’s awareness of all aspects of the participation that are relevant to describing the act.”¹⁴³ And, since “the only specific ingredient that could possibly be explained [when giving an informed consent to take part] is the right to withdraw from the database at any time”¹⁴⁴, the use of informed consent does meet the requirement of securing the voluntariness of participants. The possibility of declining to be included – and if included, to be given the permanent possibility to opt out – is a *necessary* condition for the voluntariness of research participation. But isn’t it, in contrast to the view of Kristinsson and Árnason, also a *sufficient* condition for the voluntariness of participation?

Rather than defining the concept of voluntariness in terms of intentionality, Serena Olsaretti defines voluntariness negatively in terms of options in this way: “A choice is non-voluntary if and only if it is made because the alternatives which the chooser believes she faces are unacceptable.”¹⁴⁵ For Olsaretti, the existence of *acceptable alternatives* is essential to

¹⁴¹ It seems, however, more accurate to say that, because of its nature (or more precisely because of the unknown future nature of the protocols), biobanking is unsuitable for the use of any form of *one-time kind* of consent.

¹⁴² Ibid., p. 206.

¹⁴³ Ibid., p. 205

¹⁴⁴ Ibid., p. 212.

¹⁴⁵ Olsaretti, Serena, 2008: The Concept of Voluntariness – A Reply, in *The Journal of Philosophy*, vol. 16, no. 1, p. 114.

voluntariness. This distinguishes voluntariness from freedom: I might be free to leave an island, but since I will die if I try get away by swimming, my decision to nevertheless stay on the island is non-voluntary, since no acceptable alternative is available.

Olsaretti's concept of voluntariness makes moral responsibility depend on voluntariness rather than freedom. I am not responsible for handing over money to a robber pointing at me with a gun, even if I am free to do so. But does the linking of moral responsibility to acceptable alternatives make acts done out of duty non-voluntary? If I am in a position to prevent a robbery in such a way that this is the only morally acceptable thing to do, do I do this non-voluntarily?

If that is the case, and moral responsibility depends on voluntariness, I am not responsible for acting in a morally laudable way. I just *had to* do it. Moreover, according to Ben Colburn, since I am not responsible for my way of acting, it makes my act ineligible for moral praise. This is contra-intuitive. This account, however, fits with the intuition that I am eligible to claim some kind of compensation for any damage to myself from the victim pointed out by the robber, again since I had to do it – I did not do it voluntarily.¹⁴⁶

In order to account for our intuitions in terms of her view, Olsaretti distinguishes between moral and substantive responsibility. I am morally responsible if I act deliberately and in a morally reasonable way, while I am substantively responsible if I act from moral obligations. Thus, if I prevent a robbery I am acting voluntarily in the sense that I recognise other acceptable alternatives. I choose however to act morally responsible in a deliberate way, and thus I am praiseworthy. On the other hand, I see that I have an obligation to act in a certain way – no other choice is morally possible – so I act substantively responsible and non-voluntary in this sense. I might be acting voluntarily from the perspective of moral responsibility, while the same act is non-voluntarily from the perspective of substantive responsibility.

Olsaretti's notion of voluntariness brings out vital elements of consent based on principled autonomy. On the one hand I should be voluntary in the sense of not being coerced,

¹⁴⁶ Colburn, Ben, 2008: The concept of voluntariness, in *The Journal of Political Philosophy*, vol. 16, no. 1, pp. 101-11 Colburn's solution is to say that I act voluntary even if the alternatives are *morally* acceptable. So, if I refuse to rob a bank purely on moral grounds, this does make me responsible for the continuation of my poverty. In this way my choice is eligible for praise, and I am responsible for the consequences. Colburn's view, however, seems to draw an unwarranted distinction between alternatives which are morally and prudentially unacceptable. He also seems to lead us back to an account of moral responsibility in terms of freedom rather than voluntariness.

which means that not taking part is a real and acceptable alternative. On the other I might perceive of my participation as a substantive moral obligation, which makes it involuntary in this sense. Olsaretti's notion of voluntariness as "acceptable alternatives" thus seems to offer a more intuitive way of describing the important element of non-coercion of consent based on principled autonomy, than the notion of voluntariness as "awareness of all aspects of the act" used by Kristinsson and Arnason.

Moreover, her notion of voluntariness is in accordance with the opinions of HUNT participants. They emphasise both the right to take part on the basis of trust in the biobank institution on the one hand, and the right not to take part without sanctions (for instance in the form of impaired rights to health care) on the other hand. Olsaretti's notion of voluntariness also seems to bring out in a precise way the justification of consent made by Hansson and Taylor – mistakenly in the name of autonomy – in *PA*: The absence of coercion and manipulation – but also the absence of a requirement to know the details of the research project.

Trust and negatively informed consent

In the last chapter it was argued that informed consent based on personal autonomy is neither a necessary nor a sufficient condition for legitimate biobank research. In *PA* it is argued that the exercise of individual autonomy is a necessary condition for informed consent. Is it, however, the case that giving informed consent is a necessary condition for being autonomous? Or can I be autonomous even if I do not give *specific* informed consent (even though it might be *implicit*)?

Sometimes an individual might want to give up her autonomy, and leave decisions concerning herself to others. Ulrik Kihlbom, however, argues that an individual's ignorance of the specifics of a research project does not have to compromise her autonomy. He aims to show that there is a way to leave decisions to others without giving up her autonomy. To do this he asserts the falsity of a common assumption of what the autonomous decision to give an informed consent requires, namely that "it is necessary that she has positive belief in the methods, means and risks concerned".¹⁴⁷ The assumption alluded to, and which Kihlbom finds illustrated in Beauchamp and Childress' *Principles of Biomedical Ethics*.¹⁴⁸, is that "to exercise one's autonomy is a matter of being the direct and intentional cause to what happens to oneself, and, in turn, the

¹⁴⁷ Kihlbom, Ulrik 2008: Autonomy and negatively informed consent, in *Journal of Medical Ethics*, 34, p. 147.

¹⁴⁸ Beauchamp, T. and Childress, J.: 2001, *Principles of biomedical ethics*, Oxford UP.

presupposition that this can only be the case if you understand and are aware of what is happening to you.”¹⁴⁹

For Kihlbom, the exercise of my autonomy does not necessarily depend on *positive* knowledge about the research project: It might be more important for me to have some crucial *negative* knowledge as to what the research project does not and will not include. *Negatively informed consent* in a clinical setting, accordingly, requires that the patient have a clear understanding of the aims of the treatment, but not the methods, difficulties and risks involved. He knows that the treatment is voluntary and that he can be given more information about – and withdraw his consent to – the treatment at any time. The patient who gives negatively informed consent not to receive more information regarding the treatment then explicitly chooses to trust the physician to promote the best possible treatment for him. This trust should be well-founded. For Kihlbom, “this rules out negative IC in situations where the physician and patient know little about each other.”¹⁵⁰

In Kihlbom’s view, a relaxation of the specificity of informed consent requirements might even turn out to *enhance* a patient’s personal autonomy. It is a bit unclear as to how this might work, but it seems that Kihlbom is thinking of a patient’s ability to reach his personal aims¹⁵¹, which indeed might be enhanced by someone else. He does not argue for Varelius’ view that autonomy in the end is merely of instrumental value, and as such might legitimately be overridden by the physician to promote a patient’s real interest – namely his well-being. But holding that trusting others to promote your ends might enhance your autonomy implies that the instrumental value of autonomy is important.

The crux of the matter, however, is the tenability of Kihlbom’s distinction between giving up autonomy and trusting others to make decisions for you. Kihlbom is correct in pointing out that “many of the means we use are we not familiar with. These states of ignorance do not

¹⁴⁹ Kihlbom, op. cit., p. 146.

¹⁵⁰ In requiring that personal acquaintance between patient and physician, and knowledge about the patient’s personal values, be a necessary condition for negatively informed consent, Kihlbom does not argue for Kristinsson’s view that principled autonomy is the justification for informed consent requirements that best secures respect for individuals.

¹⁵¹ See *ibid.*, p. 148: “If I, as the patient, choose to let you, as the physician, determine my treatment, and I have well founded beliefs that you will choose the treatment that best promotes my values, and that the risks of the treatment you will choose are in accordance with my attitudes towards different kinds of risks, I will exercise my autonomy, not waive my right to exercise it.”

threaten our autonomy.”¹⁵² Indeed, instead of saying that I must know all the health consequences of drinking the tea you are offering me, in order to make the autonomous choice to have tea with you, it is better to say that it is enough to have the well-grounded belief that you are not trying to poison me.

But this tells us something about the situations in which we employ the concept of autonomy, rather than about the relationship between autonomy and positive versus negative knowledge. Autonomous choices must be significant, and related knowledge – positive or negative – must be relevant to making such choices. Thus, neither general nor negatively informed consent is grounded in personal autonomy, *if* it entails that you leave significant decisions to others. If it does not, the consent is specific, since there are no further significant choices for the individual to autonomously decide.

Now, if personal autonomy is promoted as an ideal, an individual should learn to see the personal significance of more choices. This creates the paradox described in *IC*, in which participants see no problem in giving general consent, while the government pushes for more specific consent – *because the participants should recognise that there are still significant choices to be made*. From this perspective, Kristinsson and Árnason’s authorisation model promotes the autonomy of the participants by taking the possibility of future significant choices to be made by the participant into account.

In the case of HUNT, one might reasonably say that Kihlbom’s negatively informed consent quite accurately describes the idea a majority of the focus group participants expressed concerning their consent: Their idea of the nature of the research was vague, while their trust in the research institution to promote their interests in the form of the common good was firm. In addition, the renewed consent form of HUNT2 explicitly stated that no research using controversial methods was to take place.

Summary

Rather than as just to provide the opportunity to promote their personal autonomy, informed consent was in this chapter regarded also as the means to respect biobank participants on the basis of principled autonomy. The negative purpose of informed consent in making participants able to avoid harm (or indeed to avoid research participation) was thereafter emphasised. The main aim of informed consent was in this perspective argued to be a legitimate way for biobank participants to waive rights to privacy. The crucial question raised by this perspective, however, is

¹⁵² Ibid., p. 148.

when and whether biobank participants have any privacy rights to be waived. A consequence of the relational perspective of privacy is that the nature of the information depends on the relation it is a part of, and how it is put to use. This in turn determines the rights and duties concerning the handling of the information. Regardless of whether the justification of consent is viewed as promoting the control over private information, or in terms of avoiding harm, the question becomes whether the information in the relevant context is to be regarded as private. And in the case of certain kinds of biobank research, it is possible to argue that the relevant relation and intention is such that biobank information is not of a private nature. Thus the need for requiring consent will fall away. As argued by Manson and O'Neill: "Where research is non-invasive, as in the case of secondary research using anonymised data that have already been legitimately obtained and stored, nothing is done to the 'research subjects' to whom these data pertain and it may be hard to establish a case for requiring informed consent."¹⁵³ It is thus not possible to single out once and for all what kinds of information that is subject to personal control. The personal nature of any information is anyway not a sufficient condition for requiring consent to any use made of it.

¹⁵³ Manson and O'Neill, *op. cit.* 2007, p. 82

The common good and normative recruitment

From the perspective of conflict of interest between science and the individual, informed consent requirements seem to be an extra safeguard against abuse of the individual. But, if society ought not to treat the individual just as a means, does the individual have a corresponding moral commitment not to treat society just as a means? An affirmative answer to this question would emphasise the moral duty of participants in a universal health care system to take part in upholding the research-based medical treatment to which all have a right. This perspective would question the adequacy of the conflict model: Are the interests of individuals really different from those of science and society? And, even if autonomy is of value in protecting the interests of the individual, these interests do not need to be valuable or even permissible to promote. Everybody is worthy of respect as people, and their autonomous decisions should be respected. However, their decisions seem to command our respect only if through their decisions they respect everybody else. Exercising autonomy implies partaking in responsibility.¹⁵⁴

An important question in connection to this is how ownership and self-governance relate to arguments for making reasonable sacrifices for the common good, for instance by taking part in biobank research. This leads back to the discussion of if, why and how citizens are faced with duties to participate, and whether such duties interfere negatively with and limit rights to ownership and self-governance, or rather are a positive part of their realisation. Moreover, an important question is whether recruiting biobank participants by *arguing* that they have certain duties to take part weakens or strengthens their ability to make autonomous decisions concerning biobank participation.

This chapter will look into the concept of the common good in order to bring the question of research design back into the discussion of motivations for biobanking and biobank

¹⁵⁴ See Draper, Heather and Sorell, Tom: 2002, 'Patients responsibilities in medical ethics', in *Bioethics*, vol. 16, no. 4, pp. 335-352, and Stirrat, G. and Gill, R: 2005, 'Autonomy in medical ethics after O'Neill', in *Journal of Medical Ethics*, vol. 31, pp. 127-30

participation, as well as the adequacy of the descriptions of how the requirements of biobank recruitment could or should be justified.

The common good of medical research

In *NR* the normativity of promoting the common good by taking part in medical research is discussed.¹⁵⁵ Rosamond Rhodes and John Harris have both argued that we all have a general moral duty to participate in medical research, and there seems to be some truth to the view that when people are asked to take part in medical research, their choice is not completely morally neutral. In *NR* it is argued that the proper question to ask is *when*, rather than *if*, a certain moral duty to volunteer for medical research can be appealed to. It is suggested that normative recruitment is not just a question of principles and ethics. It is also a question of research design.

Rhodes argues that everybody should take part in research, because the vulnerable individuals in this context are the future patients rather than the present research participants. Rhodes intends to establish medical research as one of society's central tasks. From this perspective, the demand that all research be of direct benefit to participants undermines its social and long-term purposes. In the regulation and evaluation of specific research projects, it is important to focus on the quality of the research, and to maintain legitimate trust on the part of participants. By making participation the norm, the default position for Rhodes is that everybody can and will contribute to the common good resulting from medical research.

John Harris discusses the question of a putative duty to participate in research as a moral, and not a juridical or a political, question. He emphasises two principles in the article *Scientific research is a moral duty*, both of which he thinks commit us to a moral obligation to participate in medical research.¹⁵⁶ The first principle is our moral duty not to harm others. Harris argues that such harm is the consequence of declining to contribute to this kind of research. The second principle is the principle of justice, which results in the problem of the free rider.¹⁵⁷

¹⁵⁵ This section and the two sections below on “dugnad” offer a synopsis of *NR*.

¹⁵⁶ Harris, J. *Scientific research is a moral duty*. *Journal of Medical Ethics* 2005; 31: 242-248.

¹⁵⁷ Michael Hechter distinguishes among private, public, and collective goods. (In Hechter, Michael: *Principles of Group Solidarity*, 1987, University of California Press, p. 30-39.) The differences between these goods are their degree of jointness of supply and excludability: *Private goods* typically have no jointness of supply. If I eat an apple, no one else can eat it. Private goods are also typically exclusive. The owner of an apple has the rights of disposal of it. *Public goods* such

Harris does not argue in support of any legal duty to take part in research, but holds that these principles make it ethically problematic to refuse participation. To participate is required, both to contribute to the common good, as well as to be able to respect oneself as a moral actor. On the basis of this, it is possible to presume that a safeguarded participation also would be in the interest of those deemed to be without full competence to consent. Harris concludes: “There is then a moral obligation to participate in research in certain contexts. This will obviously include minimally invasive and minimally risky procedures such as participation in biobanks, provided safeguards against wrongful use are in place.”¹⁵⁸

Rhodes aims to make medical research a common good that is part of a larger social contract. Another way of thinking about this, however, is that such an understanding can be created for every research project. It is the research project – through its design, context and intention - that has to construct and establish the common good, in order to justify normative recruitment.

as clean air, on the other hand, typically have a jointness of supply. My breathing clean air does not prevent you from doing the same. Public goods are also typically non-excludable. Everyone has the right to the same clean air. To benefit from a *collective good*, you have to be a member of the group that has the rights of disposal of it. To make a public good collective, it has to be excludable.

Hechter points out that according to rational choice theory, it is rational to abstain from contributing to the production of a public good, since as a free rider you get to benefit from it anyway. This implies that “the more public a joint good is, the greater the obstacles to its production.”¹⁵⁷ The ability to enjoy a free ride can be eliminated by making those people who enjoy public goods pay for their production. The state can, for example, collect a universal tax covering all expenses involved in keeping the air clean. Another way to promote the production of a public good is to make it excludable by legal or technological means, such as encoding formerly publicly available television signals. In this way private or collective goods are created.

A group that produces and benefits from a collective good is likely to have a high level of group solidarity, in the joint making and enjoying of their collective good. Groups producing or benefiting from private or public goods are likely to have less or no solidarity. They are paid to produce, or are rivals to enjoy, private goods with no jointness of supply. Alternatively, they make, or simply benefit from, public goods that are open to free riders.

¹⁵⁸ Harris 2005, p. 247.

Solidarity and the common good

What is meant, however, by these allusions to the common good? Which kinds of good can be common, and in which kinds of ways? What distinguishes different kinds of organisations and solidarity aimed for protection and promotion of the goods deemed common?

Mark Murphy distinguishes between three conceptions of the common good: The instrumentalist view, the distinctive good view, and the aggregative view¹⁵⁹. Hobbesian solidarity can illustrate the *instrumentalist* conception. For Thomas Hobbes, everybody is able to live peacefully by giving a sovereign the task of securing societal peace. The motivation for this agreement for each and every one is to promote his or her interest in personal security, in a way that only accidentally benefits everybody. The *distinctive good* conception can be illustrated by team sports¹⁶⁰, in which the motivation for participants is the success of their team. The success of a team player is defined by his contribution to the success of his team: A soccer player cannot win the World Cup, but his national team can. The *aggregative* conception can be illustrated by the Millian promotion of liberty. John Stuart Mill argues that the protection of personal liberty will allow the State to prosper in allowing its citizens to flourish. Liberty in this way is a common good, which is the sum of the amount of individual liberty.

Murphy thinks that both the conceptions of the common good as instrumental and distinctive lack essential features contained in the aggregative conception of the common good. The instrumental conception is parasitic upon the aggregative, Murphy argues, in that the aggregative level is necessary in order to point out a common good as *common*. The instrumentalist motivation for realising a common good might be different for every participant, for example that everybody just cares about his or her own profit. Thereby the community aspect of the good will be an illusion or unaccounted for.

The instrumental conception further simply presupposes the way in which the common good is defined by the group rather than individuals, as pointed out by William Rehg: “Whereas the instrumental associations form on the basis of pre-existing understandings of the good, life-world solidarities depend on a mutual understanding that individuals can achieve and sustain only by joining the group and taking up its practices.”¹⁶¹ For Rehg, a *voluntary instrumental association*

¹⁵⁹ Murphy, Mark: ‘The Common good’, in *the review of metaphysics*, 2005, vol. LIX, no. 1, p. 136.

¹⁶⁰ See Rehg, William: ‘Solidarity and the Common Good: An Analytic Framework’, in *Journal of Social Philosophy* 2007, vol. 38, no. 1, p. 12.

¹⁶¹ Ibid, p. 13.

exemplifies the kind of group pursuit for the common good for which an instrumental conception of the common good is able to account.

Voluntary instrumental associations are formed in order to achieve an individually valued good, like establishing an insurance system. The group is brought and held together by parallel individual conceptions and pursuits of a good, like the protection of one's property. The good that is promoted is not necessarily identical for each member of the group: Every policy-holder might just care about whether his or her own property is protected. The motivation to promote the good is also independent of any association with the group. In other words, such a group presupposes the identification and appreciation of a *converging*, but not a *common*, good. In this way the instrumental – unlike the aggregative – conception for Murphy is insufficient for characterising a good as common, or characterising goods that just appear to be common.

On the other hand, according to Murphy, the intuitive appeal of the distinctive good conception of the common good rests on an ambiguity. It can be taken to mean that the common good by itself is social, or moreover that only groups can benefit from it. Concerning the first meaning, Charles Taylor points out that there are “two ways of defining irreducibly social goods: (1) the goods of a culture that make conceivable actions, feelings, valued ways of life, and (2) goods that essentially incorporate common understandings of their value.”¹⁶² For Taylor, all goods have an irreducible social dimension because language and culture are partly constitutive of any human good. A common good such as friendship is not decomposable into individual goods, and presupposes a common understanding of its value: It is not possible to conceive of me being your friend if you do not share my understanding of us being friends.

Murphy contends that the aggregative conception of the common good has no problem with endorsing the idea that goods are irreducibly social in Taylor's sense. For Murphy, this sense concerns the fundamental constitution of any good rather than the distinctive feature of common goods as opposed to other kinds of goods. The aggregative conception excludes, however, endorsing the second meaning of the common good as basically social; that a common good is of value for a group rather than for individuals. Murphy argues that the sense in which one can say that something is good for a team or an institution is derivative from the participants' appreciation of the relevant good. To say that something is good for a football team is nothing more than a metaphor for the sum of the good experienced by the individual players. In this way,

¹⁶² Taylor, Charles: 'Irreducibly Social Goods', in *Philosophical Arguments*, 1995, Harvard UP.

Murphy concludes that the distinctive good conception of the common good presupposes the aggregative conception, just like the instrumental conception of the common good.

Rehg takes issue with Murphy's conclusion. He argues that social units such as sports teams create and define goods that can only be enjoyed by the individual as part of the team, rather than being the aggregate of individual goods. The common good is enjoyed by the social unit in more than a metaphorical way, Rehg argues; "the common good of excellent teamwork is irreducibly social because (1) it is predicated of and perfects the team as a whole; (2) it is logically prior to the identification of individual excellence; and (3) it conditions the pursuit of individual goods."¹⁶³ In team sports, the players might not just depend on being part of a team, but depend on their particular team-mates to bring out their best and achieve excellence. Adding players with better individual qualities to a team does not have to make the team play better, because of a lack of synergy effects. Destructive group dynamics might even make the team play worse. The players are also committed to forsake their own interests in order to win a competition, and to make possible the partaking in the team's celebration of the victory.

It is *as a particular group* that the common good is both created and enjoyed. The aggregative conception of the common good thus puts the cart before the horse: It is unable to accurately describe the way in which this kind of good is genuinely common, as qualitatively distinct from the aggregated goods for and of the individual.

The concept of solidarity implies a certain social unity of purpose within a group, and a readiness to help others in the group. For Rehg, solidarity and the pursuit of common goods require that the members of a group "understand and value their belonging to the group"¹⁶⁴. This characterises what he calls *intentional groups*, as opposed to random groupings of people in *crowds*.

The members of a crowd have no project that unites them, while the members of the voluntary instrumental association do have such a project. Rehg claims that such an association might be said to display the minimal amount of shared intentionality required for solidarity, even if its members take part primarily for purely instrumental reasons. This, however, seems to be a false approach. An ascription of solidarity presupposes a social and not just an individual motivation for forming and joining a group. If the members of a group just take part to promote their own pre-conceived interests, then they pursue a converging but not a common good. In line with this, Rehg quite rightly goes on to say that the more a project belongs to a group, rather than

¹⁶³ Rehg, op. cit., p. 13.

¹⁶⁴ Ibid., p. 10.

the individuals, which defines the common good, the more the group promotes solidarity and the common good.

HUNT as a dugnad

In *NR*, the idea of promoting the common good by taking part in biobank research is explored by taking a closer look at HUNT in light of the Norwegian concept of “dugnad”. The concept of dugnad would classify as a “voluntary instrumental association” in the Rehg’s sense, which promotes a converging – rather than a strictly common – good. A standard definition is that “dugnad is when the neighbours of a farmer gather at his farm to help him, without getting paid, to accomplish a large task”.¹⁶⁵ The traditional dugnad concept excluded communal and legal duties, and singled out the kind of informal duty to take turns in helping one another. The dugnad institution relied on a mutual understanding of reciprocity between economically equal farmers, and the “relation of reciprocity comprised of generations”¹⁶⁶.

The activities nowadays called “dugnad” are different from the original dugnad work, but share certain aspects of the “good old” dugnad or maybe just the “dugnad spirit”. The *dugnad spirit* denotes that the values of liberty, equality and fraternity are actively promoted by a group and its members in freely committing themselves to work together as equals for the benefit of all. Present day dugnad is first and foremost associated with volunteering to do unpaid work for the common good. The dugnad spirit is then seen as a manifestation of an unselfish attitude that runs counter to a disintegrating society based on purely contractual relationships, and emphasises a spontaneous solidarity that is seen as both a moral ideal and the glue of society.

In the context of biobank research, this conceptual analysis leads us to the question: How does the concept of dugnad work as a description of participation in medical research in general and biobank research in particular? The word “dugnad” does not explicitly appear in the official information material for HUNT. But the *dugnad spirit* is evoked in the way that HUNT motivates people to participate. An information folder for HUNT3 contains a request to give “each other an hour for better public health”. This refers to the time it takes to complete the HUNT questionnaire and give a blood sample. The participants contribute, from this perspective, mainly by giving their *time*. The risk of participation is conceived of as negligible, and participants are not

165 Østberg, Kr., 1926: ‘Dugnad’, in *Norske Folkeskrifter*, no. 71, p. 3.

166 *See* Norddølum, Helge, 1976: ‘Dugnaden i det førindustrielle samfunn’, in *Dugnad*, no. 2, p. 68 Also published as Norddølum, Helge, 1980. ‘The “Dugnad” in the Pre-Industrial Peasant Community. An Attempt at an Explanation’. *Ethnologia Scandinavica*, pp. 102-113.

asked to make huge sacrifices: they will leave the research centre in the same shape as before – except without a few centilitres of blood.

From this perspective, participants are primarily asked to do a bit of *unpaid work*: to show up and take time to answer questions and allow for health data and a blood sample to be obtained. It is *work* in the sense that participation is not for personal health purposes: no individual feedback is provided on the basis of biobank research findings. When participants have done their share, the job is done. In this way, participants are considered to be contributing as *citizens* rather than as *patients*. Moreover, the work is *unpaid* in the sense that except for the free brief health check, there is no compensation given to participants.

HUNT could be said to be a *dugnad* in the modern sense of being a *gathering of people to do unpaid work for some kind of common good*. HUNT could also be said to be a *dugnad* in the traditional sense of offering an *intergenerational system of reciprocation between equal parties*: No HUNT participant is more important than another, everybody contributes in more or less the same way, and everybody can expect the same kind of possible benefit from the research from an intergenerational perspective.

The normativity of research recruitment

The principles of the Helsinki Declaration are both meant to secure the autonomy of potential participants, and to protect from them from harm. It is thus important to guarantee that no one is deceived or coerced to take part. The crucial question, then, is whether and when normative recruitment implies the deception or coercion of individuals, which would thereby make it illegitimate. Is it possible to defend an ideal of free and informed decisions by all potential biobank participants as to whether or not to take part, if participation in the research project in question is presented as morally laudable or obligatory? Is it legitimate to appeal to the *dugnad* spirit in recruiting people for HUNT?

The Helsinki Declaration and Harris agree that a fundamental principle of medical research is that participation is voluntary, and that no one is invited to take part in research with an unfavourable risk-benefit ratio. Granting this, one starting point is to say that any medical research should identify the dangers and the interests of participants and society in the project, in order to be able to state these dangers and interests clearly in the invitation to take part. It would now be unethical for researchers to invite individuals to take part in a study in which they did not think the invited really should take part. In other words: Researchers who invite people to take part in a project not only generally *have* an interest in a high participation rate; it is more precise to say that researchers always *should have* an interest in a high participation rate. Researchers are

obliged to think that it is in everybody's interest that everyone who is invited will choose to take part, provided that the stakes is not too high both regarding the risk of taking part and the risk not to take part. But in that case, the research in question clearly does not fill the criteria for being a dugnad.

The dugnad model is demanding in its aim for a collective consensus on the need and legitimacy of the research, and the moral duty to take part. This puts normative pressure on the invited participants and the project designers alike. The importance of being precise in terms of the justifications used must again be stressed. Autonomy does not presuppose absence of constraints, and might be enhanced by normative recruitment. But autonomy is negated by coercion and manipulation. Making biobank research a legal duty might promote the interests of participants, even if it negates their local freedom:

A theory which claims that we are only free if we are participating actively in a communal project, that we make ourselves unfree by not doing so, and that certain constraints imposed by society are not real constraints at all, is not a viable candidate for an account of social freedom. (...) a person often undertakes commitments which, through someone else's agency, will restrict his freedom, not because he is forced to do so, but because he wants to; because he prefers some other value to certain liberties.¹⁶⁷

This of course brings us back to the question of when and whether it is legitimate to make research participation a civic or even a legal duty. To present a medical research project as a dugnad should in general be undertaken with extreme caution, as it is a strong rhetorical device that might blur reflections on personal risk, as well as the nature of the common good involved. This puts great normative pressure on the research institution and the relevant governmental bodies. They have to ensure and be sure that a project meets the criteria of being a dugnad. Only if these criteria are met is the invitation to take part in a research dugnad valid; only if these criteria are met is this use of normative recruitment legitimate.

Given a transparent and informative process of voluntary recruitment, research institutions depend on the trust of potential participants. This makes an appeal to the dugnad spirit a double-edged sword: If research projects are conceived by participants to rightly deserve the dugnad label, it might improve the participation rate, but if the project is seen as not deserving the dugnad label, it might mean that participants lose their trust in the project

¹⁶⁷ Kristjánsson, *op. cit.*, pp. 140-1.

altogether. Rather than being a simple way to recruit people for research, normative recruitment is a demanding way to recruit volunteers for a transparent project that relies on trust.

Normative recruitment might nevertheless be a way to make clear the mutual duties of a research-based health service, and its potential patients and research participants. This might promote rather than hamper the ability of participants to make an *autonomous* decision as to whether or not they should take part. Normatively neutral recruitment might downplay ethical aspects of the research, such as urgency and justice, because people are simply invited in a neutral way and may participate if they want. Nobody has said that they should take part, so the motivation to autonomously question the ethical aspects of the relevant research is significantly lower.

Normative recruitment is a powerful rhetorical device. Medical research is not in general a *dugnad*, and normative recruitment is not in general legitimate. Appeals to civic duty, membership, “*dugnad*”, and solidary work for the common good all need to be justified in the research design. The *dugnad* concept gives a normative model that offers the opportunity to understand how a specific research project should be designed to support a perceived moral obligation to take part. Ignorable risk, ignorable inconvenience and a common good that addresses each person as a member of a community rather than just an individual, are core elements in the *dugnad* design. Normative recruitment should be seen as legitimate in these cases. That the criteria essential to the legitimacy of HUNT coincide with the criteria to qualify as a *dugnad* shows the potential suitability of such an approach.

Several reasons can be given for promoting participant freedom and authenticity, and these aims could be achieved without requiring informed consent. The voluntariness of the participants can be promoted by the ability to take part or not, without requiring autonomous decisions. The liberty, trust, identification and dignity of participants do not require promotion of autonomy, but can be promoted by high-quality research, respectful attitudes towards participants, safe and discrete handling of their contributed material, reliable handling of the relevant ethical and political issues including protection of participant interests, and openness about the means and the aims of the research projects.

Summary

An important message of all the articles of this thesis – but especially of the *NR* and the *IC* article – is to suggest that as early as the design phase of a project, researchers should reflect on the relationship of their project to the community of potential participants and to the common good. This will imply a “*politicisation*” of medical researchers and medical ethics desired by researchers

and participants alike, which would be fruitful for the ethics of biobanking. In the model described in this chapter, the importance of the research design for the legitimacy of normative recruitment is emphasised. Few medical research projects will be able to meet the standards proposed here, but quite a few biobank research projects, perhaps. In *NR*, however, a biobank research project which did not meet these standards is described.

The main message of this thesis is the importance of thinking with *precision* of the ethical issues involved in biobank research. This plea for preciseness is in a way the very *raison d'être* of this thesis: If the solution to any ethical problem of biobank research is to make sure that if we err, we err on the side of overextending the scope of participants' rights and/or autonomy, there would be no ethical problem to solve. Rather, biobank ethics would be a matter of finding ways to promote, rather than merely secure, participants' rights and autonomy.

There *is* indeed no dilemma of biobank ethics in the sense that it is an open question how to balance the *rights* of the individual against the interests of society. Society cannot legitimately forsake the rights of the individual not to be harmed, in order to benefit the common good. The basic principle of research ethics, namely that concern for the interests of the individual should always prevail over the interests of science and society, as stated in paragraph 5 of the Helsinki Declaration, is non-negotiable.

However, biobank research does aim to promote an important common good, namely the possibility of better public health and health care. This presents a challenge to interpret the principle of paragraph 5 in a precise way in the context of biobank research. Should the principle be interpreted to imply that it is sufficient to protect persons from actually being harmed, or from commonly recognisable harm? Or, should the interpretation be understood as a kind of precautionary principle, and extend to also cover protection from potential harm? Should it protect from harm objectively or subjectively conceived?

This thesis defends the view ethically sound biobank research should be secured by applying an interpretation of protection from harm that puts the emphasis on the identified risks of the actual use made of the biobank material. It is argued that viewing biobank material as the private property of the individual might lead one astray: Privacy rights are dependent on the use made of the relevant information, and the rights and duties involved in the relevant relation of confidentiality. It should be clear which rights are invoked by exploring the nature of the actual involvement requested of the research participant.

Concerning consent requirements in biobanking, they are, on the one hand, a way to deal with *rights*, such as the right not to be harmed. If consent is justified by the waiving of individual

rights, the importance of identifying the norms which ground these rights is emphasised in this thesis. On the one hand, consent requirements are a way to balance the *interests* of the individual against those of the society: If consent is justified by the promotion of personal autonomy, the value of autonomy should be clear. It should also be clear what autonomy means, and stands in opposition to. In this thesis it is argued that the exercise of personal autonomy implies an obligation for the individual to make the choices deemed to be of significance, but that the exercise of autonomy does not presuppose the absence of normative pressure.

The question posed in the introduction can now be repeated: Provided that the participants have already decided to volunteer for biobank research, is it in anybody's interest to go through repeated rounds of providing consent for new projects? The ethical challenge is to answer this question by identifying the relevant norms grounding the duties and rights and by clarifying the values involved. On the basis of such identifications of interests and rights, the appropriate measures for securing them can be found. In the interest of the common good – like making research to the benefit of public health possible – misguided or exaggerated measures should be avoided.

To require fully explicit and specified consent for participation in medical research is a case in point here: As argued in *RP* and in the previous chapter, the content of any information is dependent on context. This makes the very idea of being fully explicit in any kind of communicative act futile: “Once we grasp that all communication is partial, is rooted in background knowledge and inferential competences, we see that the ideal of a ‘fully explicit’ consent is nonsense.”¹⁶⁸ This general point implies that preciseness, rather than completeness, is an ideal of biobank recruitment and consent requirements. The articles of part 2 should be read with this view in mind.

¹⁶⁸ Manson and O'Neill, *op. cit.* 2007, p. 67

Part 2

Not worth the paper it's written on? Informed consent and biobank research in a Norwegian context

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Abstract

In January 2003 the Norwegian Parliament passed the Biobanks Act, regulating biobank research in Norway. There have been strong differences of opinion both in the process of making the law as well as in its first years of implementation. The main controversy relates to what kind of informed consent should be required for biobank research. Central to the controversy over current interpretations of the Biobanks Act is the informed consent given by the donors to the biobank of the Nord-Trøndelag Health Study (HUNT), and whether the consent given 'was worth the paper it was written on'. This article traces the history behind the informed consent procedure of the blood samples in the largest research biobank in Norway, the HUNT biobank. Second, findings from a focus group study with biobank participants are presented. Third, a philosophical analysis is made of the concept of informed consent in light of the findings from the focus-group study as well as the history behind the HUNT biobank. Findings from the focus-group study show that the consenters base their participation on trust in the researchers and the regulation of research in Norwegian society, rather than on specific information on the research in question. The history behind the HUNT biobank fosters trust. The story provides a strong case for not limiting the debate to legalistic and formalistic ethics but also including a research ethics that says that process and trust matter. Otherwise no informed consent in medical research is worth the paper it is written on.

Key words

Informed consent, biobanks, trust, focus-groups, Norwegian context

Introduction

Informed consent is an essential part of clinical research, as a means of securing the autonomy of research subjects. In research such as a randomized controlled trial individuals exercise their autonomy by giving their voluntary, explicit and written consent to participate in a research project, based on specific information about the aims and procedures of the project. They do so knowing that they can opt out of the project at any time, without having to explain themselves. Although there are critical issues related to this kind of consent, such as what constitutes sufficient and comprehensive information, there is little debate over this procedure as good ethical practice in clinical research.

In contrast to this, there is at present substantial controversy regarding the role of informed consent in biobank research. An indication of this is the fact that there is incoherence in the jurisdictions regulating biobank research across several European countries (Kaye et al., 2004).

Simply put, the source of this controversy is the fact that biobank research differs from clinical research in a number of important ways. Whereas clinical research has specific aims, the aims of biobank research may be vague or non-existent at the time of the participants' donation to the biobank. Hence, the acceptability of consent given on the basis of general information about the research purpose is among the themes of the current debate.

Another related issue is whether donors should give renewed consent whenever a new, specific biobank project is being designed. The issue of debate here is the feasibility of such procedures, as a likely outcome would be that the donors will find such a repeated procedure tiresome and stop responding, thus in effect bringing biobank research to a halt. An option within the frame of renewed consent would be passive consent, where the donor receives the information and only acts if she/he wants to opt out of the research project. The acceptability of this latter option is another issue for debate, as it is dubious whether such procedures fulfil the requirement of explicit consent.

Furthermore, no biobank research is being done on individuals but is being undertaken on blood or tissues that have been sampled from these individuals, implying that there is little risk of physical harm to the donors. Rather, the potential harms are those of breach of privacy, confidentiality and reputation. It can thus be argued that there is only minimal risk involved, which could imply that this kind of research may be done without the donor's informed consent. If so, this would be to put biobank research on a level with register-based epidemiological research, where no explicit individual consent is required, only presumed consent.

These are but some of the ethical challenges under debate in relation to biobank research, but they are the issues we aim to cover in this paper. Much of the current debate on the status of informed consent in relation to biobank research has been related to the biobanks in Iceland, the United Kingdom and Estonia. In this paper we shall contribute to the debate through the presentation of a Norwegian case, including an empirical study on the ethical reflections of the participants in biobank research.

The HUNT biobank

In the county of Nord-Trøndelag, in the middle of Norway, there have been two extensive health surveys (HUNT 1 and 2). Both have been well supported by the population, with participation rates of 88.1% and 71.3% of the adult population, respectively (Midthjell et al., 1999). This, together with the fact that the Nord-Trøndelag population is stable and homogenous, has been presented as making the data from these surveys well suited for epidemiological studies, including functional genomics (Holmen et al., 2003).

As part of HUNT 2 (1995–97) blood samples were taken from 65, 291 adults. These samples were subsequently frozen at minus 70C, and at present comprise the HUNT biobank. (For a more detailed description of the contents of the HUNT biobank, see Holmen et al., 2003.) In the process of establishing this biobank, the informed consent form was developed through three stages.

A crucial stage of most research projects in Norway is gaining the approval of the national Data Inspectorate. In the process of approving the informed consent form for HUNT 2, differences of opinion existed between the HUNT board and the Data Inspectorate. As the time for the scheduled start of HUNT 2 approached, a solution had to be reached. In the words of the HUNT researchers, the approval process ended with the Data Inspectorate ‘dictating’ the consent form (Holmen et al., 2004). It had the following statement about the storing of the blood samples: ‘I hereby consent to the storage of my blood sample. If the sample is to be used for medical research, my consent will be obtained.’¹ Consequently, the first half of the survey was performed with a consent form permitting storage but not actual research on the biobank material.

Unhappy with this outcome, the HUNT board appealed the Data Inspectorate’s decision. After deliberations involving the National Committee for Medical Research Ethics, the Data Inspectorate accepted the following revised statement, which was used in the second half of the survey: ‘I hereby consent to the storage of my blood sample. All further use of it will be subject to approval by the Data Inspectorate and the Regional Committee for Medical Research Ethics.’

Thereby the participants gave their general consent, relying on the institutions concerned to scrutinise the ethical challenges of whatever research proposals the researchers would come up with.

In the years following HUNT 2 the question arose as to the use of the biobank material for genetic research. Along with the situation of having half the material eligible for research, and the other half requiring new consent, this contributed to the obtaining of a third, common consent from the whole study population. This was done in April 2002, when a personal letter was sent to the remaining 61, 426 participants. After negotiations with the Regional Committee for Medical Research Ethics (REK) and the Data Inspectorate, a procedure involving passive, general consent was accepted, i.e. participants who no longer wanted to contribute to the biobank signed and returned the statement, and those who still wanted to contribute remained passive.

Besides informing the participants through the personal letter and an attached information folder, information was also provided on the HUNT research centre's web pages and in the local media. A specific telephone service was established to answer any questions related to the information given. The compact time span of the distribution of the information was chosen with the aim of stimulating discussion among family members, neighbours and colleagues (Holmen et al., 2004).

As a result 1187 (1.9%) persons chose to express this reservation and their blood samples were subsequently destroyed (Holmen et al., 2004). This number is similar to the those obtained in the Swedish branch of the MONICA project, where 2.2% of the study population opted out (Stegmayr & Asplund, 2002). With REK's approval, it was decided that the samples from individuals who had died since donating should be kept in the biobank, based on presumed consent.

The Norwegian Biobanks Act

The Norwegian Biobanks Act is based on the comprehensive report made by the government-appointed Biobanks committee, whose commission was to evaluate the various aspects of collection, storing and application of human biological material (NOU, 2001). Subsequent to the obtaining of comments on the report, the Government's bill was passed by Stortinget (the Norwegian parliament) without any major changes, and the Act came into effect in July 2003.

The regulation of informed consent was the hottest topic of debate throughout the law-making process, and even more so after the passing of the Act. For research biobanks voluntary, explicit and informed consent from the donor is required. If the collected material and data are to

be put to altered, extended or new use, new voluntary, explicit and informed consent is required. Only when new consent is very hard or impossible to obtain does the Ministry of Health have the option to make an exception to these consent requirements.

The requirements reflect the view of the minority of the Biobank Committee. Whereas the committee agreed on the principle of informed consent as the basis of all biobank activity, the minority regarded the involved human biological material as an ‘extension’ of the individual, and extended the rights of the individual accordingly. For the majority, however, this did not entail the informed consent having to be specific and active. Their proposal read: ‘The consent can be specific or general, active or passive. The type of consent used is to be evaluated by the Regional Committee for Medical Research Ethics’ (NOU, 2001).

The majority argued that individuals should be able to participate in biobank research that involves no or minimal risk for the participants, and is approved by the REK, without being asked for repeated explicit consent. As biobank projects would rarely be specified at the time of consent, because they will emerge from future knowledge, the majority saw the use of passive consent as an acceptable option when already collected material is to be put to new use, or in other instances where the initially given consent becomes inadequate. The minority, however, saw explicit consent based on specific information as vital both in order to respect the dignity and integrity of the individual, and to secure the trust of the individuals in biobank research.

Most of the comments on the Biobank Committee’s report were in favour of including the use of general consent in research biobanks. A more critical position was taken by the Data Inspectorate, which pointed out that the inclusion of general consent would make the Act inconsistent with existing laws and EU directives (Ot. Prp. 56. (2001–2002)). On this basis, the Ministry of Health avoided the use of the terms general and specific consent in their version of the bill, and suggested that: ‘The demands of information and specification [of the consent] must be decided after an evaluation of risk factors, the sensitivity of the material, the vulnerability of the research subject, etc.’ (Ot. Prp. 56. (2001–2002)). This formulation is part of the Act that was passed.

In the parliamentary debate there was also a minority and a majority. The parliamentary majority, including the government coalition, supported the consent proposal from the committee minority, whereas the parliamentary minority supported the majority of the committee on this issue. These coalitions were formed against the traditional left–right continuum of Norwegian politics.

Since the passing of the act, researchers have expressed their frustration concerning the consent requirements (see for instance Austgulen, 2004; Egeland, 2004; Hustad, 2004). This

frustration is based on the feeling that their research for the benefit of future patients—for the common good—is rendered suspect. They also argue that biobank research is severely impeded and unduly bureaucratized by the requirements. A governmental committee was appointed to compile guidelines on how the biobank administrators can meet the consent requirements in a way that merges the interests of the individual and the society, and makes biobank research both fruitful and legitimate (Forus & Myklebust, 2004). The committee delivered its report in December 2004, advocating openness in biobank research, strengthening of the role of the REK, and reintroduction of the use of broad consent—if accepted by the REK (NOU, 2005).

Symptomatic of the ongoing debate is that it involves researchers and bureaucrats. The lay populace has so far remained silent and no advocacy groups have shown any interest in these issues.

Invalid consent?

At the same time as the public debate, arguments have also been exchanged in the process of gaining approval for a study on possible links between pre-eclampsia and genes, based on the HUNT biobank material. In an approval process that lasted more than 18 months, the central issue was the status of the informed consent given by the HUNT participants.

Passive consent based on general information is not in accordance with the Biobanks Act. It was therefore argued that the given consent was invalid, and that new explicit, active consent should be obtained before a research project based on the HUNT biobank can be approved. As the Biobanks Act was passed after the consent was obtained, others argued that the consent has to be understood in the context in which it was given. Part of this context is the Personal Health Data Filing System Act and the Personal Data Act, which both render passive consent as an option if it serves the interest of society and the common good.

After a period of extensive correspondence the Data Inspectorate finally approved the project, provided that further passive consent is obtained. This consent will be based on new and explicit information being sent to the participants, with a clear reminder of their right to exclude themselves from participation in the project. In contrast to this the Directorate for Health and Social Affairs for some time demanded that new, explicit consent based on specific information should be obtained from the participants.

To accommodate this latter interpretation of the law, the project's principal researcher sought the approval of the REK to perform the project accordingly. Such approval was denied by the committee, however, who argued that the continuous seeking of active consent will undermine research perceived to be in the public's interest (Rigmor Austgulen, personal

communication, October 2004). As a consequence of these contrasting interpretations of the Biobanks Act, research based on the HUNT biobank material was in a state of limbo for nearly two years. It was resolved when the Directorate for Health and Social Affairs changed its position.

As illustrated by the HUNT example, controversy exists over the interpretation of the law and its consequences. At the same time little is known about the reflections of the HUNT participants. To contribute to a more research-based discussion on the issue of informed consent and biobank research, we decided to perform an empirical study.

Methods and material

We have conducted a focus-group study, involving people who have given their consent to participate in the HUNT biobank, people who have excluded themselves from participation in the biobank and researchers who have an interest in biobank research. The findings reported here are based on the data from the groups of biobank consenters, which we believe provide sufficient empirical illumination for the ethical analysis that follows. More detailed analyses from all three groups will be reported elsewhere.

The sampling of focus-group participants was done in two steps. Through strategic sampling, three municipalities were selected to fulfil the criteria of including both rural and urban areas. One urban and two rural sites were chosen, the latter two representing an agricultural and an industrial area, respectively. A random sample consisting of an equal number of men and women in the age group 20–75 was drawn from each municipality. In two of the sites the response allowed us to have two gender-specific groups, making the total number of focus groups with consenters five, with six to eight participants in each group. All group discussions were held at public locations in the participants' local community, such as community centres, schools and the town hall. The discussions were audiotaped on minidisks and subsequently transcribed into full text.

The findings reported here are based on the discussion of the following topics:

- the use (and abuse) of biobank material
- the decision to give consent
- commercialization of biobank research.

Data were analysed by means of meaning condensation (Kvale, 1996) for each focus group, before making comparisons across the groups to identify common themes. These themes were then developed into the following data presentation.

Findings from the focus groups

The participants' reflections on the potential use (and abuse) of the biobank material can at best be described as vague. Vague in the sense that there is a lot of general hope but few specific expectations. These expressions of hope were mainly stated with regard to benefits for coming generations, reflecting an altruistic element in the donors' motivation for their participation. Their hopes were related to future disease prevention and improved treatment through the development of more effective medicines, with fewer side effects than the present options. Concepts such as designer drugs or pharmacogenetics were not used but lay descriptions reflecting these phenomena were found among the expressed reflections. Hopes related to specific diseases were not a frequent feature, but included such diseases as cancer, diabetes, osteoporosis, rheumatism and Alzheimer's. Acknowledgement of their lack of expert knowledge also made these donors accept the researchers' competence and prerogative in choosing research topics:

I haven't thought much about it. But if I try to think, I maybe expect that they will find out something about diseases and the curing of diseases. (Woman, 41)

It must be things that will be useful in relation to the prevention of diseases. (Woman, 48)

My expectations are that the researchers will use these samples in a manner that will serve the health sciences. Maybe both we and the coming generations may benefit from it.

(Man, 48)

Despite having vague notions about the use of the biobank material, there is a strong sense of trust that the material will not be abused. This trust is based on specific trust in the local researchers at the HUNT research centre, researchers in general, the REK, and that Norwegian society is a well-regulated society wherein such abuse will not take place. Despite unclear notions about the existing possibilities for combining data from the biobank with other health information from the HUNT surveys and other health registries, such possibilities are not perceived as threatening. Cloning was mentioned as an example of possible abuse but was not considered as a serious option, because of existing regulations.

As we're living in a well-organized society with laws and regulations, I'm pretty confident that [the samples] won't be abused in the society we have at present. And will continue to have—in my day, anyhow. (Man, 60)

It sounds fine, the ethical committee. I don't know what they do, but it sounds good.

Regional committee for medical research ethics. Yeah, to me that's good enough. Really. I have great faith in that. (Woman, 48)

Although they had given passive consent in the last round of informed consent for the HUNT biobank, the participants remembered it as being active consent, referring to 'when we signed that paper'. In line with their vague descriptions of the use of the biobank material, there were few specific descriptions of what they had actually given their consent to. To refresh their memory they were given copies of the information they had been sent in 2002. When given the chance to read through the material, there were no expressions of regret regarding the consent given. Although preferring the initial consent to be active, the need for explicit, active consent for each new research project was perceived as unnecessary.

I thought this would be a contribution from me to future generations. I must say that I've actually donated much more than I've realized, then, and I've done it from great trust in the system. That it will be used in an ethically good manner What I've consented to, if we go into detail ...I'm really not sure what I've given my consent to. (Man, 43)

Whereas trust was expressed in local and national research institutions and regulating bodies, a similar distrust was expressed of for-profit organizations. Among the latter the American pharmaceutical industry was repeatedly mentioned as the most untrustworthy and unacceptable actor. This distrust reflected scepticism about whether this industry would be using the biobank for the benefit of the needy poor if more profitable options were available. Commercialization of the biobank was thus not seen as a viable option, although some differentiation was made between the biological material and the results of the biobank research. When challenged about how the eventual fruits of the research were to be reaped, answers were sought in options that could benefit all of humankind. Putting the results in the hands of an international institution was seen as one such option. More common, however, was the answer that the Norwegian authorities have to put more money into biobank research and the development of subsequent diagnostic devices and therapeutic measures.

If you can imagine that international corporations enter the scene, and we know what that means ...with cloning and gene modification and all that. I'm personally against it. That would be abuse, in my view. (Woman, 60)

Let's say that HUNT has a successful project, and they hand the results over to the World Health Organisation, where Gro Harlem [Bruntland] has been in charge. Then a certain amount of money could be donated to HUNT by the World Health Organization, as a 'thank you' for the information, which then may come good for all humans. And then [HUNT] can continue research on the project and even other projects. (Man, 43)

The general impression from these focus groups is that the participants are happy with the consent that they have given, despite their preference for initial active consent and their imperfect memory of what they have actually given consent to. As long as the actors in the research sector and society in general appear trustworthy, information details remain just that. These findings do also reflect a social democratic welfare state mode of thinking, where the state is seen as much more trustworthy than private entrepreneurs.

Discussion

Based on the history of the HUNT informed consent, the Biobanks Act and the controversy around it, and our own empirical findings, we now turn to an analysis of some ethical challenges related to autonomy and trust in biobank research.

What is wrong with general consent?

The Norwegian Biobanks Act states that the use of human biological material in research requires explicit and informed consent, as does every altered, extended or new use of the material. Such consent should be specified according to the risks related to the research in question. Its importance was argued for in several ways in the law-making process. The Declaration of Helsinki (WMA, 2000), which in 5 states that: 'In medical research on human subjects, considerations related to the well-being of the human subject should take precedence over the interests of science and society', was taken to imply the use of specified consent in biobank research (Inst. O. nr. 52 (2002–2003)). It was argued that in order to defend the participants against abuse of information, and from paternalistic and unethical medical research, specified consent is needed.

In this interpretation of the Declaration of Helsinki, the very notion of informed consent seems to rule out the use of general consent. How can anyone possibly make an informed

decision (not) to participate in unknown future research projects? Thus Winickoff and Winickoff (2003, p. 1180) argue that: 'Because it is impossible for the donor to make an informed choice about the risks and benefits of unspecified future research protocols, such permission should never be called informed consent.' Consequently, consent is only informed if it is specific.

In the law-making process, it was also argued that to require specific informed consent is vital to ensure public trust in biobank research (Inst. O. nr. 52 (2002–2003)). Specific consent is thus not only the way to respect the autonomy of the participants, but also the way to secure the necessary participation for future biobank research. This seems to be the argument against general or broad consent.

What is wrong with passive consent?

The use of both general and passive consent forms can impair the trust in biobank research, it was argued in the law-making process. This would cause imbalance in the threefold system of responsibility stated in the Declaration of Helsinki (NOU, 2001). As with general consent, the very term 'passive consent' was questioned: Is passive consent anything but information about new research projects and fields of research, and your rights as a research subject, which you agreed to when giving initial active consent? According to the Biobanks Act, all new research projects and fields of research would be of such importance for the research subjects as to demand active deliberation and active consent. On this view, 'general consent' cannot be informed consent, because it is not informed, whereas 'passive consent' cannot be informed consent, because it is not consent. In some areas of life, we all agree that consent is compatible with not getting up from the sofa. But when important and devastating matters are at stake, involving risks for individuals, people should get up from the sofa in order to say yes, and not just silently become part of a research project. So the argument goes. A crucial premise here is that population-based research involving genetics in fact involves risks for individuals.

What's wrong with specified consent?

As George Annas has pointed out, informed consent has been seen as a necessary but not a sufficient condition of ethical medical research involving humans since the Nuremberg Code of 1947, but '[c]onsent forms are not mentioned in the Nuremberg Code; it is the substance of the consent that matters' (Annas, 2001, pp. 2326–2327).

The notion that informed consent is not only necessary but also sufficient to safeguard the autonomy of research subjects has been called the consumerist view (O'Neill, 2002,

p. 47). In this view, the participant signs a contract, which clearly states the nature of the research, and the rights and obligations of the two parties, as in other client or consumer relationships. But in biobank research this choice is not between several offers, it is the choice to accept or refuse the only offer. And as citizens, even non-participants might benefit from this research. To escape this minimalist conception of autonomy, we should view the relationship between biobank research and its participants from a different perspective, O'Neill argues.

In a study on the consent perception of the donors to the biobank in Umeå^o, Sweden, Klaus Hoeyer followed up 29 persons through the donation and consent process, and subsequently conducted interviews with them. His findings resemble those of our focus groups. People placed trust in the activity and the regulation of the biobank, and were not preoccupied with consent deliberations. They relied confidently on the biobank research to promote the common good, and saw commercialization as a possible deviation from this aim. Their perception of the nature of biobank research was vague, and they had low expectations of being able to really assess the quality or legitimacy of the research. Hoeyer (2003, p. 240) thus concluded that for the participants, '[i]nformed consent presents itself as an option that can be left unused'. The consent procedure is taken to be formal, rather than literal. If the informed consent requirement is taken literally, it would mean asking the donors to take part of the responsibility for the research they consent—or do not consent—to take part in: 'Either they must assume the responsibility for no research, or for the risk of research gone mad' (Hoeyer, 2003, p. 240, emphasis in original).

It is ironic that the requirement for specified consent here can turn out to be paternalistic (Barr, 2005; Kerr, 2003). If a participant trusts the research institution to promote her/his best interests, the demand to evaluate the research design in detail 'for her/his own good' will be out of place. The research institute frames the study design and the consent form, and has superior knowledge of the research in question. As a means to obtain the approval of the participant, and to make the research legitimate, the consent form thus turns out to protect the research institution, rather than the participant. As pointed out by Arnason (2004, p. 43): 'Stubborn demands for individual informed consent might not only impede the advancements of medical research, but also falsely legitimise complex research'.

The problem with specified consent is that information is meant to replace trust. Information and trust go together. But anyone who has accepted a 'licence agreement' on a computer program knows for sure that there are no limits to information and specification. Most of us do not perceive it as a gain in autonomy the more specified information we get, and the

more options the consent form offers, unless we are already familiar with the issues and have a special interest in the details.

A layperson in epidemiological research is likewise not in a position to be fully aware of the research design, and to give detailed consent to its various implications and consequences. This is not only due to the fact that she/he lacks information. By the nature of epidemiological research, these implications and consequences are partially unknown to all—researchers and laypersons alike—when the consent is given. An important part of epidemiological research concerns the discovery of relations between diseases and risk factors in large cohorts. These relations are essentially unknown beforehand: ‘Many risk factors can lead to the same disease, and the same risk factor can lead to many different diseases New methods comprise so-called “data-mining” unguided by a specific hypothesis, by which with the use of modern information technology one can detect correlations between risk factors and diseases in large sets of data’ (NOU, 2001:19:5.3.3.1). With regard to HUNT, it is even unclear which sets of data, other than those of the HUNT study itself, the researchers will be allowed to incorporate in their detection of correlations: the 11-digit personal identification number of every Norwegian citizen allows in principle cross-reference in all kinds of registries in Norway. To participate in HUNT is thus not to participate in a research project but to contribute to a reservoir of material for future research projects.

Informed consent in the HUNT study

Population-based genetic epidemiology generates results at a group level, not at an individual level. The HUNT biobank will not give genetic information to individuals. Individual feedback could ‘transform a research project into genetic screening, requiring an enormous budget for genetic counselling of all donors’ (Williams & Schroeder, 2004, p. 93). This does not mean, however, that individuals do not get something back. Neither does it mean that communication between donors and the research community is broken as soon as the consent form has been signed. In 2001 an American multidisciplinary group presented an approach to how these two different concerns can be met. They stated that ‘participants should be given the option to receive an aggregate report of overall study results, for example, through a newsletter. In the rare event that results unexpectedly have clinical significance, participants could still receive through this mechanism any recommendation to be tested for a particular trait in a clinical laboratory, without revealing individual results’ (Beskow et al., 2001, p. 2321). This underlines the common nature of biobank research and the shared benefit for the community but does not rule out personal gain from the research.

As mentioned, HUNT obtained passive and general consent in 2002 from donors who still wanted to participate when provided with new information. Half of them had already given their active general consent for research on the biobank material, while the other half had only permitted storage of the material. They had all, however, freely contributed their sample and their time for the benefit of medical research. At the time of the distribution of the consent letters in 2002, the HUNT group applied various means of communication with the donors (Holmen et al., 2004). In this sense they acted in accordance with Winickoff and Winickoff's (2003, p. 1180) description that '[Informed consent] should be a process of communication, not simply a form to be filled out.' In this perspective autonomy is not equivalent to a consumerist choice between consent and non-consent as if it were a choice between two brands of cheese or two insurance companies. The context of consent provides reasons to participate, or to continue to participate, or to opt out.

O'Neill (2002) argues that you cannot claim anyone's rights, without stating who has the duty to fulfil these rights. Duties precede rights. Present epidemiological research is a way to better healthcare tomorrow, from which anyone can benefit. To claim the right to (better) healthcare, there is a real sense in which one ought to take part in good health research, unless there are good reasons not to. Given opportunities to debate and influence the research designs and priorities, not only researchers but participants and all others involved or interested will be able to exercise a communicative autonomy that matches the nature and level of the research. To make this happen should be a main focus in the debate on informed consent. This promotes the kind of 'principled autonomy' that takes its course of action from the Kantian notion of autonomy as the 'ways of thinking [that] must be lawlike rather than lawless, and will thereby be in principle intelligible to others, and open to their criticism, rebuttal or reasoned agreement' (O'Neill, 2002, p. 95). To state reasons for joining or not joining epidemiological research should not just be left to private pondering.

Conclusion

As noted, the participants in the HUNT biobank had imperfect memories of what they had given consent to, and vague reflections of the potential use or abuse of the biobank material. Passive consent was remembered as active consent. Given that this passive consent now can be set aside in Norway, this consent will, ironically, not even be worth the paper it never was written on. What can this story tell us about the legal and ethical aspects of Norwegian biobank research at present?

First of all it tells us that the trust we have found among the participants in the HUNT study is met with distrust from the political institutions responsible for the legal framework for biobank research. Trust is difficult to transform into legal terms. Informed consent is not. Trust is a complex mixture of experiences, knowledge, ignorance, feelings, intuitions, relationships, values, political governance, economical infrastructure and various other factors. Informed consent is a signature on a piece of paper. The concreteness of a signature contrasted to the vagueness of trust may lead us to the idea that a stronger focus on the signature is an expression of an improved research ethics. But, as O'Neill (2001, p. 702, emphasis in the original) notes, this idea is faulty: 'The construction of trustworthy institutions is a vast task. It is obstructed rather than implemented by fantasies that individuals can provide informed consent to questions of great complexity, and by assumptions that the improved regulation will by itself guarantee trust.' The construction of a relationship of trust has a history. In this paper we have tried to describe how the HUNT study gained trust through the process of obtaining informed consent from its participants. To strengthen the demands for an active, specified, informed consent again and again does not necessarily lead to more ethical practice. Rather, the opposite could be true. Trust could be undermined by the demands of a formalistic ethics. It can convey the notion that (the regulation of) the research is not to be trusted, and pass the ethical responsibility over to the participant.

In the HUNT donors' opinion, they have taken part in a project that is meant to realize some sort of common good. What exactly the common good is, or will turn out to be, is unclear. That it will be fruitful, relevant and of high quality is at the moment a question of trust. Recurring specified consent forms may erode the fruitfulness of the research, by inducing 'consent fatigue' among the donors, possibly reducing the participation rate, and consequently the quality of the research material, and, among researchers, possibly reducing the time available for doing research, instead of applying to do so.

From the focus groups, one major threat to trust in the biobank research was found: the fear of commercialization. Commercialization introduces other aims than the common good. However, the ethics of informed consent has no problem with commercialization. In fact they suit each other perfectly with the stress on the legal contract between two parties. A legal contract between two parties can be with or without trust. For medical research in the future we need an ethic which says that trust is relevant. Otherwise no informed consent in medical research is worth the paper it is written on.

Acknowledgements

The authors are grateful to the participants in the focus groups who trusted them by sharing their information. Thanks are also due to the HUNT Research Centre and the National Institute of Public Health for their practical assistance in recruiting the members of the focus groups. The study was supported by the National Programme in Functional Genomics in Norway (FUGE) in the Research Council of Norway and the Norwegian University of Science and Technology. JAS, BS and LØU designed the study. JAS moderated the groups with BY as co-moderator. BS, LØU and EC participated in the groups. All members of the group participated in the data analysis. JAS and LØU drafted the manuscript and the rest of the group contributed to the revisions of the manuscript.

Note

1. All translations from Norwegian in this text were made by JAS & LØU.

References

- Annas, G. (2001). Reforming informed consent to genetic research. *Journal of the American Medical Association*, 286, 2326–2328.
- Arnason, V. (2004). Coding and consent: Moral challenges of the database project in Iceland. *Bioethics*, 18, 27–49.
- Austgulen, R. (2004). Retten til a° vite nok. *Adresseavisen*, 13 May.
- Barr, M. (2005). Informed consent and the shaping of US and UK population based genetic research. In D. Guston & D. Sarewitz (Eds), *Shaping science and technology policy: The next generation of research*. Madison: University of Wisconsin Press.
- Beskow, L., Burke, W., Merz, J., Barr, P., Terry, S., Penchaszadeh, V., Gostin, L., Gwinn, M., & Khoury, M. (2001). Informed consent for population-based research involving genetics. *Journal of the American Medical Association*, 286, 2315–2321.
- Egeland, T. (2004). Biobankloven—til pasientens beste? *Dagbladet*, 27 June.
- Forus, A., & Myklebust, I. (2004). Med lov skal forskningen trygges. *Morgenbladet*, 21 May.
- Holmen, J., Kjelsaas, M.B., Kru°ger, Ø., Ellekjær, H., Bratberg, G., Holmen, T. L., Midthjell, K., Stavna°s, P.A., & Krogstad, S. (2004). Befolkningens holdninger til genetisk epidemiologi iillustret ved spørsmå¹ om fornyet samtykke til 61.246 personer—Helseundersøkelsen i Nord-Trøndelag (HUNT). *Norsk Epidemiologi*, 14, 27–31.

- Holmen, J., Midthjell, K., Kru"ger, Ø., Langhammer, A., Holmen, T. L., Bratberg, G. H., Vatten, L., & Lund-Larsen, P. (2003). The Nord-Trøndelag Health Study 1995–97 (HUNT 2): Objectives, contents, methods and participation. *Norsk Epidemiologi*, 13, 19–32.
- Hoeyer, K. (2003). 'Science is really needed—that is all I know': Informed consent and the non-verbal practices of collecting blood for genetic research in northern Sweden. *New Genetics and Society*, 22, 229–243.
- Hustad, J. (2004). Det ma° komme en endring. *Morgenbladet*, 25 June.
- Inst. O. nr. 52 (2002–2003). Innstilling fra sosialkomiteen om lov om biobanker (biobankloven).
- Kaye, J., Helgason, H. H., No"mper, A., Sild, T., & Wendel, L. (2004). Population genetic databases: A comparative analysis of the law in Iceland, Sweden, Estonia and the UK. *Trames*, 8(58/53), 15–33.
- Kerr, A. (2003). Rights and responsibilities in the new genetics era. *Critical Social Policy*, 23(2), 208–226.
- Kvale, S. (1996). *Interviews: An introduction to qualitative research interviewing*. Thousand Oaks, CA: Sage Publications.
- Midthjell, K., Kru"ger, Ø., Holmen, J., Tverdal, A., Claudi, T., Bjørndal, A., & Magnus, P. (1999). Rapid changes in the prevalence of obesity and known diabetes in an adult Norwegian population. *Diabetes Care*, 22, 1813–1820.
- Norges Offentlige Utredninger (2001). NOU 2001:19: Biobanker. Innhenting, oppbevaring, bruk og destruksjon av humant biologisk materiale.
- Norges Offentlige Utredninger (2005). NOU 2005:1: God forskning—bedre helse. Lov om medisinsk og helsefaglig forskning, som involverer mennesker, humant biologisk materiale og helseopplysninger (helseforskningsloven).
- O'Neill, O. (2001). Informed consent and genetic information. *Stud Hist Phil Biol & Biomed Sci*, (Studies in history and philosophy of biological and biomedical sciences)32, 689–704.
- O'Neill, O. (2002). *Autonomy and trust in bioethics*. Cambridge: Cambridge University Press.
- Odelstingsproposisjon nr. 56 (2001–2002). Om lov om biobanker (biobankloven).
- Stegmayr, B., & Asplund, K. (2002). Informed consent for genetic research on blood stored for more than a decade: A population based study. *British Medical Journal*, 325, 634–635.
- Williams, G., & Schroeder, D. (2004). Human genetic biobanking: Altruism, benefit and consent. *New Genetics and Society*, 23, 89–103.
- Winickoff, D. E., & Winickoff, M. D. (2003). The charitable trust as a model for genomic biobanks. *New England Journal of Medicine*, 349, 1180–1184.

WMA (2000). World Medical Association's Declaration of Helsinki. Ethical Principles for Medical Research Involving Human Subjects.

The informed consenters: Governing Biobanks in Scandinavia

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Personal Autonomy and Informed Consent

Abstract

Two ways of understanding the notion of autonomy are outlined and discussed in this article, in order to clarify how and if informed consent requirements in biotechnological research are to be justified by the promotion of personal autonomy: A proceduralist conception linking autonomy with authenticity, and a substantivist conception linking autonomy with control. The importance of distinguishing autonomy from liberty is emphasised, which opens for a possible conflict between respecting the freedom and the autonomy of research participants. It is argued that this has implications for how consent requirements based on different criteria of specificity and understanding should be viewed and justified.

Keywords

Autonomy, liberty, informed consent, research ethics

Introduction

In relation to biobank research, the use of a general or broad consent is advocated as a way to facilitate research by avoiding the time and money spent on the administration of specific consent forms for every new research project. The use of general consent is in this context argued to promote the interest of the researchers and the research participants alike in using the resources on research rather than bureaucracy. In the article *Should donors be allowed to give broad consent to future biobank research?*, Mats Hansson et al. argue that participants could be allowed to give a broad consent to biobank research on their material, if they decide that the ethical and legal regulation of the research institutions is trustworthy and reliable. This means that the participants would be allowed to tick the “yes to all” box: Giving their consent for their submitted material to be used in any unknown future research project. As a crucial part of their argument they state that: “Less restriction on the types of consent allowed implies increased respect for autonomy.” (Hansson et al., 2006, p. 268)

In this article it is argued that such a view rests on a confusion of autonomy with freedom of choice. This view confuses our understanding of the relation between autonomy and informed consent in general, not just concerning general consent. It might be tempting to say that the greater the freedom participants are allowed to have with regards to research participation, the more their autonomy is respected. But this does not have to be the case. The substantivist position developed in this article will arguably entail that if the participants are allowed to waive their interest in how their own biobank material is used in future projects, their freedom of choice is increased at the same time as their personal autonomy is decreased.

Two accounts of autonomy

The *personal* autonomy of the individual is an ideal of modern culture¹⁶⁹. It is seen to be desirable that people should be set free from constraints which hamper their ability to govern their own lives. The means and routes of achieving the goal of autonomy differ, however, as does the view of where the goal is and when it is reached. Moreover, when autonomy is attained, one of the definite implications is that further ends can then be pursued: Autonomy is as much a precondition for people to pursue their ends as an end in itself. Three aspects of the ideal of autonomy need as a consequence to be determined: How do we attain autonomy, when do we attain it, and why do we want to attain it?

An influential way of understanding autonomy is that it essentially involves the reflective authentication or endorsement of a plain volition by the agent¹⁷⁰. This view brings together the

¹⁶⁹ The imprisoned conscientious objector is an example of a person which has retained his moral but not his personal autonomy. He is autonomous in terms of which moral codes he chooses to adhere to, but not autonomous when it comes to other aspects of his freedom of choice. In this way we can distinguish moral and personal autonomy. The concept of political autonomy describes a third aspect of autonomy, namely the way in which a citizen is granted self-government vis-à-vis interference by the state. The personal and political autonomy of a person can be highly independent: A person granted political autonomy might nevertheless lack personal autonomy, and vice versa. Given the right to vote enhances your political autonomy, but not your personal autonomy, if you do not care to vote or just vote whatever your mother tells you to vote. To place high taxes on alcoholic beverages would restrict the political autonomy of the average citizen, but could enhance the personal autonomy of the potential heavy drinker.

¹⁷⁰ See Frankfurt (1971), Dworkin (1988), Juth (2005) and Taylor (1985)

concepts of *authenticity* and autonomy.¹⁷¹ It is only if, on reconsideration, that the agents continue to identify with – or conversely are not alienated from¹⁷² – the motivations for their own acts that they are to be regarded as autonomous. I am accordingly autonomous if I not only want to take the last cookie on the serving dish, but also endorse this action upon reflection. Authenticity is thus a necessary condition for autonomy, and autonomy is a sufficient condition for authenticity.

The general problem with the account of autonomy based on second-order authentication of first-order impulses involves the conflation of autonomy with authenticity. There is clearly more to autonomy than internal authentication. To rely solely on subjective endorsement misses the *intersubjective* aspect of ascriptions of autonomy. It is not entirely up to me to say which of my acts are autonomous, and which are not. As Gerald Dworkin points out, it seems paradoxical to say that if I randomly decide today to identify with the addiction which I felt alien to yesterday, I thereby go from being non-autonomous to being autonomous. (Dworkin, 1988, p. 16) Furthermore, a person who is forced to perform an action will authenticate the desire to perform the act in order to avoid injury, but it seems counterintuitive to say that the coerced person acts autonomously.¹⁷³ It is not simply up to me to decide whether my acts are autonomous or not, and nor is up to other people's impressions of those acts.

The autonomy of my acts is a matter of intersubjective assessment in the social setting in which I act. I might “do it my way”, but the autonomy of my acts is not constituted by my independence from social or emotional influences or justifications. In the *social-relational* account of Marina Oshana, “the state of being autonomous is primarily a function of the external situation a person finds himself in rather than being predominately a function of a person's psychological state or practical skills.” (Oshana, 2006, p. 6) In other words: The *capacity* for autonomous choices is but one of many prerequisites for attaining the *condition* of being autonomous.

To make autonomy a matter of individual preferences becomes paradoxical if the individual prefers to depend on the decisions of others. The individual might quite rationally

¹⁷¹ There is considerable variation when it comes to the details of proceduralist theories of autonomy, but the version described here brings out most clearly those aspects which are directly relevant to the later discussion of how autonomy in general versus specific consent requirements in biobank research can be justified. The same goes for the version of the substantivist theory of autonomy developed in this article.

¹⁷² See Christman, 2004, p. 154

¹⁷³ For a discussion of this example, see Thalberg (1989), and Taylor (2003)

decide to trust someone with more knowledge and experience, and thus to defer to her judgement. For Dworkin this creates a dilemma: On the one hand it would be difficult to claim that such a person is autonomous, since he “does not form independent judgements about what he should do” (Dworkin, 1988, p. 22). On the other hand it would be hard to say that such a person is not autonomous, since “he is doing what he wants to do” (Dworkin, 1988, p 23). Dworkin’s solution is that such a person is autonomous, since to say that he is not makes autonomy incompatible with other central values, such as commitment to others. To him, claiming that autonomy excludes dependence has the unwanted consequence of making a selfish person more autonomous than a benevolent one, since a selfish person is more substantially independent of the needs of others than a benevolent one.

In arguing that autonomy is vital for respecting others and giving meaning to life, Dworkin does not simply limit himself to providing an account of autonomy, but also defends autonomy as a universal ideal. In contrast to Dworkin’s *proceduralist* account of autonomy, where the content of the desires of the individual is irrelevant¹⁷⁴, the content of your autonomous decisions do affect your autonomy according to a *substantivist* (or *perfectionist*) account of autonomy. Autonomy can be viewed as a purely neutral and procedural concept, which simply denotes the absence of any factors such as manipulation, coercion and irrationality in any decision-making process. Consequently, based on a purely procedural account of autonomy it is possible autonomously to enter conditions which will substantially restrict one’s choices and have a marked influence on one’s own situation – and still retain one’s autonomy despite this.

¹⁷⁴ Dworkin thinks that there should be “no specific content to the decisions an autonomous person makes. Someone who wishes to be the kind of person who does whatever the doctor orders is as autonomous as the person who wants to evaluate these orders himself.” (Dworkin, 1988, p. 108-9) He argues that a substantivist conception of autonomy “not only has the consequence that no government is legitimate, but also that such values as loyalty, objectivity, commitment, and love are inconsistent with being autonomous.” (Dworkin, 1988, p. 109) Though sweeping, Dworkin’s claim is surely correct, if interpreted as pointing out the incoherence of being both governed and relevantly autonomous when it comes to a specific act. Surely, there is no contradiction in being nonautonomous in a specific relation or situation, and generally capable of acting autonomously at the same time. It is entirely possible to forgo one’s autonomy in a specific relation and still retain one’s general autonomy. But why should a person aim to act autonomously in every situation and relation? Alternatively, why should we aim for a concept which grants people full autonomy in every voluntary relation? *See* also Christman (2005)

According to a substantivist account of autonomy, this implies a contradiction in terms: it is not possible to subject oneself to the will of others without compromising or fully negating one's autonomy.

The substantivist would say that the person in Dworkin's dilemma is not autonomous, since his decision to live in an obedient way is effectively a decision to live non-autonomously. If an individual's endorsement of his acts and aims is what makes them autonomously chosen, then authenticity is crucial for autonomy. But for the substantivist the autonomy of a person is to be judged intersubjectively by his ability to control his own acts and aims, and not privately by his ability to endorse his acts and aims. A slave does not gain autonomy by approving of his chains.

Autonomy versus liberty

On the substantial side, the argument would be that a monk is not autonomous, even if he autonomously chose to enter the monastery and abide by his superiors¹⁷⁵. The simple fact of devolving authority over his actions and aims to others means that he is no longer autonomous. If however he is granted the right to leave the cloister whenever he wishes, he can be said to be autonomous in the limited proceduralist sense that he affirms the choices being made for him. He somehow takes them to be his own, and he wouldn't want these decisions to be altered or his authority to make them to be restored: He might be said to happily forego his *autonomy* – but might perhaps still be said to retain this *liberty*.

The example of the monk can illustrate the difference between subjective authenticity and intersubjective autonomy. As long as he adapts and identifies with the situation and the choices made for him, he lives authentically even if he lacks the power to change the circumstances of his life. But he is not autonomous. Or the other way round¹⁷⁶: A person who wishes to be a monk, but is not admitted to the monastery, may still live an autonomous life even though it isn't an authentic one by his own standards. His autonomous wish to surrender his will to God as a monk is not fulfilled, but this does not compromise or negate his autonomy. I might wish to have been a surgeon instead of a philosopher, and feel that this unfulfilled wish makes my life lose its some of its authenticity. In my life as a fake, I nevertheless retain my autonomy.

In a procedural account of autonomy, the monk and the slave would be viewed as autonomous - as long as they agreed autonomously to accept the conditions under which they live. The content and consequences of their autonomous decisions do not matter, as they are the

¹⁷⁵ See Oshana (2006, pp. 62-4)

¹⁷⁶ See Dworkin (1988, p. 22-23), and Oshana (2006, p. 64)

only ones in any position to judge their autonomy. In a substantive social-relational account of autonomy, the autonomy of a person is based on social facts which bar the paradoxical claim that a person can forgo and retain his autonomy at the same time: “A proceduralist would claim that the person continues to be autonomous if she continues to reaffirm her choice, where the substantivist would deny this. Autonomy, for the substantivist, is not a matter of being free to act as one pleases, but a matter of living in a particular way. Autonomy is a notion primarily driven by a conception of the good, by some traits of character rather than others, and by the nondiscretionary presence of substantively specified relations, social roles, and natural circumstances.” (Oshana, 2006, p. 73)

Autonomy is a thicker concept than those of negative and positive freedom¹⁷⁷: In addition to presupposing the condition of being able to manage one’s own acts and aims, and the capacity to do so, it comprises of the element of choice – the decision to do so. In this way, we can see that autonomy and freedom of choice are distinct concepts. *Autonomy is about actually steering the course of one’s life, while freedom is about doing whatever you like.* A person can be independent without using or valuing her independence – out of a specific conception of her own well-being. The free man does not have to choose to be autonomous – he can for instance just “go with the flow” if he so chooses.

Dworkin tries to distinguish between autonomy and freedom in arguing that Odysseus, in asking to be tied to the mast, relinquishes his liberty but retains his autonomy. In protecting himself against the overpowering song of the sirens, Odysseus gives up the *freedom* to act according to his first-order volition in order to protect the *autonomy* to act according to his second-order volition. Thus, for Dworkin, freedom is not a necessary precondition of autonomy. According to the substantivist perspective, however, freedom is a necessary, but not a sufficient, condition of autonomy. Consequently, both Odysseus and the monk give up their autonomy by putting themselves in positions where their ability to act freely is hampered¹⁷⁸.

The substantivist account of autonomy implies that a person is autonomous if she has the capacity to take charge of her acts and aims, is in a condition to do so, and actually exercises this capacity. Whether a person’s acts and motives are autonomous is to be judged by intersubjectively assessable conditions, rather than subjective assessments of authenticity.

¹⁷⁷ See Berlin (1969)

¹⁷⁸ Odysseus deprives himself of any and all alternative options to act, even the possibility of exit, while the monk deprives himself of all options except for those of departure or obedience.

According to the substantivist, autonomy is not compatible with total individual freedom, since that includes not opting for exercising one's autonomy. Freedom is thus a necessary, but not a sufficient condition for personal autonomy. Autonomy is, on the other hand, not compatible with total social dependence. I will now turn to examine some of the implications of this account of autonomy, which are significant when it comes to evaluating the importance of personal autonomy in justifying informed consent requirements for medical research.

Justifying informed consent by autonomy

A prevailing concept in bioethics research is that autonomy is the primary justification of informed consent. In their *Principles of Biomedical Ethics* Beauchamp and Childress state for instance that “since the mid-1970s the primary justification advanced for requirements of informed consent has been to protect autonomous choice” (Beauchamp and Childress, 2001, p. 77). Their concept of autonomy is comprised of both the negative freedom that involves protection from “controlling interference by others and from limitations, such as inadequate understanding, that prevent meaningful choice”, and the positive freedom to act “freely in accordance with a self-chosen plan, analogous to the way an independent government manages its territories and sets its policies” (Beauchamp and Childress, 2001, p. 58).

The rationale behind present day thinking on informed consent is that it is necessary both to protect individuals from harm, and to promote an active assessment on their part of any medical treatment and research projects they might participate in. The ideal is that any involvement with health care and medical research is the autonomous choice of the individuals concerned. To require informed consent in medical research thus has two quite distinct justifications in terms of autonomy: On the one hand, it safeguards the well-being of the participants by promoting the instrumental use of their autonomy, and on the other hand it foregrounds autonomy as a right in itself.

If it is a question of the well-being of the participants alone that is meant to justify the requirement of consent, then the matter of participant autonomy is at best of instrumental value. However, autonomy might be thought of as both a means and an end for the participants, since it enables the justification of consent requirements both as a way of avoiding harm and of promoting autonomy. This suggests that requirements of informed consent that are grounded on autonomy may share an ambiguity in how they conceptualize autonomy. On the one hand, it is possible to emphasise the aspect of non-maleficence and to assign to the principle of autonomy “the more precise title of the principle of non-exploitation” (Warnock, 2001, p. 129). On the

other hand, it is just as possible to highlight the intrinsic value of self-governance in the more precise sense of non-paternalism.

Justifying informed consent by well-being

In the article *Autonomy and Informed Consent: a Much Misunderstood Relationship*, James Stacey Taylor analyses how informed consent requirements are justified in medical research. In his article, Taylor challenges the prevalent conception of autonomy as the primary justification of informed consent. In his view, autonomy is restricted by manipulation and coercion, but not necessarily by lack of information. Autonomy is – unlike communication and informed consent – not a *success term*. No communication has taken place unless the content has been transferred. Likewise, no consent is informed unless the consenting person is allowed to arrive at an adequately informed decision. Autonomy, however, denotes the ability of a person to govern his actions freely, but does not imply that these actions actually enable the person to reach his goals.

Thus, if a person consents to participate in a research project, only to find out later that the information provided was inadequate, he is justified in saying that his consent was invalid. But in Taylor's view he is not justified in saying that the decision to grant his consent was non-autonomous, unless the researchers *intended* to manipulate him by giving him inadequate information at the time. If the inadequate consent procedure stemmed from negligence, the autonomy of the consenting research participant was not compromised. No one tried to control him at any point, and he was thus fully autonomous all the time.

If this is the case, a research participant might be autonomous even if he does not give a legitimate informed consent to his participation. The participant might be autonomous even if he consented to participate in a study which involved risks he was unaware of, and where the researchers involved failed to inform him about these risks because they thought they were obvious to everyone. Researchers are, however, morally culpable if they fail to obtain an informed consent from research participants before they are included in the relevant study. Why? According to Taylor, the reason is that they potentially put the well-being, and not the autonomy, of their research subjects at risk. The value of autonomy in relation to informed consent requirements is in its connection to the good of well-being, rather than in its own right: Paradoxically, even the purpose of respecting the autonomy of research subjects might be because they value exercising their autonomy, and in this way their well-being is promoted. This brings Taylor to state that “it cannot be the case that the ethical foundation of the doctrine of informed consent is concern for autonomy. Instead, it should be recognized that the ethical foundation of informed consent is really concern for human well-being.” (Taylor, 2004, p. 384)

It is Taylor's view that a lack of information is not necessarily as detrimental to autonomy as coercion and manipulation are. He dismisses as self-defeating the argument that the autonomy of the participants should be promoted by giving the researchers the responsibility to inform the participants from the perspective of their interests. The purpose of imposing such a responsibility would be to help the participants to pursue their aims, not to promote their autonomy. As Gopal Sreenivasan notes, to understand informed consent as requiring "that the physician shoulders the entire responsibility for achieving comprehension in the patient [is] an unwitting irony from the advocates of individual autonomy." (Sreenivasan, 2003, p. 2016-8) Experts are responsible for providing patients with as accurate, adequate and accessible information as possible, but are they responsible for how the patients understand of this information? The latter responsibility seems closer to paternalism than autonomy, as Taylor concludes: "If patient well-being, and not patient autonomy, is the pre-eminent value of contemporary medicine then the case for medical paternalism gains strength." (Taylor, 2004, p. 391)

Consent as agreement

Taylor's analysis, however, fails to note that any ascription of personal autonomy presupposes a certain level of instrumental rationality, and a certain grasp of the situation in which the autonomous person acts. This aspect distinguishes personal autonomy from freedom and political rights. And in the case of informed consent, the participant has the reasonable expectation that he is given complete and accurate information on which to base his consent. Informed consent *does* make this the obligation of the researchers. To require informed consent from research participants means that researchers should not allow anyone to take part in research unless they adequately understand the nature of the research and their participation.

This might considerably restrict the number of eligible research participants.¹⁷⁹ Angus Dawson points out that a moral or legal obligation to obtain informed consent from research participants presupposes that this is in fact possible. If ought implies can, and if it turns out that a fair amount of the participants do not adequately understand the nature of the research project, an obligation to obtain informed consent *justified by personal autonomy* makes little or no sense. If we are serious about the need to require informed consent by medical research participants in order to respect their personal autonomy, this requirement should be based on empirical material showing that the participants are actually able to make informed decisions with regards to their participation. If the consent requirements are justified by the political rights and liberty of the

¹⁷⁹ See Dawson (2004, p. 41-51) and Lemaire (2006)

participants, on the other hand, showing that the participants fully and adequately understand the nature of the research project is not a mandatory part of defending their political right to take part in or abstain from taking part in medical research.¹⁸⁰

The obligations researchers are under to be open about the nature of their research means that most participants will normally believe that their consent is given on the basis of adequate information, a fact which will compromise their autonomy in retrospect if it then emerges later that crucial information was withheld, however accidentally.¹⁸¹ Those who fail to assure researchers that their consent is based on a well-informed choice should not be accepted for enrolment in a study which requires their informed consent. This rules out those who cannot arrive at an adequate understanding of the research, as well as those who deem it unnecessary to do so, but who want to participate anyway¹⁸². This also excludes any research project which cannot be satisfactorily explained to the participants. The personal autonomy of the participants

¹⁸⁰ It is possible to draw a distinction between two criteria for ascribing autonomy: The *information* criterion, which requires that a person must be adequately informed in order to be autonomous, and the *execution* criterion, which requires that an autonomous person must make the relevant decisions herself, and not just leave them to others. Taylor then argues that the criterion of information is vital to giving informed consent, but not for being autonomous. I argue that the context of consent make the information criterion vital to autonomy, because being inadequately informed in this context is detrimental to your autonomy. If you, on the other hand, are adequately informed but nevertheless leave the relevant decision to others, you do not fill the execution criterion for being autonomous. There is a difference between being informed about the research but still leaving the decision to participate or not to others, and trusting others to decide for one and not caring about being informed. For this difference to be significant for the legitimacy of consent, however, requires that the consent is justified by something other than securing the autonomy of the potential research participant.

¹⁸¹ See Maclean (2006) and O'Neill (2001, p. 692)

¹⁸² If it is argued, cf. section B1 of the *Belmont Report*, that the point of giving one's consent is to respect those who are competent to give it, while the interests of other participants is secured without the use of consent, then those who have no such competence should be allowed to participate without giving their consent. This argument implies, however, that the interests of all participants is or could be secured without the use of informed consent, and that the point of asking for the consent of those with competence is to show them respect rather than enable them to promote or secure their interests from their unique point of view.

is in this way a central justification of the informed consent requirement – even if the autonomous choice is thus paternalistically imposed on the participants because it is both a right and a duty.

Alasdair Maclean reminds us that the word consent derives from “the Latin *con sentire*; to feel together.” (Maclean, 2006) Such etymology promotes an understanding of consent as arriving at agreement, a process that can be distinguished from consent as the act of granting permission. To view consent as giving someone *permission* to enter one’s private space is to emphasise political rights over personal autonomy. This view seems to take the literal and welcome imperative of protecting the participant against physical harm and to extrapolate it into a metaphorical protection of individual autonomy. Consent as *agreement* places more emphasis on the responsibility of researchers to promote *both* the well-being and the autonomy of the research participant through the provision of knowledge and not just information.¹⁸³ The researchers should not, *pace* Taylor, confine themselves merely to supplying relevant information, but should also make sure that the patient understands what is at stake. The quality of informed consent is secured through an active and even challenging approach, and not simply by non-directive counselling and individual contemplation.

Justifying general consent by liberty

Using the concept of autonomy to justify the principle of informed consent is, as we have seen, paradoxically paternalistic in the sense that it seeks to protect the interests of and promote self-reflection in potential research participants. The substantivist account of autonomy carries with it the implication that the participants are not at liberty to waive their autonomy and simply trust the researcher to take good care of them. Moreover, the participants have to critically examine the trust they place in the researchers: Are they really fulfilling their part of the social contract, their duty to help the participants exercise their autonomy on the basis of all the relevant information? The autonomy of the research participants might thus be secured at the sacrifice of their authenticity: The participants might long to throw themselves into the strong and loving arms of a researcher, in order to be relieved of any anxiety associated with their participation. Informed consent requirements based on a substantivist notion of autonomy prevent this possibility. As remarked by Ulrik Kihlbom: “A patient might prefer that a trusted physician decide what he or she judges to be the best course of action. Though it seems perfectly possible

¹⁸³ See Maclean (2006), and also Annas (2001, p. 2327)

and sometimes reasonable to make such a waiver, it would be a matter of giving up your autonomy, no matter how autonomous your decision is.” (Kihlbom, 2008, p. 146)

Dworkin tries to avoid the paradox mentioned in the last paragraph, when he argues that: “If a patient has knowingly and freely requested of the doctor that he not be informed or consulted about his course of treatment then to seek to obtain informed consent would itself be a violation of autonomy.” (Dworkin, 1988, p. 118) The substantivist would oppose such a proceduralist position, and insist that obtaining informed consent might involve a violation of the *liberty but not the autonomy* of the patient. The patient might have the freedom to relinquish autonomy by waiving his right to give an informed consent, but this does not mean that his informed consent can be confused with such a waiving of his right to veto any interference with his own body by the doctor.

A purely procedural understanding of autonomy would make it possible for individuals to retain their autonomy while accepting conditions which would place considerable restrictions on their choices and the influence they had over certain aspects of their lives. Dworkin, for instance, states that “autonomy includes the possibility of a decision to give up one’s independent determination about what one should do.” (Dworkin, 1988, p.118) According to the substantivist account of autonomy, this implies a contradiction in terms: It is not possible to place severe constraints on the choices available to us, or to subject ourselves to the will of others, without relinquishing or to some degree compromising our autonomy.¹⁸⁴ The substantivist account of autonomy in this way precludes the possibility of giving a general or broad consent which allows for the possibility of our materials to be used in future research projects which are still of a partly unknown nature. One would then place oneself in the position of the monk described earlier in

¹⁸⁴ Except in the previously mentioned negative sense, where one is free to withdraw from the relevant study at any time – and is therefore seen to affirm any decision made on one’s behalf on the grounds that one does not withdraw. For the substantivist, however, the important point is that there is more to autonomy than the ability or right to leave.

¹⁶ Of course the use of a general consent might be supplemented with the provision of extensive information about the on-going research projects to the participants, together with the right to withdraw from the study at any time. But this would then make the general consent work as a specific consent, in practice (if the participants really keep themselves updated and retain their critical attitude) if not in principle.

this article. Consenting to trust a research institution is simply not the same as making use of one's personal autonomy.

Autonomy comes in degrees, and one might argue that the degree of autonomy increases with the specificity of an informed consent. Broad consent in this way marks the end of a spectrum of types of consent and corresponding degrees of autonomy. The substantivist would agree to this, but say that if the concept of autonomy is to have any definite meaning, the consenters cannot consent to lose control of their involvement with a research project and still be deemed autonomous. For Hansson it is the other way around: He argues that the degree of autonomy increases with the generality of the consent offered.

To justify the use of general consent by autonomy is to conflate the notion of autonomy and liberty amounts for the substantivist to an attempt to have it both ways: To proclaim that people should always be in control of their involvement with biotechnological research, but at the same time to allow them to let go of their control if they want to.¹⁸⁵ To say that autonomy is but one of the several important interests of the research participants to be respected would in this perspective constitute a more sound approach. There are more ways to show respect for research participants than to respect their personal autonomy in the substantivist sense. To require consent in order to respect the well-being or liberty rather than the autonomy of the participants would, however, make the criteria for a legitimate consent markedly different than those described in this article. But it might, for instance, open up for a more fruitful approach to the legitimacy of general consent than insisting that the justification of any kind of consent *must* be in terms of personal autonomy. General consent must in the latter case be described as the autonomous informed decision to be non-autonomous by accepting to participate in research of unknown nature, which either makes the concept of autonomy vacuous, or makes general consent a contradiction in terms.

Conclusion

Respect for the autonomy of participants is the standard justification for informed consent requirements in medical research. On a substantivist account, however, informed consent requirements in medical research may bring about a conflict between the interest a participant has in personal autonomy with the interest he or she has in liberty. Informed consent justified by the value of the autonomy of the participants excludes both the use of general consent and the inclusion of research participants who fail to act in a way that adequately preserves their

autonomy. Both general consent and inclusion of non-autonomous participants should rather be sought to be justified out of respect for their liberty and well-being.

Acknowledgements

I would like to thank Berge Solberg, Bjørn Myskja, Alasdair Maclean, James Stacey Taylor, Jukka Varelius, Marit Hovdal Moan, Domhnall Mitchell and two anonymous reviewers from MHEP for their valuable comments on and discussions of earlier drafts of this article. I would also like to note my appreciation for helpful suggestions made by members of the audience who attended a presentation of mine at the 21st European Conference on the Philosophy of Medicine and Health Care in Cardiff in August 2007, where I touched on some of the issues more fully covered in this article.

References

- Annas, George: 2001, 'Reforming Informed Consent to Genetic Research', in *JAMA*, vol. 286, no. 18
- Beauchamp, T. and Childress, J.: 2001, *Principles of biomedical ethics*, Oxford UP
- Berlin, Isaiah: 1969, *Two concepts of Liberty*, in *Four Essays on Liberty*, Oxford UP
- Christman, John: 2004, 'Relational autonomy, liberal individualism, and the social constitution of selves', in *Philosophical Studies*, vol. 117
- Christman, John: 2005, 'Procedural Autonomy and Liberal Legitimacy', in James Stacey Taylor (ed.): *Personal Autonomy*, Cambridge UP, pp. 277-298
- Dawson, Angus: 2004, 'What should we do about it? Implications of the Empirical Evidence in Relation to Comprehension and Acceptability of Randomisation', in Søren Holm (ed.): *Engaging the World: The use of Empirical Research in Bioethics and the Regulation of Biotechnology*, IOS Press, pp. 41-51
- Dawson, A. and Garrard, E.: 2006, 'In defence of moral imperialism: four equal and universal prima facie principles', in *Journal of Medical Ethics*, vol. 32
- Dworkin, Gerald: 1988, *The Theory and Practice of Autonomy*, Cambridge UP
- Feinberg, Joel: 1986, *Harm to Self*, Oxford UP
- Frankfurt, Harry: 1971, 'Freedom of the Will and the Concept of a Person', *Journal of Philosophy* 68

- Hansson, Mats et al.: 2006, 'Should donors be allowed to give broad consent to future biobank research?', in *Lancet Oncology*, vol. 7
- Juth, Niklas: 2005, *Genetic Information, Values and Rights*, Acta Universitatis Gothoburgensis
- Kihlbom, Ulrik: 2008, 'Autonomy and negatively informed consent, in *Journal of Medical Ethics*, vol. 34
- Lemaire, R.: 2006, 'Informed consent – a contemporary myth?', in *The Journal of Bone and Joint Surgery*, 88-B, pp. 2-7
- Macleay, Alasdair: 2006, 'Autonomy, Consent and Persuasion', in *European Journal of Health Law*, vol. 13, no. 4, pp. 321-38
- Nedelsky, Jennifer: 1989, 'Reconceiving Autonomy: Sources, Thoughts and Possibilities', in *Yale Journal of Law and Feminism*
- O'Neill, Onora: Informed Consent and Genetic Information, in *Stud. Hist. Phil. & Biomed. Sci.*, 2001, vol. 32, no. 4, p. 692
- Oshana, Marina: 2006, *Personal Autonomy in Society*, Ashgate
- Sreenivasan, Gopal: 2003, 'Does informed consent to research require comprehension?', in *The Lancet*, vol. 362, pp. 2016-8
- Taylor, Charles: 1985, 'What Is Human Agency?', in *Philosophical Papers*, Vol. I, Human Agency and Language, Cambridge University Press
- Taylor, James S.: 2003, 'Autonomy, Duress, and Coercion', in Ellen F. Paul et al. (eds.): *Autonomy*, Cambridge UP
- Taylor, James S.: 2004, 'Autonomy and Informed Consent: A Much Misunderstood Relationship', in *The Journal of Value Inquiry*, 38; pp. 383-391
- Thalberg, Irving: 1989, 'Hierarchical Analyses of Unfree Action', in John Christman (ed.): *The Inner Citadel: Essays on Individual Autonomy*, Oxford UP
- Warnock, Mary: 2001, 'Informed Consent – a publisher's duty', in Len Doyal and Jeffrey S. Tobias (eds.): *Informed consent in Medical Research*, BMJ Books

Biobank Research and the Right to Privacy

Abstract

What is privacy? What does privacy mean in relation to biobanking, in what way do the participants have an interest in privacy, (why) is there a right to privacy, and how should the privacy issue be regulated when it comes to biobank research? A relational view of privacy is argued for in this paper, which takes as its basis a general discussion of several concepts of privacy and attempts at grounding privacy rights. In promoting and protecting the rights that participants in biobank research might have to privacy, it is argued that their interests should be related to the specific context of the provision and reception of health care that participation in biobank research is connected with. Rather than granting participants an exclusive right to or ownership of their health information, which must be waived in order to make biobank research possible, health information should be viewed as part of the relation between doctor and patient, and in light of the moral rights and duties that accompany any involvement in a research based system of health services.

Key words

Privacy; biobank research; research ethics; health information

Introduction

Participants in biobank research are not like participants in other kinds of medical research. Biobank research is not about measuring the effects of a medical intervention: it should leave the health of the participant's body and mind virtually untouched. Neither will participating in biobank research tell the participant anything more about their own present or future health. And the general health of those who choose to take part will not improve or be any better than the health of those who choose not to participate.

Biobank research is group level research on information provided by the participants themselves or derived from a blood sample, tissue or registries. It is therefore not easy to say exactly how the individual participants can be said actively to take part in biobank research projects. Moreover, it is not easy to say either which or what kind of research projects biobank participants are actually going to participate in. It goes without saying, then, that this makes it less

than straightforward for potential participants in biobank research, when approached, to make an informed decision as to whether or not they should agree to participate.

Since participation in a biobank is restricted to the use of tissue already procured from medical treatment, or minimally invasive procedures such as giving a blood sample, bodily harm is not a primary concern. The primary concern is rather that biobank research involves collecting sensitive health information about the participants and updating this through linkage to other medical and non-medical registers. In biobank research, the primary concern thus is that there needs to be protection against infringements of the *privacy* of the research subjects¹⁸⁶.

The information collected about an individual in a biobank is widely held to be private in some sense. It is not just gathered from those individuals: the idea is that it continues to belong to them. It is somehow *still part of their person*. The information contained in and by health registries and tissue samples in therapeutic and diagnostic biobanks, together with the information obtained when participants fill in a questionnaire and have their blood sample taken, are all taken to be information which somehow falls under the jurisdiction of the individual. The collecting and collating of this kind of information is seen as something the individual should have a right to be informed about, and which he or she can deny access to or otherwise control.

Protecting the privacy of the patient is a basic principle of medical ethics from the time of the Hippocratic Oath to today. In contemporary research ethics the principle of non-maleficence thus includes protecting the privacy of the research subject. Failure to do so is seen as being harmful in itself as well as harmful to the integrity and autonomy of the participant, as we will see. In this paper we will discuss how different notions of privacy can illuminate the major issues of privacy interests and rights, and how the privacy issue relates to participation in and regulation of biobank research.

Protecting privacy in biobank legislation

Biobank legislation in different countries permits the individual's right to autonomy over biobank information to be waived in a variety of ways. The waiving can be done by the participant giving

¹⁸⁶ van den Hoven, J. 2000. Privacy and health information: the need for a fine-grained account. *Int. Journal of Quality in Health Care*. vol. 12, no. 1, Julie R. Ingelfinger and Jeffrey Drazen. *Registry Research and Medical Privacy*. *NEJM* 2004; 350;14;1452-3, and Norges offentlige utredninger. *God forskning – bedre helse. Lov om medisinsk og helsefaglig forskning, som involverer mennesker, humant biologisk materiale og helseopplysninger (helseforskningsloven)*. NOU 2005:21.

his or her informed consent, through approval from research ethics committees or some other authority, or by legal permission. What unites all these ways of governing biobank research is the premise that the individual's contribution to the biobank is a private concern – even if its usage in biobank research is to generate anonymised data about various groups for the benefit of public health in general, with any feedback being given to the individual.

When participation is mandatory, the element of immediate autonomy is no longer an issue, but the element of privacy remains. When consent is required, participants are asked to entrust their interest in or right to privacy to the biobank. The ethical issue of privacy in relation to biobank research has implications not only for the prevention of distress or harm brought about by an unsolicited flow of information, but also touches on considerations of equality, justice and fairness as well.¹⁸⁷ In order to see the importance of the philosophical debate on the nature of privacy, it is helpful to have a look at how ethical issues are played out in practice in relation to the regulation of biobank research. The discussion about the legislation of biobank research in Norway is illustrative for this purpose.

A white paper which prepared the groundwork for the current Norwegian Personal Data Act defines privacy as being composed of four individual interests, and three collective ones.¹⁸⁸ The individual interests are identified as *discretion*, *access*, *completeness*, and *private life*. Firstly, individuals are said to have an interest in controlling how information about them is used and distributed. The interest in *discretion* involves limiting the permission to register health information without consent from the persons involved: limiting who has access to these registers, and what use the information is put to, is also in the private interest. Secondly, individuals should be allowed *access* to registers in which they are listed. Otherwise, there is no way for them to see what information is included in which registers, and to what use it is put. Thirdly, individuals should know that any decisions made about them on the basis of registered information are fair and reasonable – such information should therefore be *complete* and correct. Fourthly, individuals should be shielded from unwanted requests and attention. There is thus a right and a need for a *private life*, in addition to the right to control the flow of information about oneself.

The collective interests are threefold: We want the institutions of the State to be *accessible* to all citizens; any and all personal information should be treated with a high level of *security*; and there should be only a *limited level of surveillance*. Any leak or abuse of information should be avoided. The different individual and collective interests that are bound up with the issue of

¹⁸⁷ van den Hoven, *ibid.*

¹⁸⁸ Norges offentlige utredninger, *op. cit.* 1, p. 38

privacy will sometimes come into conflict with other interests, such as the interest in medical knowledge. But more often than not they will overlap with other interests instead. And even if we limited our attention exclusively to privacy itself, the different interests which it comprises of might be in conflict – for instance the interest in discretion versus the interest in completeness.

The Norwegian Parliament has recently decided that entries in the formerly anonymous Norwegian Patient Register (NPR) will now be linked with every patient's personal ID number. This will be sanctioned by law, and the consent of the patients will no longer be sought. By having identifiable patient entries, the NPR can now be used for the purposes of research.

During the round of hearings that preceded the new Act, the Norwegian Data Inspectorate (NDI) argued against the proposal to make the NPR identifiable by person. The NDI argued:

Such a change will in any case represent an erosion of professional secrecy, and of the principle that everyone should be able to control the use of any information about them. The fact that information conveyed in personal communication with the doctor is to be registered centrally, regardless of the wishes of the patients themselves, will create anxiety and insecurity for many patients. In evaluating the need for a change, one should take into consideration the possibilities for and consequences of the fact that some patients will fail to contact the health service, or will give incorrect information, out of fear that information might be passed on elsewhere. The registration might be counter-productive in realising its purpose, and this possibility must be kept in mind in assessing the need for an NPR identifiable by person. There is no doubt that information about persons can be misused and that errors will occur, and the question now must be how soon and how often this will happen. The greater the amount and the greater the collections of data, the greater the possibilities of misuse, and the consequences thereof.¹⁸⁹

The arguments of the NDI in this statement are partly based on matters of principal and partly empirical. The principal objections are against the weakening of client confidentiality, the loss of control over personal information, and the lack of consent. The empirical arguments which the NDI points to are that potential research participants might decide against participation (involving informed consent) on the grounds that this would be linked to the

¹⁸⁹ Datatilsynet (The Norwegian Data Inspectorate). 2005. Høringsuttalelse om etablering av Norsk pasientregister som et personidentifiserbart register. Translated by LØU.

proposed NPR. Information might go astray and compromise the patient's right to privacy. If enlistment in the proposed NPR is mandatory for all patients, they might choose not to submit relevant information, or to give incorrect information. The violation of the patient's interests in discretion may lead them to have less trust in the health care system. In addition, the proposed NPR will ultimately not only conflict with the patient's interests in privacy, but also impair the quality of the register, and consequently the quality of the research, administration and therapy based on the register.

David Korn recognizes two primary causes for this anxiety about information and privacy: "One, which I call 'pragmatic', is the concern about such things as loss of health insurance, discrimination in employment, and social stigmatization. The second root is 'ideological' and springs from a strong, deeply held belief in an individual's right to privacy."¹⁹⁰ Korn's "pragmatic" root and the "empirical" arguments of the NDI both highlight a right to privacy which translates into a right not to be harmed. Any citizen should have the right not to experience social harm or unjust treatment as a consequence of participating in medical research. Korn's "ideological" root and the "principal" arguments of the NDI both highlight a right to privacy which translates into a right to property. Any citizen should have the right to decide what is going to happen inside their own private sphere, as well as what can be done with (material from) their bodies and information about themselves.

The questions and concerns of the NDI are highly relevant for the regulation of biobank research. Biobank research is most often conducted using anonymised information files, partly because it is concerned with relevant properties at the level of groups, not individuals, and partly to minimize the risk for sensitive information being leaked. Provided that all research projects are subjected to thorough ethical scrutiny by the relevant ethics committee, the risk the participants most meaningfully can be said to run is that risk of their personal information being accidentally leaked and misused – they do not run the risk of the material being abused in otherwise unethical research projects. It is therefore ethically imperative to minimize the risk for information being leaked or used inappropriately, as this is one way to address both the principal and the empirical arguments mentioned by the NDI in their statement above.

In a liberal society, the individual's rights to autonomy and privacy also extend to biobank information, albeit in a qualified way. The current biobank legislation in Norway, for instance, states that in order for research biobanks to be established in a legitimate way, there are three

¹⁹⁰ Korn, David: Medical Information Privacy and the Conduct of Biomedical Research, *Academic Medicine* 2000, vol. 75, no. 10, p. 964.

acceptable ways of relating to the participants, legally speaking: Firstly, biobank information may be used if the individuals taking part waive their right to keep the relevant information private, and exercise self-determination by giving their informed consent. Secondly, biobank information may be used if the scientific goal and benefit clearly exceeds any inconvenience caused to the individual. Thirdly, biobank information may be used if this right is specifically founded in the Biobank Act for the biobank concerned.¹⁹¹ This means that the interests of the individual, of society and of the researchers involved must be balanced. It is up to the Law to state principles by which such a balance is achievable. In either case, privacy is a good which is protected by the relevant body. How is the interest in and value of privacy to be understood and balanced against other interests and values?

Aspects and concepts of privacy

The importance of privacy is already emphasized in the story of Adam and Eve eating from the tree of knowledge: “mythically, we have been taught that our very knowledge of good and evil – our moral nature, our nature as men – is somehow, by divine ordinance, linked with a sense and a realm of privacy”¹⁹², as Milton Konvitz points out. Of course, a felt duty to hide parts of ourselves is not the same as an interest in or a right to hide parts of ourselves. There is a distinction between *mandatory privacy* – the duty not to engage in certain activities or to expose one’s “private parts” in public – and a *right to privacy* – the right to engage in certain activities and to expose one’s “private parts” out of the public eye. But the idea that we should have some kind of social control over aspects of our own person is a shared one. Controlling the social aspects of one’s person is fundamental for understanding our nature and preserving our dignity as morally and aesthetically sensitive beings.

Aristotle’s division between *polis* and *oikos*, the public and the domestic, paves the way to mark off one arena as generally less accessible than another. In ancient Greek culture, of course, freedom was equated with participation in public life, unlike the modern notion of freedom as something to be enjoyed in private. Locke likened one’s relation to oneself and one’s surroundings in terms of private property: Everyone *owns oneself*, and in working on objects one can come to own them too. In the wake of new inventions in the late 19th century Warren and Brandeis redefined the right to privacy as the right to be let alone: “Instantaneous photographs

¹⁹¹ The Norwegian Biobank Act. 2003.

¹⁹² Konvitz, Milton: Privacy and the Law: A philosophical prelude. Law and Contemporary Problems, vol. 31, Spring 1966, no. 2

and newspaper enterprise have invaded the sacred precincts of private and domestic life; and numerous mechanical devices threaten to make good the prediction that ‘what is whispered in the closet shall be proclaimed from the house-tops’.”¹⁹³ In their view, the right to privacy did not stem from the right to property, but from the more spiritual “right to one’s personality”¹⁹⁴. Or, to put it another way, the kind of property under discussion in questions of privacy is not material as such, not a printed word or a picture: it is information about and images of oneself.

These concepts of privacy are reflected in the following excerpts from the descriptive definitions provided by the *Oxford English Dictionary*: “*Privacy* - The state or quality of being private. 1. The state or condition of being alone, undisturbed, or free from public attention, as a matter of choice or right; freedom from interference or intrusion. 2. Private or retired places; private apartments; places of retreat. 3. Absence or avoidance of publicity or display; a condition approaching to secrecy or concealment. 4. A private matter, a secret, the private parts. 5. Intimacy, confidential relations.”¹⁹⁵ Definition 1 highlights the notion of privacy as *a right to be left alone*. The right to privacy afforded by property rights is clearer in definition 2, while definition 3 and 4 both deal with the same two notions of privacy. Firstly, there is the notion of privacy as an aspect of dignity, which involves the mandatory privacy necessary to distinguish civilized humans from barbarians and animals, as alluded to in the parable of Adam and Eve in Genesis.¹⁹⁶ Secondly, the connection to the related but not identical concept of secrecy is emphasized. That these two concepts are quite distinct can be illustrated by the courtesy we make use of in order to enable and sustain a social life. Keeping my opinion of your divorcing my sister to myself is something other than keeping it a secret. Likewise, that I have a naked body under my clothes is a private matter, but not a secret.¹⁹⁷ Definition 5 opens up for a relational notion of privacy.

It will be useful for our purposes to make a distinction between *negative privacy* as the right to be left alone, versus *positive privacy* as the right to share information with someone without

¹⁹³ Warren, S. and Brandeis, L.: The Right to Privacy, Harvard Law Review, vol. IV, no. 5, Dec. 15. 1890

¹⁹⁴ Ibid., p. 215

¹⁹⁵ <http://dictionary.oed.com/> Accessed the 24th of February 2007

¹⁹⁶ See also Etzioni, Amitai. 1999. The Limits of Privacy. Basic Books, pp. 196-7.

¹⁹⁷ See Nagel, Thomas. 1998. Concealment and Exposure. Philosophy & Public Affairs; vol. 27 no. 1 (winter 1998):3-30.

them passing it on¹⁹⁸. Both pertain to a discussion on informational privacy generally and to participation in biobank research specifically, but looking at the issues from the angle of negative or positive privacy, respectively, provides different perspectives on and insights into the same matter, as we will see.

The task is threefold: We should arrive at a clearer understanding of what privacy is, how (or if) privacy can be said to constitute a right, and how privacy relates to biobank participation. To link privacy to autonomy is the most common way of dealing with all of these three tasks. Privacy is then viewed as a precondition of autonomy, and as autonomy is a basic value, its promotion and protection gives us a right to privacy – also when it comes to biobank participation. We will therefore examine some of the ways in which privacy is thought of and further investigate the relationship between privacy and autonomy.

Privacy as a property right

If privacy is not only an *interest*, but indeed a *right*, it is a good and can be justified in itself without involving a simple trade-off relation with conflicting goods. It must be shown that the right to privacy overrides considerations of the social good or harm inflicted by respecting this right. If privacy of information is a right, individuals should not be asked to give it up even if this might be in the public interest. As we will see, several attempts have been made to ground a right to privacy, most notably by linking it to inalienable human rights such as a respect for autonomy and dignity. Giving up the right to privacy, then, would imply giving up qualities deemed to be essential to personhood.

The status and the very existence of a right to privacy are, however, matters of considerable debate¹⁹⁹. Is the putative right to privacy a distinct right on its own, as argued by Warren and Brandeis, or is it wholly reducible to various other rights and norms?²⁰⁰ Judith Jarvis Thomson claims the latter, and argues that if we take a closer look at the putative right to privacy, we will see that it has no force of its own. Not to respect someone's privacy might be rude, but is

¹⁹⁸ See Havinghurst, Clark C. 1966. Foreword. *Law and Contemporary Problems*, vol. 31, Spring 1966, no. 2.

¹⁹⁹ See Kalven Jr., Harry: Privacy in tort law – were Warren and Brandeis wrong?, *Law and Contemporary Problems*, vol. 31, Spring 1966, no. 2 and DeCew, Judith. 2002: Privacy, *The Stanford Encyclopedia of Philosophy*, summer 2002, Edward N. Zalta (ed.)

²⁰⁰ See Schoeman, Ferdinand, ed. 1984. *The Philosophical Dimensions of Privacy*. Cambridge UP

not illegal in itself. The “right to privacy” is simply an expression for an aggregate of features which other, real, rights more or less have in common: “I don’t have a right to not be looked at because I have a right to privacy; I don’t have a right that no one shall torture me in order to get personal information about me because I have a right to privacy; one is inclined, rather, to say that it is because I have *these* rights that I have a right to privacy.”²⁰¹ For Thomson, a right not to be looked at would for instance stem from property rights (people are not allowed to peek through my curtains), while the right not to be forced by torture to reveal private information stems simply from the right not to be harmed.

Thomson’s focus is on negative privacy and on the ethical justification for drawing a border between what is genuinely in the public interest and what is not. This puts the individual who claims and defines such a right in a rather vulnerable position. As Harry Kalven Jr. put it: “whatever is in the news media is by definition newsworthy, the press must in the nature of things be the final arbiter of newsworthiness.”²⁰² A right to negative privacy ought thus to be handled as a counterpart to the right to free speech: You have the right to say – or report - just about whatever you want to, but sometimes you ought to watch what you say – or leave people alone – anyway. But, in order to make privacy into a robust right instead of a custom or matter of courtesy, it seems necessary to ground it in something more fundamental, most notably the right to property.

A posted sign saying: “Private property – trespassers will be prosecuted” provides a clear message and has a clear legal standing, grounded in the laws of property. The idea of Warren and Brandeis was not to extend the right to property, but on the contrary to subsume it within a more extensive right to be left alone. As we remarked, Locke promoted the idea that we do not merely exist in our bodies, but also *own* them. Could this mean that, in relation to biobank research, we might pursue the more specific idea of owning the information which stems from our bodies? Such a strategy would provide us with a very clear legal precedent, and one which is easy to render intelligible: People have property rights which require other people to seek permission before entering their private property, whether it be their land, house, body or personal information.

²⁰¹ Thomson, J.J.. The right to privacy. *Philosophy and Public Affairs*, vol. 4, no. 4, summer 1975, p. 312

²⁰² Kalven Jr., *op. cit.* 14, p. 336

The question is of course if the analogy between property rights and the putative rights to informational privacy (or the subordination of the one to the other) is tenable. Remarking on the analogy between owning property and information, R. G. Frey asks:

Suppose that I have a certain illness and do not want the fact of my having it to be released: how do I acquire a private property right in this information in such a way that the fact that I have this illness becomes, as it were, mine? For, notice, nothing less than owning the fact – as it were, owning the information that that I have the illness – would be compatible with others learning this information but violating no private property right of mine. (...) if the theorist stipulates that this private property right to privacy, located in the core, is not to yield at all to utilitarian concerns (...) we should have to tolerate contagions and the rapid spreading of disease.²⁰³

Property rights do not entitle the owner to do anything he or she wants to on his or her property, so even property rights do not make all acts purely private matters. Nevertheless, the motive for wanting to call privacy a right rather than an interest would be to endow it with a kind of immunity to a utilitarian calculus. The attempt to ground a right to privacy in rights of property suggests that it is dubious to believe that a putative right to privacy can uphold such immunity. We will, however, now turn to other attempts at providing the right to privacy of information with a solid foundation.

Privacy as the right to be left alone

John Stuart Mill advances several kinds of arguments to show that a failure to respect a person's privacy infringes on their liberties, and causes *illegitimate intrusion into the private sphere where individuals are sovereign*.²⁰⁴ According to Mill, it is crucial that people are left alone to be able to exercise their liberty, because the right to and interest in privacy has several kinds of justification. Privacy is morally valuable in and of itself – it is essential to self-realization.²⁰⁵ Privacy is educationally valuable – it is essential to promoting self-esteem and an ability to exercise mature

²⁰³ Frey, R. G. 2000: Privacy, control, and talk of rights, in *The Right to Privacy*. Ellen F. Paul, Fred D. Miller Jr., Jeffrey Paul eds. Cambridge UP, pp. 64-5.

²⁰⁴ Mill, John Stuart. 1977. *Collected Works of John Stuart Mill*, vol. XVIII, University of Toronto Press

²⁰⁵ *Ibid*, p. 277.

choice.²⁰⁶ Privacy is even of instrumental value – it is essential to developing a more prosperous State.²⁰⁷

People should accordingly be (made) able and entrusted to make up their own minds. This perspective makes autonomy and privacy two sides of the same coin. As noted by Lawrence Gostin: “One standard account holds that the primary justification for respecting privacy resides in the principle of respect for autonomy. To respect the privacy of others is to respect their autonomous wishes not to be observed or have information about themselves released.”²⁰⁸ To obtain and distribute private information without the consent of the persons concerned undermines their ability to govern their relations to others, such that failure to respect peoples’ negative privacy undermines their autonomy. Ernest van der Haag puts it quite bluntly: “Individuation rests on privacy.”²⁰⁹

To say that autonomy presupposes privacy is not necessarily to assert that the two concepts are synonymous. But to a closer look at the concepts of privacy and autonomy might show that the links between them are not as strong as they appear. Gerald Dworkin shows that autonomy and privacy are quite separate concepts through the following two examples. Firstly, *deception* violates your autonomy, but not your privacy: “What is controlled is the information coming to you, not the information coming from you.”²¹⁰ Secondly, covert *surveillance*, conversely, violates your privacy, but not your autonomy, since “your decisions, your actions, your values, are in no way changed or altered from what they might be otherwise. You are as self-determining as ever.”²¹¹

James Stacey Taylor draws a more nuanced picture which qualifies Dworkin’s second example. Taylor argues that in failing to respect someone’s negative privacy by putting them under surveillance, one not only shows a disrespect for their autonomy, one even *undermines* their

²⁰⁶ Ibid, p. 277.

²⁰⁷ Ibid, p. 310.

²⁰⁸ Gostin, Lawrence. Health Care Information and the Protection of Personal Privacy: Ethical and Legal Considerations, *Annals of Internal Medicine* 1997, vol. 127, issue 8, part 2, pp. 683-690.

²⁰⁹ van den Haag, Ernest. 1971. On Privacy. In *Privacy*. J. R. Pennock and J. W. Chapman eds. Atherton Press. p. 152

²¹⁰ Dworkin, Gerald. 1988. *The Theory and Practice of Autonomy*. Cambridge UP, p. 104.

²¹¹ Ibid, p. 104

autonomy, since surveillance involves something more than keeping an eye on someone. The person doing the surveilling must in addition have the intention of controlling the behaviour of the person being surveilled in order to undermine her or his autonomy. The surveiller must therefore intend to discipline her by *overtly* surveilling her, or conversely control her acts so as to reveal something by *covertly* surveilling her. An invasion of someone's privacy does not as a consequence undermine her autonomy by itself – the invasion must in addition effectively control her acts in some way or other.²¹²

If violating a person's privacy does not in itself undermine their autonomy, but requires a further element of control, where can this element of control stem from? That there are several ways to control the behaviour of a person is nicely illustrated by Stanley Benn: "Threatening a man with penalties, or taking away his stick, are ways of preventing his beating his donkey; but if he stops simply because he is watched, the interference is of a different kind."²¹³ In this case it seems to be a kind of Kantian "principled autonomy"²¹⁴ which was invoked in the man by his being watched, thereby preserving the autonomy of the donkey owner in *that sense* of the concept. But it is argued, by Mill, Benn, and others, that the gaze of others controls the individual and induces heteronomous behaviour. The individual realm should therefore be shielded from the controlling influence of the social realm.

The general problem, however, with anchoring a right to privacy in a right to autonomy is that privacy might then end up being a metaphor for, rather than a precondition of, autonomy. Lloyd L. Weinreb brings this out clearly in his discussion of the various attempts to ground the right to privacy in the claim that autonomy is inconceivable without privacy. But, as Weinreb points out, even if we could all read each other's minds, and were subjected to persistent scrutiny by others, this would not then be unable to act autonomously, since obviously "it is not the case that whenever a person is not in private, he ceases to act autonomously and does not determine his conduct for himself"²¹⁵. A lack of privacy would change the way we act, change our social culture, and perhaps lead to a loss of well-being. But as the presence of constraints – rather than

²¹² Taylor, James Stacey. 2002. Privacy and Autonomy: A Reappraisal, *The Southern Journal of Philosophy*, vol. XL

²¹³ Benn, Stanley. 1971. Privacy, Freedom, and Respect for Persons. In *Privacy*. J. R. Pennock and J. W. Chapman eds. Atherton Press.

²¹⁴ O'Neill, Onora. 2002. *Autonomy and Trust in Bioethics*. Cambridge UP.

²¹⁵ Weinreb, Lloyd L. 2000. The Right to Privacy. In *The Right to Privacy*. Ellen F. Paul, Fred D. Miller Jr., Jeffrey Paul eds. Cambridge UP, pp. 37-38.

absolute freedom – is a precondition of autonomy, privacy in itself is not then a precondition of autonomy.

Ultimately, Weinreb argues, all attempts to make privacy a precondition for the autonomy of an agent “fails because in each instance it *directly* concerns what *others* know. Although the context in which he acts has changed, the person whose privacy is invaded is, *qua* actor, the same after the invasion as before; or if he is not, it is because of *his own* reaction to the fact that others have acquired the information in question about him. (...) Although privacy may strengthen one’s sense of autonomy and afford scope for autonomous action, autonomy as a human characteristic is the predicate of privacy, not its consequence.”²¹⁶ To say that an autonomous agent requires a private a realm tells us nothing specific about this realm other than its reference to autonomy: It makes the notion of privacy nothing more than a metaphor for agent autonomy.²¹⁷ While such a metaphor makes for a powerful and poetic message, metaphors in themselves do not make convincing arguments for the values and rights associated with privacy.

Privacy, control and dignity

Another aspect of the right to be left alone has to do with preserving dignity, rather than autonomy. For any of us assume that there must be a right not to be watched (in the very widest sense of the word) and that we should be able to control this in some way? The idea that privacy entails being in control of personal information about oneself again links privacy to autonomy, but in this perspective autonomy is a precondition of dignity, not a value in itself.

The idea of privacy as a kind of control is, however, not very robust. It is, for instance, not the ability to listen in on your private conversations *per se* which makes me violate your privacy – but the fact that I listen to them illegitimately.²¹⁸ Taylor nicely illustrates that even if a person retains control her privacy may still be violated: “Consider, for example, a person who is rather absentminded and frequently forgets to close her curtains while she undresses, so enabling her prurient neighbour to stand outside her bedroom and watch her. If he does so look he violates his neighbour’s privacy, but she still retains control over whether or not he is able to see her; she can simply draw the curtains.”²¹⁹

²¹⁶ Ibid., pp. 41-42.

²¹⁷ See *ibid*, p. 34.

²¹⁸ Thomson, op. cit. 16, note on p. 305

²¹⁹ Ibid., p. 589

We do find arbitrary surveillance to be an affront to our autonomy; it is a violation of our privacy which clearly overrules our interest in being left alone. And since loss of control makes such violations possible, it is easy to link privacy and control. But, protecting people's ability to control does not seem to be the way to fully understand the damage inflicted by violating people's privacy. One's interest in privacy does not consist solely of an ability to ensure that no one is able to eavesdrop on us.

Taking the perspective of the state, Amitai Etzioni argues that the absence of scrutiny by the state does not presuppose the absence of state control. It is not the case that "a state that seeks to control certain kinds of behaviour must be able to scrutinize them and thus cannot allow them to take place in privacy. (...) In free societies, the state does not scan homes pre-emptively to ensure that no child abuse is taking place."²²⁰ From the viewpoint of the citizen, a specific right to privacy does not entail personal autonomy: My duty not to perform certain bodily functions in public likewise shows that privacy and autonomy are quite distinct concepts.

Another approach to the question of why we feel there is a right not to be watched is that it negates our subjectivity and dignity. Benn promotes a "principle of respect for persons to underpin a general principle of privacy"²²¹. For him, the way the gaze of the other who scrutinizes my person as if I were an object seems to imply a loss of dignity as a conscious, creative and choosing subject. But Benn also invokes Sartre's argument that we reach self-awareness by being objectified by others, and sees no reason why a relationship based on mutual respect where one sees the other as both subject and object cannot be possible. Benn's reasoning does not so much justify a general right to privacy, as it contributes at a fundamental level to general debates on how norms of privacy play a cultural role in respectful social interplay, and on whether protection from or exposure to various social settings is the way to build integrity, character and an independent mind.²²²

Persons should be respected – which indeed is a conceptual and not just a normative remark – and regarding them as *just* objects is not an act of respect. It seems that such a basic right to be respected as a person is a right which cannot meaningfully be waived. This, then, does not provide us with a clear-cut ground for not to be under surveillance – which might be

²²⁰ Etzioni, Amitai. 1999. *The limits of Privacy*. Basic Books. p. 211.

²²¹ Benn, op.cit. 28, p. 13

²²² See Simmel, Arnold. 1971. *Privacy Is not an Isolated Freedom*. In *Privacy*. J. R. Pennock and J. W. Chapman eds. Atherton Press, and Beate Rössler ed. 2004. *Privacies: Philosophical Evaluations*. Stanford UP.

legitimate for several reasons, for instance to prevent criminal acts. By extension, it does not explain why privacy is an important factor in treating people with respect. As Lubor Velecky reminds us, “the *privacy* of a person is the *privacy of a person*”²²³: We might be justified in disregarding a person’s interest in privacy if it is obviously outweighed by another of his interests.

Privacy and social freedom

All the discussed attempts at justifying the right to privacy have brought out interesting aspects of an interest in privacy, both in its own right and as something that is instrumental for other values. It has not, however, been convincingly demonstrated why we should regard privacy as a right rather than as one value among many others. Neither have we managed to come up with a fully satisfactory definition of what exactly makes something private or not, or why and even if we should regard some kinds of activities or information as inherently private. We will now turn to another way of linking the notions of autonomy and privacy which is more promising in these respects, namely Ferdinand Schoeman’s theory of privacy as a precondition of social freedom.

A point of departure for Schoeman is Mill’s idea of social control putting limitations on personal liberty. Schoeman, however, takes issue with the idea of *individual* privacy as a precondition of autonomy, and defines the twin concepts of autonomy and privacy in this way: “Both privacy and autonomy suggest that some people have no business crossing a threshold. But in addition to this, privacy suggests that on the other side of that threshold there may be something still interpersonal.”²²⁴ The right to privacy delineates social spaces which should be allowed their own internal dynamic. For Schoeman, the essence of privacy is that it enables the individual to associate with other individuals in a way that promotes social freedom. The concept of autonomy highlights the ideal of independence as a means of gaining social freedom, while the concept of privacy highlights the relational nature of the ways in which we attain such social freedom. We can express ourselves freely in the privacy of our family, and among other groups to which we belong.

Schoeman criticizes Mill’s idea that we need a private space to escape conformist thinking, to rebel and renew, and be creative and critical. He likens the contemporary idea of the fully rational and informed autonomous person to the decision-theoretic models of an economy, which neither normatively nor descriptively fit social reality. For Schoeman instead, we exercise

²²³ Velecky, Lubor C. 1978. *The Concept of Privacy*. In *Privacy*. John B. Young ed. John Wiley & Sons.

²²⁴ Schoeman, Ferdinand D. 1992. *Privacy and Social Freedom*. Cambridge UP, p. 21.

our privacy in social settings which we are able to shape, and where we can safely express ourselves and get relevant feedback instead of undue sanctions: “Social freedom, we concluded, did not describe a condition in which individuals are left alone by others. Social freedom, instead, is a condition of having opportunities to pursue with others significant ends without enduring unfair or unreasonable sacrifices.”²²⁵

Does Schoeman’s account leave out privacy proper – the notion that each one of us needs some private space of our own? He does not think so: “Privacy restricted to seclusion of a person from others affords us only a glimpse of only a fraction of the role of privacy. (...) Primarily, privacy functions in the context of enabling and facilitating associative features of life, features that in certain stages of history are constitutive of social freedom.”²²⁶ Schoeman’s point is that privacy’s value to the individual is that it enables social freedom. Thus, freedom is something other than individual independence. In this way, privacy defined as the “right to be left alone” does not constitute part of Schoeman’s account of privacy.

When Charles Fried argues that love and friendship built on trust are inconceivable without privacy²²⁷, this should be taken to mean that people should be able to relate closely without undue interference, instead of implying that individual privacy is a precondition of intimacy. The main merit of Schoeman’s account of privacy is that it eases the antagonism between promoting the common good, and promoting the privacy, autonomy and dignity of the individual by identifying and respecting her or his right to privacy. It likewise lessens any potential antagonism between the individual and the goals of social freedom and flourishing.

But, does this not simply happen at the expense of the interests of the individual? Even if ‘privacy restricted to seclusion of a person from others affords us only a glimpse of only a fraction of the role of privacy’, how is the value of this “fraction” in the lives of individuals to be accounted for in a theory such as Schoeman’s? One answer would be: That if your activities, or personal information about you, are irrelevant to your relationship to others, and you value keeping these to yourself, there should be a mutual obligation to respect this interest in privacy. This answer brings us to a relational concept of privacy.

²²⁵ Ibid, p. 193.

²²⁶ Ibid, pp. 193-4.

²²⁷ Fried, Charles. 1984. Privacy. In Ferdinand Schoeman, ed. 1984. *The Philosophical Dimensions of Privacy*. Cambridge UP

A relational concept of privacy

One way of looking at the right to privacy is to argue that the closer you come to a person, the greater the burden of responsibility is on you doing so legitimately. In the world of medical research, this could be achieved through an agreement or principle along these lines: the nearer the permitted contact, the clearer and more explicit informed consent must be. This makes respect and legitimacy key approaches in establishing the required type of informed consent.

Information about a person can be misused by companies, employers, or public authorities in order to control, deceive or harm. In the medical research setting, such abuse of power could take the following form: The participants of an epidemiological research project dutifully answers questions about their smoking habits, only to find out years later that this information is used to restrict their rights to free treatment for smoke-related diseases.

These perspectives of integrity and power²²⁸, however, provide us only with a metaphor for what it is to be a person, and illustrate some of the potentially negative consequences of sharing information. The provision of information makes one vulnerable to harm: If I get to know your credit card details I can empty your bank account; if as your doctor I give confidential information about your health to a potential employer this might compromise you in some way; and if I share confidential information with your friends or colleagues this might ruin your relationship with them.

What makes the relevant information private here, however, is not its special relation to you, but the special relation it creates between you and someone else. The significance of all kinds of information depends on its context and collocation, which (for instance) means that information about an individual is not inherently private – or even public for that matter. The exact significance of privacy is social. Unlike the idea of an essentially private sphere of spiritual activity, the ideas associated with privacy are essentially social in nature. There would of course be no point in concealing something you cannot show anyway. People who live perfectly secluded lives in their private realm have no more privacy than people who live under total surveillance.

The right and duty to hide your “private parts” is not rooted in their particular expressiveness, but in the role they are assigned in how a culture handles sexuality. Your visible face, on the other hand, makes an important contribution to expressing your personality, and being obliged to hide your face would erase a significant part of your personality in the public

²²⁸ See Scanlon, Thomas. Thomson on privacy. *Philosophy and Public Affairs*, vol. 4, no. 4, summer 1975, and Norges offentlige utredninger. 1997. Et bedre personvern. NOU 1997:19

arena. The connection between rights and privacy is therefore ambiguous and shows the importance of distinguishing between privacy and personality.

By opening a bank account I enter into an understanding with my bank when it comes to my financial transactions. This information is private, meaning that the bank is obliged not to share this information with others, except under certain circumstances that I am aware of. The staff at the bank is furthermore obligated to handle this information respectfully – they should not read my bank transcript aloud as lunch entertainment, for instance. Any information should be handled securely by the bank and by me – we both have a responsibility not to let information fall into the hands of others, because of the potentially harmful consequences.

As my friend or my doctor you likewise enter into a contract of privacy with me. You promise, casually or formally, to handle my personal information with secrecy, confidentiality and discretion. What is shared under mutual understanding differs from relation to relation. What can be shared in one relation could ruin another, and vice versa. We have all kinds of relationships which involve the sharing of different kinds of private information in this sense. If the sharing is mutual, then we can define these relations as ones of friendship and intimacy.

But “to share everything” expresses mutual confidence rather than an agreement involving mutual surveillance. To demand total disclosure is more a way of controlling people than to find out about their true nature. Any relationship works in a certain way, and to enter into a bond based on total disclosure will not form the basis of ultimate intimacy, or provide a way to find the “real person” – it is simply yet another, special, way to relate. This shows that privacy is more about restricting the potential for being controlled socially by others than about controlling a certain set of information ourselves.

The reason why some sorts of information are more private than others is thus that they can have a negative impact on one’s relations to other people, and not that such information is in itself inherently part of an “inviolable personality” and thus under the jurisdiction of the individual in every instance. The reason why we would want to avoid total surveillance is that we would want to avoid total social control. We do not want to be exposed either literally or metaphorically, because it harms our ability to enter into different kinds of relationships with different people. In this way James Rachels’ answer to his own question make sense: “What about our feeling that certain facts are ‘simply nobody else’s business’? (...) In general, a fact about ourselves is someone’s business if there is a specific social relationship between us which entitles them to know.”

Instead of trying to single out what does and what doesn’t belong to our core self and what is therefore essentially private, a relational perspective sees privacy as something which

depends on the relationships we enter. In this way, privacy does not have the status of an absolute right, but achieves value and is protected through various social relations. Weinreb touches on this when he remarks that: “The recognition of a person’s privacy is not, as is the application of a right, independent of circumstances. On the contrary, it is freighted with assumptions about circumstances and varies accordingly.”²²⁹ Privacy can be said to be more than an interest and less than a right, in the way that the keepers of privacy have an obligation to treat it as an absolute right within the relationship. The Hippocratic Oath can readily be understood this way: “All that may come to my knowledge in the exercise of my profession or in daily commerce with men, which ought not to be spread abroad, I will keep secret and will never reveal.” This promise of secrecy exemplifies privacy in a way which brings out its relation to confidentiality.

We saw that one of the problems of grounding a right to informational privacy was to identify which information is private *without circularity*, and on what grounds. How would, for instance, the view that I *own* my personal information work in terms of how I acquire such ownership, and what kinds of information does my ownership include and exclude? To single out certain kinds of information as intrinsically private seems misguided, as the meaning of any piece of information is dependent on context.

The notion of privacy as dependent on relation and context still leaves us with a similar kind of problem. A relational concept of privacy involves having to identify which relations the information can most appropriately be said to be a part of. As we will see, health information may be understood to encompass several relations which patients and research participants take part in. The identification of the appropriate relation necessarily includes determining which kinds of information may be deemed relevant to which relation: If you are a player on my favourite team, does that entitle me to know something about your hobbies? Such identifications are additionally complicated by the fact that often we engage in several separate roles and relations with the same persons.

Biobank research and the right to privacy

Why is a right to privacy more readily claimed in order to protect health information, than to protect economic information? Is it because health information is of a more delicate nature than

²²⁹ Weinreb, *op. cit.* 30, pp. 43-4.

information about personal finances? Or is it more as Alexander Rosenberg suggests²³⁰: Peoples' economic situation is something they have generally earned, both literally and metaphorically, and consequently it is to a large extent something they have to accept or cope with. The make-up of peoples' bodies (health, race, sex, looks, etc.), on the other hand, is something which is more inherited than earned, and leads easily to kinds of personal or structural discrimination which we try to discourage. To have a right to privacy in these matters is then to put up a temporary and local Rawlsian "veil of ignorance", while waiting for these kinds of discrimination to disappear because of new attitudes or through the making of new policies, both of which should do away with certain forms of contemporary discrimination. In this perspective, privacy is a good which is instrumental and reciprocal in the sense that its justification lies in a levelling of the playing field if we all grant it to each other.

In order to promote the specific privacy interests of participants in biobank research, it is important to situate and value these interests in their proper contexts. As pointed out by the Norwegian NDI, this context might be ambiguous for a patient who relates both to his physician and to registry research by mandatory participation in the NPR. The context here might, however, also be viewed as a relation between a participant in a universal health care system which offers medical treatment based on research. The right to receive medical care could then be argued to correspond to a duty to take part in the maintenance of the system. In such a relation of mutual obligations the relevant health information is private in the sense that the information should be handled with respect, it should not be passed on, and it should be ensured that its usage does not adversely affect or otherwise compromise the participants in the system.

Conclusion

A relational view of privacy has been argued for in this paper, on the basis of a general discussion of several concepts of privacy and previous attempts at defining and grounding privacy rights. In promoting and attempting to uphold the privacy interests of those who take part in biobank research, it is argued that that their interests should be related to the specific context of the provision and reception of health care that participation in biobank research is connected with. Rather than granting participants an exclusive right to or ownership of their health information,

²³⁰ Rosenberg, Alexander. 2000. Privacy as a Matter of Taste and Right. In *The Right to Privacy*. Ellen F. Paul, Fred D. Miller Jr., Jeffrey Paul eds. Cambridge UP.

which must be waived in order to make biobank research possible, health information should be viewed as part of the relation between doctor and patient and in light of the moral rights and duties that accompany any involvement in a research based system of health services.

Acknowledgements

Thanks to Berge Solberg, Bjørn Myskja, Domhnall Mitchell and Sophie Kasimow for valuable comments, and the staff at the Hastings Center for their comments, kind hospitality, and for providing the privacy needed to write this paper.

References

- Benn, Stanley. 1971. Privacy, Freedom, and Respect for Persons. In *Privacy*. J. R. Pennock and J. W. Chapman eds.
- DeCew, Judith. 2002: Privacy, *The Stanford Encyclopedia of Philosophy*, summer 2002, Edward N. Zalta (ed.)
- Datatilsynet (The Norwegian Data Inspectorate). 2005. Høringsuttalelse om etablering av Norsk pasientregister som et personidentifiserbart register. Translated by LØU.
- Dworkin, Gerald. 1988. *The Theory and Practice of Autonomy*. Cambridge UP
- Etzioni, Amitai. 1999. *The Limits of Privacy*. Basic Books
- Frei, R. G. 2000: Privacy, control, and talk of rights, in *The Right to Privacy*. Ellen F. Paul, Fred D. Miller Jr., Jeffrey Paul eds. Cambridge UP
- Fried, Charles. 1984. Privacy. In Ferdinand Schoeman, ed. 1984. *The Philosophical Dimensions of Privacy*. Cambridge UP
- Gostin, Lawrence. Health Care Information and the Protection of Personal Privacy: Ethical and Legal Considerations, *Annals of Internal Medicine* 1997, vol. 127, issue 8, part 2
- van den Haag, Ernest. 1971. On Privacy. In *Privacy*. J. R. Pennock and J. W. Chapman eds. Atherton Press
- Havinghurst, Clark C. 1966. Foreword. *Law and Contemporary Problems*, vol. 31, Spring 1966, no. 2.
- van den Hoven, J. 2000. Privacy and health information: the need for a fine-grained account. *Int. Journal of Quality in Health Care*. vol. 12, no. 1
- Ingelfinger, Julie R. and Drazen, Jeffrey. 2004. Registry Research and Medical Privacy. *NEJM*; 350;14

Norges offentlige utredninger. God forskning – bedre helse. Lov om medisinsk og helsefaglig forskning, som involverer mennesker, humant biologisk materiale og helseopplysninger (helseforskningsloven). NOU 2005:21.

Kalven Jr., Harry: Privacy in tort law – were Warren and Brandeis wrong?, *Law and Contemporary Problems*, vol. 31, Spring 1966, no. 2

Konvitz, Milton: Privacy and the Law: A philosophical prelude. *Law and Contemporary Problems*, vol. 31, Spring 1966, no. 2

Korn, David: Medical Information Privacy and the Conduct of Biomedical Research, *Academic Medicine* 2000, vol. 75, no. 10

Mill, John Stuart. 1977. *Collected Works of John Stuart Mill*, vol. XVIII, University of Toronto Press

Nagel, Thomas. 1998. Concealment and Exposure. *Philosophy & Public Affairs*; vol. 27 no. 1 (winter 1998)

Rosenberg, Alexander. 2000. Privacy as a Matter of Taste and Right. In *The Right to Privacy*. Ellen F. Paul, Fred D. Miller Jr., Jeffrey Paul eds. Cambridge UP.

Scanlon, Thomas. Thomson on privacy. *Philosophy and Public Affairs*, vol. 4, no. 4, summer 1975, and Norges offentlige utredninger. 1997. Et bedre personvern. NOU 1997:19

Schoeman, Ferdinand, ed. 1984. *The Philosophical Dimensions of Privacy*. Cambridge UP

Schoeman, Ferdinand D. 1992. *Privacy and Social Freedom*. Cambridge UP

Simmel, Arnold. 1971. Privacy Is not an Isolated Freedom. In *Privacy*. J. R. Pennock and J. W. Chapman eds. Atherton Press, and Beate Rössler ed. 2004. *Privacies: Philosophical Evaluations*. Stanford UP.

Taylor, James Stacey. 2002. Privacy and Autonomy: A Reappraisal, *The Southern Journal of Philosophy*, vol. XL

Thomson, J.J.. The right to privacy. *Philosophy and Public Affairs*, vol. 4, no. 4, summer 1975

Veale, Lubor C. 1978. The Concept of Privacy. In *Privacy*. John B. Young ed. John Wiley & Sons.

Warren, S. and Brandeis, L.: The Right to Privacy, *Harvard Law Review*, vol. IV, no. 5, Dec. 15. 1890

O'Neill, Onora. 2002. *Autonomy and Trust in Bioethics*. Cambridge UP.

Weinreb, Lloyd L. 2000. The Right to Privacy. In *The Right to Privacy*. Ellen F. Paul, Fred D. Miller Jr., Jeffrey Paul eds. Cambridge UP

When is normative recruitment to medical research legitimate?²³¹

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Abstract

Rosamond Rhodes and John Harris have both recently argued that we all have a general moral duty to participate in medical research. However, neither Rhodes nor Harris's arguments in support of this obligation stand up to scrutiny, and severe and convincing criticism has been levelled against their case. Still, to refute their arguments is not to refute the conclusion. There seems to be some truth to the view that when people are asked to take part in medical research, their choice is not completely morally neutral. In this paper, we argue that the proper question to ask is *when*, rather than *if*, a certain moral duty to volunteer for medical research can be appealed to. To answer this question, we need a denser description of relevant research projects and their context rather than just describing medical research in general. In a departure from our study of participants in the Norwegian HUNT biobank, we use the normative implications of the Norwegian concept "dugnad" to discuss the requirement of providing neutral information to potential biobank participants in order to promote their free and informed decision as to whether or not to take part. We suggest that normative recruitment is not just a question of principles and ethics. It is also a question of research design.

Key words

Research ethics, dugnad, biobanking, the HUNT study

²³¹ The authors would like to thank John-Arne Skolbekken and Nancy Bazilchuk for their valuable comments to, and linguistic improvements of, this article.

A general duty to participate in medical research

In an attempt to interpret anew the autonomy and obligations of participants in biobank research, Rosamond Rhodes in the article *Rethinking Research Ethics*²³² makes a frontal attack on contemporary research ethics. In bioethical literature, informed consent is argued for on the basis of an ambiguous concept of autonomy, Rhodes says. On the one hand, autonomy is taken as an *ideal* for the individual. The ideal, then, is that the foundation for an individual's choice is freedom and reflection. On the other hand, autonomy is taken to be a *norm* for how an individual's choices are to be understood.

While such a norm demands an assumption that an individual makes autonomous choices, according to Rhodes the opposite position is prevalent in bioethics literature. The norm of autonomy is replaced by the ideal, which drastically restricts the kinds of people who can truly be said to be autonomous. In this manner, the kinds of people who are genuinely autonomous, able to give an informed consent, and to take part in research, are separated from the kinds of people who do not possess these qualities, and who are consequently excluded from research.

Rhodes accentuates autonomy as a social norm, and argues against the exclusion of groups of people as participants in research on the basis of an ideal of autonomy. Indeed, everybody should take part in research, Rhodes argues, because the vulnerable aspect in this context is the future patient rather than the present research participant. And to assume that it is against the will and interest of people to take part in a morally laudable and other-regarding project such as improving medicine through research is for Rhodes deeply disrespectful²³³. She states the implication of her views on autonomy regarding research participation thus: "So, in light of our appreciation of human vulnerability to injury and disease and our appreciation of the value of clinical research, reasonable people should endorse policies that make research participation a social duty."²³⁴

On the basis of these considerations, Rhodes puts forward a *novel proposal*: Her idea is that society, after thorough deliberation, should institute obligatory participation in medical research at regular intervals for all citizens. The choice is then not *if* you want to participate in a study or not, but *which* study to participate in. All studies would have to be approved by public medical authorities. This would draw attention to the approval process, and would require full disclosure

²³² Rhodes, Rosamond: *Rethinking Research Ethics*. *The American Journal of Bioethics* 2005; 5(1), p. 7.

²³³ Rhodes 2005, p. 14.

²³⁴ Rhodes 2005, p. 15.

of the study design, in order for institutions to be judged trustworthy by prospective participants. Projects should also be deemed of high quality and importance, and with few or no inexpedient burdens placed on participants. The granting of informed consent in this context would be part of the active exercise of one's autonomy, inside of a field restricted by law.

Rhodes intends to establish medical research as one of society's central tasks. And from this perspective, the demand that all research be of direct benefit to participants undermines its social and long-term purposes. In the regulation and evaluation of specific research projects, it is important to focus on the quality of the research, and to maintain legitimate trust on the part of participants. By making autonomy and participation the norm, the default position for Rhodes is that everybody can and will contribute to the common good resulting from medical research.

John Harris discusses the question of a putative duty to participate in research as a moral, and not a juridical or a political, question. He emphasises two principles in the article *Scientific research is a moral duty*, both of which he thinks commit us to a moral obligation to participate in medical research.²³⁵ The first principle is our moral duty not to harm others. Harris argues that such harm is the consequence of declining to contribute to this kind of research. The second principle is the principle of justice, which results in the problem of the free rider.

Harris does not argue for any legal duty to take part in research, but holds that these principles make it ethically problematic to refuse participation. To participate is required, both to contribute to the common good, as well as to be able to respect oneself as a moral actor. On the basis of this, it is possible to presume that a safeguarded participation also would be in the interest of those deemed to be without full competence to consent. Harris concludes: "There is then a moral obligation to participate in research in certain contexts. This will obviously include minimally invasive and minimally risky procedures such as participation in biobanks, provided safeguards against wrongful use are in place."²³⁶

Perfect and imperfect duties

Although the views put forward by Rhodes and Harris touch upon something important, their arguments are far from unproblematic, as shown by the debate and criticism sparked by their

²³⁵ Harris, J. Scientific research is a moral duty. *Journal of Medical Ethics* 2005; 31: 242-248.

²³⁶ Harris 2005, p. 247.

articles.²³⁷ John Harris argues, for instance, that to choose not to participate in medical research conflicts with the principle of fairness. Non-participants are illegitimate free riders if they later benefit from the research in receiving improved health care. In making this argument, however, Harris overlooks the fact that even non-participants pay for the health care they receive through taxation or insurance premiums, and that they also have no choice but to benefit from research-based health care. Furthermore, it can be argued that one of the benefits of modern society is precisely a kind of institutionalised free riding in the form of division of labour. This makes it unnecessary (and unfeasible!) for everybody to take part in any kind of research from which we might possibly benefit.

A similar kind of objection has been made to Harris's use of the principle of a duty to help others by taking part in medical research²³⁸. Sharpsay and Pimple invoke the Kantian notion of *imperfect* moral duties as the most precise way to describe the relevant obligation here, saying that "participation in medical research per se is not morally obligatory, but neither is it supererogatory; it is one way in which people may choose to discharge their imperfect obligation to help others."²³⁹ A *perfect* moral obligation always to help others would make our lives unmanageable, as we are finite beings with limited means. And because participating in medical research is but one of many ways to help others in need, it can at most be argued to be an imperfect obligation to take part.

For Rhodes, consenting to take part in medical research is to contribute to the common good. The debate on informed consent for, or a compulsory participation in, medical research,

237 See Beauchamp, T. How Not to Rethink Research Ethics. *The American Journal of Bioethics* 2005; 5(1): 31-33, London, A. Does Research Ethics Rest on a Mistake? *The Common Good, Reasonable Risk and Social Justice. The American Journal of Bioethics* 2005; 5(1): 37-39, Sharp, R. & Yarborough, M. Additional Thoughts on Rethinking Research Ethics. *The American Journal of Bioethics* 2005; 5(1): 40-42, Wachbroit, R. & Wasserman, D. Research Participation: Are We Subject to a Duty? *The American Journal of Bioethics* 2005; 5(1): pp. 48-49, McGuire, A. & McCulloch, L. Respect as an Organizing Normative Category for Research Ethics. *The American Journal of Bioethics* 2005; 5(1): W1-W2, Sharpsay, S & Pimple, K. Participation in biomedical research is an imperfect moral duty: a response to John Harris, *J Med Ethics* 2007;33:414-417, Brassington, I. John Harris' argument for a duty to research, *Bioethics* 2007; 21; 3:160-168.

²³⁸ See Brassington 2007, and Sharpsay and Pimple 2007.

²³⁹ Sharpsay and Pimple 2007, p. 416.

must therefore take place in the context of a common understanding of the common good. But in a pluralistic and liberal society, such a consensus is not necessarily reached, or even aimed at.²⁴⁰ Different answers will be obtained for questions such as: What are the merits of good health? What constitutes good health? Do biobank and other medical research promote public health in the right way?

Rhodes's system of mandatory research participation entails a limited obligation to take part in research projects. Even such a limited obligation is, however, hard to uphold. As argued by Robert Wachbroit and David Wasserman, "research participation should be seen as a valuable civic activity, like school tutoring, volunteer fire-fighting, and neighbourhood patrolling. Like those other activities, it is a way for individuals to serve a community from which they derive many benefits. It should be encouraged and praised like those other activities, but there is no reason to single it out as the subject of a universal duty."²⁴¹

This line of argument removes medical research from the prominent position that compels Rhodes and Harris to see it as subject to a duty to take part. The prominent position of medical research establishes both for Rhodes and Harris a duty to take part based on intergenerational fairness: We have an obligation not only to maintain the present level of medical care, but have an obligation to improve it through research for the sake of future generations, just as preceding generations by their research participation have made the present level of medical care possible.

Such an imperative to undertake research should stem from the moral obligation we have to help alleviate the suffering of today and tomorrow. But for the research imperative to be a moral obligation, something we *must* do, failing to do medical research must not only harm people; it must also be indispensable in avoiding (future) harm. In his book *What Price Better Health*,²⁴² however, Daniel Callahan questions both of these assumptions. In countering the argument that more medical research is indispensable in avoiding (future) harm, Callahan reminds us that helping others by participating in medical research is but one aspect of our vision of a good society. Providing social security, proper education, family welfare and so forth – along

²⁴⁰ See London, A. Does Research Ethics Rest on a Mistake? The Common Good, Reasonable Risk and Social Justice. *The American Journal of Bioethics* 2005; 5(1): 37-39, and Sharp & Yarborough 2005

²⁴¹ Wachbroit & Wasserman 2005, pp. 48-49.

²⁴² Callahan, Daniel 2003. *What price better health? Hazards of the research imperative*, Berkeley: University of California Press.

with improving health care – is a necessary, but not sufficient condition for fulfilling this vision. It is also important not to mistake social and cultural problems for medical problems.

Callahan does not accept the assumption that we have a duty to develop more effective medical treatments for future generations. He quotes Hans Jonas in support of his view: “The destination of research is essentially melioristic [The belief that improvement of society depends on human effort.]. It does not serve the preservation of the existing good from which I profit myself and to which I am obligated. Unless the present state is intolerable, the melioristic goal is in a sense gratuitous, and this not only from the vantage point of the present.” Callahan, like Sharys and Pimple, thus classifies medical research as an imperfect moral duty.

The dagnad concept

Rhodes aims to make medical research a common good that is part of a larger social contract. Another way of thinking about this is that such an understanding can be created for every research project. It is the research project – through its design, context and intention - that has to construct and establish the common good, in order to justify normative recruitment. We will now explore this idea by taking a closer look at a specific medical research project and a particular way of describing participation in the project. This exploration aims to make possible a more nuanced view of the way in which participation in medical research should be taken to be a perfect or an imperfect duty – or no duty at all. The implications of the answer to this question regarding the recruitment of participants will subsequently be pursued.

The Norwegian health study and biobank research project HUNT²⁴³ is referred to by policy makers as the largest health *dagnad* in Norway – or even in the world²⁴⁴. HUNT is one of the largest existing projects in genetic epidemiology in the world. But what does the Norwegian word “dagnad” mean, and how does it relate to participation in health surveys and biobank research?

The dagnad concept stems historically from pre-industrial Norwegian farm regions. In these regions, the farms were rather small, the produce was consumed by the farm people

²⁴³ HUNT is an acronym for “the Health Study of Nord-Trøndelag” in Norwegian.

²⁴⁴ See for instance Gunnar Bovim in ‘Sikkert som biobanken?’, in *Adresseavisen*, 20. 07. 01, and in ‘Har overtatt verdens største helseundersøkelse’, in *Universitetsavisa*, No. 1, 2001, p. 12, Steinar Krokstad in ‘HUNT, nordtrønderne og helsedagnaden’, in *Trønderavisa* the 18th of September 2004, and Stig Slørdahl in ‘Hard trening mest effektivt’, in *Levanger avisa*, 15.12.05, and in ‘Store innskudd i ny biobank’, in *Universitetsavisa*, 15.2.07

themselves, and the market for goods and labour was limited. To undertake tasks like roofing and haying, which required a great deal of labour over a short time, farmers had to rely on a circle of neighbours to take turns helping out. This kind of work was not paid, but the farmer who benefited from the work was expected to treat the people who came to help by serving good food and beverages on the day of the *dugnad*, and maybe even to host a party for his workers.

A standard definition is that “*dugnad* is when the neighbours of a farmer gather at his farm to help him, without getting paid, to accomplish a large task”.²⁴⁵ The traditional *dugnad* concept excluded communal and legal duties, and singled out the kind of informal duty to take turns in helping one another. The *dugnad* institution relied on a mutual understanding of reciprocity between economically equal farmers, and the “relation of reciprocity comprised of generations”²⁴⁶.

From an international perspective, the Finnish concept of “*talkoot*”, and the English concepts of a “*bee*” or “*barn raising*”, has a similar meaning to the Norwegian concept of the “*dugnad*”. The authors of this article learned this from the entry for “*dugnad*” in the Norwegian version of the *Wikipedia* – an international project which might be termed “the largest *dugnad* ever”. The *Wikipedia* project illustrates that the *dugnad* concept can be used to describe phenomena worldwide.

The *dugnad* spirit

New technology, increased trade and social differentiation made the structural conditions for the traditional *dugnad* institution fade away in Norway in the first half of the 20th century²⁴⁷. The *dugnad* concept, however, has survived and is still widely in use in Norway²⁴⁸. The activities nowadays called “*dugnad*” are different from the original *dugnad* work, but share certain aspects of the “good old” *dugnad* or maybe just the “*dugnad* spirit”. To be able to term something a *dugnad*, and to take part in a *dugnad*, is to make the activity morally praiseworthy.

245 Østberg, Kr., 1926: ‘*Dugnad*’, in *Norske Folkeskrifter*, no. 71, p. 3.

246 *See* Norddølum, Helge, 1976: ‘*Dugnaden i det førindustrielle samfunn*’, in *Dugnad*, no. 2, p. 68 Also published as Norddølum, Helge, 1980. ‘The “*Dugnad*” in the Pre-Industrial Peasant Community. An Attempt at an Explanation’. *Ethnologia Scandinavica*, pp. 102-113.

247 *See* Klepp, 2001: p. 84.

248 This can be illustrated by the fact that Norwegians in 2004 informally selected “*dugnad*” to be the Norwegian national word, see Schjerven, Petter, 2005. ‘*Typisk Norsk*.’ NRK.

The *dugnad spirit* denotes that the values of liberty, equality and fraternity are actively promoted by a group and its members in freely committing themselves to work together as equals for the benefit of all. Present day dugnad is first and foremost associated with volunteering to do unpaid work for the common good. The dugnad spirit is then seen as a manifestation of an unselfish attitude that runs counter to a disintegrating society based on purely contractual relationships, and emphasises a spontaneous solidarity that is seen as both a moral ideal and the glue of society.

To benefit from or to take part in a dugnad should be motivated by a shared and acquired social conscience rather than by calculations of profit or from fear of sanctions. Helge Norddølum gives an example of an exploitation of the dugnad institution when a wealthy farmer in the Norwegian county of Valdres arranged a dugnad to build a mountain hotel.²⁴⁹ The dugnad principle of reciprocity was thereby violated, as the hotel owners obviously did not, nor would not, help participants build their own hotels. The dugnad spirit of solidarity was also illegitimately invoked, as these hotels were built by unpaid workers in order to profit the owners. The obligations associated with an economy of mutual dependence were taken advantage of by entrepreneurs operating in a market economy system.

Biobank participation

In the context of biobank research, this conceptual analysis leads us to the question: How does the concept of dugnad work as a description of participation in medical research in general and biobank research in particular? We take the HUNT study as a starting point for a general discussion of the relevance and implications of introducing the dugnad concept to this field.

Fully 110 000 people in the Norwegian county of Nord-Trøndelag have been or will be invited to take part in HUNT3, the third round of HUNT studies from 2006 to 2008. The HUNT cohort consists of a major part of the population of the county of Nord-Trøndelag. All citizens aged 13 and upward have been invited to participate in HUNT by completing a questionnaire on health-related issues, to undergo optional medical tests, and (from HUNT2 onward) to allow a blood sample to be taken and included in the HUNT biobank.

249 See Norddølum, 1976: p. 72-3, and Klepp, Asbjørn, 1982. 'Reciprocity and Integration into a Market Economy: An Attempt at Explaining Varying Formalization of the "Dugnad" in Pre-Industrial Society'. *Ethnologica Scandinavica*, p. 92.

In the previous HUNT1 study in the eighties and the HUNT2 study in the nineties, the participation rates were as high as 88.1% and 71.3% of the adult population, respectively.²⁵⁰ Steinar Krokstad, vice-chairman of the HUNT research centre, explains the willingness to participate in this way: “In Nord-Trøndelag, there is traditionally a strong belief in the power of cooperation and collective action. Cooperation has been strong, and when HUNT has invited people to participate in a health dugnad, they have shown up.”²⁵¹

Krokstad goes on to state that “modern society is characterised by the disintegration of the community”, and that the HUNT dugnad will contribute to counteract this development in a threefold way: Firstly, HUNT by itself promotes the dugnad spirit in its participants. Secondly, HUNT might be able to detect adverse health consequences of societal disintegration. And thirdly, HUNT promotes collective action for improved public health:

The people of Nord-Trøndelag can be the first to benefit from new ways to better public health, through knowledge that can be communicated to the whole world in international journals. (...) Norway has developed from a poor country with a lot of poor health and living conditions to be a country with the best public health in the world. The National Insurance and the social security net that protects us from poverty are based on the old principles of equality, liberty and fraternity. And these institutions still contribute to good public health.²⁵²

In a focus group study with HUNT researchers, we asked whether biobank participants should have priority in receiving public health care over those who do not participate²⁵³. No-one thought so, but one researcher expressed the general sentiment towards those who do not participate rather succinctly by remarking that “they should maybe search their consciences”.

250 Holmen, J., Kjelsaas, M.B., Krukker, Ø., Ellekjær, H., Bratberg, G., Holmen, T. L., Midthjell, K., Stavnaas, P.A., & Krokstad, S. (2004). Befolkningens holdninger til genetiske epidemiologiske undersøkelser og bruk av biomarkører—til genetiske epidemiologiske undersøkelser og bruk av biomarkører— Helseundersøkelsen i Nord-Trøndelag (HUNT). *Norsk Epidemiologi*, 14, 27–31.

251 Krokstad, 2004.

252 Krokstad, 2004.

253 For a presentation of aspects of the focus group study, see Skolbekken, John-Arne et al.: “Not worth the paper it’s written on? Informed consent and biobank research in a Norwegian context”, in *Critical Public Health*, December 2005; vol. 15(4), 335-347.

Another researcher elaborated on this remark when asked whether biobank participation should be a legal duty:

I think that everybody has a moral duty to participate. And I think that Norwegians in general see it this way, and that the participation rate in HUNT shows that the people in Nord-Trøndelag see it this way. To participate should not be a legal duty, since it interferes with the private sphere. But I think there are few people who would oppose participation in HUNT if the collective goods it entails are clearly stated, and that we all agree that such a study should be a part of our collective efforts to improve our health service.

The concept of *dugnad* has the potential both to clarify and obscure the balancing of privacy rights, civic duties and legal duties going on here. We will show how by identifying the determining factors present in the HUNT and the MIDIA²⁵⁴ biobank research project.

Is HUNT a *dugnad*?

The word “*dugnad*” does not explicitly appear in the official information material for HUNT. But the *dugnad spirit* is evoked in the way that HUNT motivates people to participate. In an information folder for HUNT3 we read:

Something very important for public health is happening in our county right now! You can contribute to vital research and increased knowledge about diseases which are of concern to us all. (...)We have every reason to be proud of HUNT. HUNT is the largest health survey of the world. (...) Please participate! Let’s give each other an hour for better public health!

The request for giving “each other an hour for better public health” refers to the time it takes to complete the HUNT questionnaire and give a blood sample. The participants contribute, from this perspective, mainly by giving their *time*. The risk of participation is conceived of as negligible, and the participants are not asked to make huge sacrifices: they will leave the research centre in the same shape as before – except without a few centilitres of blood.

²⁵⁴ “MIDIA” is an abbreviation for “Environmental causes of type 1 diabetes” in Norwegian.

From this perspective, the participants are primarily asked to do a bit of *unpaid work*: to show up and take time to answer questions and allow for health data and a blood sample to be obtained. It is *work* in the sense that participation is not for personal health purposes: no individual feedback is provided on the basis of biobank research findings. When the participants have done their share, the job is done. In this way, participants are considered to be contributing as *citizens* rather than as *patients*. Moreover, the work is *unpaid* in the sense that except for the free brief health check, there is no compensation given to participants.

HUNT could be said to be a dugnad in the modern sense of being a *gathering of people to do unpaid work for some kind of common good*. Of course, both the “gathering” and the “common good” might be said to be quite abstract in this case: The participants do not actually gather at one place, and the common good is vaguely conceivable rather than directly perceivable for the participants. Moreover, the participants are, as we will see, a bit uncomfortable regarding their contribution as “work”. Given the fact that the free personal health check offered by HUNT motivates some people to take part makes it contestable to call their participation “work”, and even debateable if the participation is wholly “unpaid”. Moreover, the participants in both a traditional and a modern dugnad enjoy benefits like good food and beverages, but this kind of benefit is not of the same personal nature as an individual health check.

HUNT could also be said to be a dugnad in the traditional sense of offering an *intergenerational system of reciprocation between equal parties*: No HUNT participant is more important than another, everybody contributes in more or less the same way, and everybody can expect the same kind of possible benefit from the research from an intergenerational perspective. This emphasises how both the HUNT study and the traditional dugnad can be viewed as a kind of insurance institution. In this view, however, a major disparity would be that while stepping outside the traditional dugnad institution might have implied grave and direct social and economic consequences for a farmer in the 19th century, a person declining to take part in the HUNT study today should, as a matter of principle, expect no personal consequences from his decision in the future provision of health care. It is an important part of the HUNT recruitment policy, however, to appeal to the direct personal gain in getting a free health check. In this way, participation is not purely altruistic – it is “something in it for me”, which makes it meet a basic criterion of the dugnad design.

The opinion of biobank participants

In a focus group study with HUNT participants, we asked whether biobank participation should be considered a legal duty²⁵⁵. Like the researchers, none of the focus group participants thought this wholly appropriate. Biobank research is conceived of as interfering with the private, or autonomous, sphere of the citizen. To protect such a sphere is viewed as fundamental to the Norwegian constitutional State, separating it from totalitarian regimes. The ability to excuse oneself from participation in HUNT based on religious views and views of bodily integrity is seen as important. Making the right to health care somehow dependent on one's participation in medical research was definitely not endorsed by the focus group participants, because of the observed right not to participate, as well as the fact that everybody take part in financing the universal Norwegian health service by paying taxes.

The general line of thought, however, echoing the opinions of HUNT researchers, is that even though a *legal* duty would be wrong, people should feel a certain *moral* duty to take part in HUNT. Everybody should participate in HUNT, one man says, because “the ideal is of course that everybody should contribute to the community, but then again you have the right to decide when it comes to your personal stuff.” Generally the interests of the State and its citizens are perceived as identical when it comes to the aims of biobank research: It is in everybody's interest to promote health by improving our ability to prevent and treat diseases.

Biobank research is perceived as a low-risk way of participating in beneficial medical research. The participants have quite vague ideas of the potential embodied in the research: Perhaps their children or future generations will benefit from HUNT.²⁵⁶ The motivation for their participation is altruistic and patriotic: They are proud to take part in a study for the possible benefit of whole world, and take pride in the fact that such an altruistic project has been initiated by, and is being accomplished with the massive participation of, people from their own county.²⁵⁷

The importance of solidarity

The main elements in HUNT that constitute a dugnad can easily be identified. Even though it is different from a traditional dugnad in some respects, it seems fair to say that HUNT is a dugnad, or at least is a project in the dugnad spirit. Does it or could it, however, have elements clearly

255 *See* *ibid.*

256 *See* *ibid.* p. 340.

257 *See* Antonsen, Stian: ‘Motivasjon for å delta i helseundersøkelser’, in Norsk Epidemiologi, 2005, vol. 15 (1), 99-109, p. 104.

incompatible with being a dugnad? We will draw on the opinions of HUNT participants in discussing this question.

The participants in our study were not asked to relate the concept of dugnad to biobank participation, but their answers concerning the importance of taking part points to elements of the concept of the dugnad: Participation should not be a legal duty, nor should the question of participation be entirely neutral in moral terms: Participation should be morally laudable as a positive voluntary commitment to contribute to the common good.

On the other hand, the participants see commercialisation of biobank research as a possible threat to this aspect of the endeavour. To make medicine for the rich rather than the needy and thereby to profit from the voluntary contributions of the inhabitants of Nord Trøndelag would be at odds with the nature of the biobank project as they perceived it. This shows that solidarity is an essential motive for participation in biobank research, and that commercialisation might frustrate this motivation and fundamentally alter the nature of the enterprise.

This can be illustrated by comparing the HUNT project to the story of the dugnad in Valdres to build mountain hotels. With their goal of private profit, the Valdres hotel entrepreneurs violated the dugnad principles of equality, reciprocity and solidarity, and therefore their framing of the project as a dugnad was illegitimate. In the eyes of participants, taking advantage of the potential commercial aspect of biobanking would transform the project in an essential way: The project would be about non-reciprocated private profit rather than about the mutual or common good, thereby exploiting participants if involvement is presented as a dugnad.

Interestingly, the principles that HUNT participants regard as both essential to the legitimacy of the study and as threatened by commercialisation, are the same as the principles the HUNT project has to adhere to in order to qualify as a dugnad: HUNT must be in pursuit of the common good in solidarity, from which all participants and their descendants equally benefit. It is, however, important to note that commercialisation *per se* is fully compatible with these principles, as long as commercial research is incorporated into the system of research ethics committees²⁵⁸, and if it just accelerates certain fields of research in addition to, rather than instead of, publicly funded research for the common good.

258 See also Kettis-Lindblad Å., Ring L., Viberth E., and Hansson M. Genetic research and donation of tissue samples to biobanks. What do potential sample donors in the Swedish general public think? *European Journal of Public Health*, 2005; Oct. 5: 1-8.

Normative recruitment and the Helsinki Declaration

According to the Helsinki Declaration, the interests of the individual should always precede those of the society (§5), “The subject should be informed of the right to abstain from participation in the study or to withdraw consent to participate at any time without reappraisal.” (§10), and in § 11 it is declared: “When obtaining informed consent for the research project the physician should be particularly cautious if the subject is in a dependent relationship with the physician /or may consent under duress.” Taken together, these paragraphs seem to say that all recruitment to medical research must be normatively neutral: One in general should never argue that a person ought to forsake his or her own interests to participate in the interest of future health care (§5), and in particular should never argue that he or she has a particular obligation to participate given the relationship of dependence between the person and the provision of health care (§10-11).²⁵⁹ As we have seen, participants and researchers in HUNT firmly reject the idea of refusing non-participants the same rights to future health care as the participants. And is the moral pressure of the dognad model exactly what these paragraphs are meant to exclude?

The principles of the Helsinki Declaration are both meant to secure the autonomy of potential participants, and to protect from them from harm. It is thus important to guarantee that no-one is deceived or coerced to take part. The crucial question, then, is whether and when normative recruitment implies the deception or coercion of individuals, which would thereby make it illegitimate. Is it possible to defend an ideal of free and informed decisions by all potential biobank participants at to whether or not to take part, if participation in the research project in question is presented as morally laudable or obligatory? Is it legitimate to appeal to the dognad spirit in recruiting people to HUNT?

The Helsinki Declaration, Harris and the HUNT participants all agree that a fundamental principle of medical research is that participation is voluntary, and that no-one is invited to take part in research with an unfavourable risk-benefit ratio. Granting this, one starting point is to say that any medical research should identify the dangers and the interests of the participants and society in the project, in order to be able to state these dangers and interests clearly in the invitation to take part. It would now be unethical for researchers to invite individuals to take part in a study that they did not think the invited really should take part. In other words: The researchers who invite people to take part in a project not only generally *have* an interest in a high participation rate; it is more precise to say that the researchers always *should have* an interest in a

²⁵⁹ See <http://www.wma.net/e/policy/b3.htm>

high participation rate. Researchers are obliged to think that it is in everybody's interest that everyone who is invited will choose to take part.

The dugnad model is demanding in its aim for a collective consensus on the need and legitimacy of the research, and the moral duty to take part. This puts a normative pressure on the invited participants and the project designers alike. To present a medical research project as a dugnad should in general be done with extreme caution, as it is a strong rhetorical device that might blur reflections on personal risk, as well as the nature of the common good involved. This puts a huge normative pressure on the research institution and the relevant governmental bodies. They have to ensure and be sure that a project meets the criteria of being a dugnad. Only if these criteria are met is the invitation to take part in a research dugnad valid; only if these criteria are met is this use of normative recruitment legitimate.

Given a transparent and informative process of voluntary recruitment, the research institutions are dependent on the trust of potential participants. This makes an appeal to the dugnad spirit a double-edged sword: If the research projects are conceived by participants to rightly deserve the dugnad label, it might improve the participation rate, but if the project is seen as not deserving the dugnad label, it might mean that the participants lose their trust in the project altogether. The fear that this might happen partly explains the reluctance of research institutes in Norway to invoke the dugnad spirit explicitly in their official documents and invitations.²⁶⁰

Rather than being a simple way to recruit people for research, normative recruitment is a demanding way to recruit volunteers for a transparent project dependent on trust. Normative recruitment might nevertheless be a way to make clear the mutual duties of a research-based health service, and its potential patients and research participants. This might promote rather than hamper the ability of participants to make an *autonomous* decision as to whether or not they should take part. Normatively neutral recruitment might downplay ethical aspects of the research, such as urgency and justice, because people are simply invited in a neutral way and may participate if they want. Nobody has said that they should take part, so the motivation to autonomously question the ethical aspects of the relevant research is significantly lower.

²⁶⁰ Likewise, the Governmental Regional Research Ethics Committees not easily approve of normative words like dugnad used for research recruitment.

When normative recruitment is not justified

Appeals to civic duties, membership, “dugnad”, and solidary work for the common good need to be justified in the research design. What then, does a research project look like, if normative recruitment is not justified? The Norwegian MIDIA research project on environmental causes of type 1 diabetes is illustrative here.

The starting point for the MIDIA project was that people with a special genotype will have a higher risk of getting type 1 diabetes. About 2 % of the population are in this group. In MIDIA, pregnant women were invited to let their future newborn children take the genetic test for type 1 diabetes. About 2000 “high risk” children were then expected to be identified. These children would be followed by researchers for about 15 years. Their mothers and fathers were asked to deliver faecal samples every month until the baby was 3 years old. In addition, blood samples and questionnaires were to be delivered four times the first year and then once a year until the age of 15 (Rønningen et al 2007;2405).²⁶¹

Although MIDIA was huge, prestigious, with substantial national governmental funding and of international interest, it was found to violate the Norwegian Biotechnology Act. After having identified about 1000 babies at risk, MIDIA came to be seen as highly controversial by Norwegians. Parents who were warned of an increased risk for their children based on the predictive genetic test expressed fear and anger about having this information. From their perspective, the fantastic experience of having a baby was tainted by the focus on a possible future disease, without any ability to prevent the disease (M døtre 2007;1824).²⁶²

The Norwegian Biotechnology Advisory Board considered the project in relation to the Biotechnology Act. They concluded that the predictive genetic testing of children for diseases that cannot be prevented is forbidden by Norwegian law (Foss 2007). However, whether MIDIA was in accordance with Norwegian law or not, is not the main point here. The important thing is just to give an example of a research project putting substantial burdens on the shoulders of the participant.

In its invitation letter, MIDIA use a language of normative recruitment: “Congratulations on the birth of a newborn citizen! [...] It may seem early, but we would still like to invite you and

²⁶¹ Rønningen, K., Stene, L., Rasmussen, T., Wetlesen, T. and Magnus, P. (2007) Miljøårsaker til type 1-diabetes. *Tidsskr Nor Lægeforen*. 18;127:2405-8.

²⁶² M døtre (2007) Gentesting - en belastning for pårørende. *Tidsskr Nor Lægeforen* 13;127:1824 Foss, G. (2007) Gentesting av barn i MIDIA-prosjektet. *Genialt*, 3;12-15.

your little newborn citizen to make your first benevolent contribution to society.”²⁶³ The invitation letter refers to citizenship, to the relationship between a citizen and society, to benevolent contributions and the common good. The baby is referred to not an individual but a citizen, with the expression of sentiments and ideas about what good citizenship and civic duties amount to. As we have already made clear in this article, our argument is not that this is principally wrong. Rather we argue that the legitimacy of this kind of normative recruitment presupposes certain kinds of research designs – such as fulfilling the criteria for being a dugnad.

Our question is then: If the MIDIA project was presented as a dugnad – was it in accordance with a “dugnad design”? MIDIA revealed the results of a baby’s predictive genetic test to their parents. There are no preventive measures available for type 1 diabetes. This caused psychological stress and worry for the parents. The child was not asked for permission to take the test, and the right not to know was neglected. For a 15-year old MIDIA participant, there was a 93 % probability that she would not get diabetes, and she would have to live with the risk awareness the rest of her life without being part of any research project. The need to provide faecal samples, blood tests and answer questionnaires on a continuous basis added to participants’ inconvenience.

In sum, it is easy to conclude that a project like MIDIA did not have a dugnad design. The inconvenience was substantive rather than negligible. It is not in accordance with dugnad criteria to subject invited participants to severe inconvenience or risk. The empirical factors of the study design decided the “principal” question of the legitimacy of normative recruitment. In the MIDIA case, implicit references to civic duties and explicit references to citizenship and contributions to society functioned as an illegitimate rhetorical device.

Accounts of duties

The aim of an account of duties in medical research is to provide a middle ground between asserting a general duty to take part in medical research, and a general principle of normatively neutral recruitment of participants – which implies that the potential participant should not feel any obligation to take part. While a general duty is argued for on the basis of a relationship of mutual duties between the health care provider and recipient, normatively neutral recruitment is argued for on the basis of fundamental principles of medical research ethics.

Daniel Callahan, as we have seen, classifies medical research as an imperfect right – a right that no one has a specific duty to fulfil. Callahan is dismissive of the argument that we have

²⁶³ <http://www.fhi.no/dav/D651389BCD.pdf>

a *duty* to conduct and participate in medical research to benefit future generations, in the way preceding generations have made our health care system possible. He must then hold either that there never really was such a social contract between generations, or that we stand in a radically different relation to our descendants concerning medical research than did our forebears. Both of these substantial claims are rather controversial, and, as we have seen, have not met with approval among HUNT participants.

More promising than generating controversy over a general duty to participate in medical research, seems to be to develop Rhodes and Harris's sense of a *prima facie* moral obligation to take part in medical research as accurately as possible. Harris argued that people who do not participate in research are free riders who opt for the benefits from medical research without making a contribution. The contrary to Harris's argument is that the division of labour in modern society is a form of an organised system of legitimate free riders. This argument can be turned on its head, however. Perhaps considerations of justice *are* relevant for individuals called on to participate in the division of labour, and infinite duties might become socially finite and perfect ones, as in a well-organised system of medical research described in Rhodes's novel proposal. The questions of both intergenerational and intragenerational justice are pertinent in the promotion of such progress, unless one dismisses any duty to contribute to medical progress, as Callahan does.

Citizenship and the ethics of belonging

Our discussion of the HUNT case and the dugnad concept has shown that talking about moral obligations to participate in medical research essentially involves detailed descriptions of the research in question, including aspects like its organisation, its aims, its beneficiaries, its potential, its urgency and aspects of belonging and membership. The discussion of whether potential participants have a perfect or an imperfect duty to participate in medical research on the basis of a limited description of the research involved is not very promising. It is difficult to make a plausible case by asserting an individual's general duty to participate. A limited description of the relevant research also does a poor job of explaining the moral *motivation* to take part in specific research projects.

A nuanced and situated description of the normative basis for individual participation in collective projects is vital to the discussion of moral motivations and obligations in this field. The concept of dugnad introduced in the HUNT case shows this in an illustrative way. People take part in dugnad, not just as individuals, but as members of a community. Their motivation is neither purely altruistic nor purely egoistic. It is more about a sense of belonging on different

levels: We belong to a society where health is a common good. We belong to a patient group or a local community that may make a difference regarding health for future generations.

In this way we are members of communities that involve a kind of *civic* duty to participate. As members, or citizens, the right thing to do is to participate. It is a kind of patriotic act, a kind of act which according to Charles Taylor “transcends egoism in the sense that people are really attached to the common good, to general liberty. But it is quite unlike the apolitical attachment to universal principle that the stoics advocated or that is central to modern ethics of rule by law. The difference is that patriotism is based on identification with others in a particular common enterprise. [...] Patriotism is somewhere between friendship or family feeling, on one side, and altruistic dedication on the other.” (Taylor 1995; 188)²⁶⁴ In this way, patriotism can be viewed as highly relevant for participation in medical research.

Patriotism and *dugnad* thus goes hand in hand. This could imply a “politisisation” of science. But there is nothing wrong with that. Rather, the opposite is true: When medical research is “politisised” through concepts like citizenship, community, belonging and patriotism, the question is also raised regarding the direction and development this community and this research should be headed towards. Opposition to biobank research is typically a political one, like the critique of biobank research representing a “geneticisation” of medical research – shifting the focus away from social inequality and health to a focus on genetic explanations. Such opposition does not lead to less civic engagement, but rather more. This challenges research communities for certain research projects to be able to defend normative recruitment, and to make an appeal to the common good.

Conclusion

The *dugnad* concept gives a normative model that offers the opportunity to understand how a specific research project should be designed to support a perceived moral obligation to take part. Ignorable risk, ignorable inconvenience and a common good that addresses each person as a member of a community rather than just an individual, are core elements in the *dugnad* design. Normative recruitment should be seen as legitimate in these cases. That the criteria essential to

²⁶⁴ Taylor, C (1995) Cross-purposes – the liberal-communitarian debate. In C. Taylor (1995). *Philosophical arguments*. Cambridge: Harvard University press, p. 181-225.

the legitimacy of HUNT coincides with the criteria to qualify as a dagnad shows the potential suitability of such an approach.²⁶⁵

Normative recruitment is a powerful rhetorical device. Medical research is not in general a dagnad, and normative recruitment is not in general legitimate. An important message of this article is to suggest that as early the design phase of a project, researchers should reflect on the relationship of their project to the community of potential participants and to the common good. This will imply a “politicisation” of medical researchers – but that would be for the better. Ethics separated from politics is anaemic. And anaemic ethics for biobanking benefits neither biobank research nor the participants.

Translations

All translations from Norwegian by Lars Øystein Ursin and Berge Solberg

²⁶⁵ The dagnad concept might be said to be more than just a model or an analogy – it might be argued that the HUNT study *is* indeed a dagnad, not just possible to view *as* a dagnad.

