Duties and rights of biobank participants:
Principled autonomy, consent, voluntariness and privacy

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In this chapter the notion of principled autonomy is presented, and the perspective enabled by this notion is applied on the field of biobanking. Some consequences of the perspective of principled autonomy on aspects of biobank recruitment are discussed in relation to concepts of voluntariness, consent, and privacy. These discussions aim to focus on the fruitfulness of the notion of principled autonomy in bringing out the interconnectedness of the duties and rights of biobank participants – both in general, and in a context of taking part in a research based universal health care system in particular.

Key words

Research ethics, principled autonomy, voluntariness, privacy, biobanking, informed consent

The assumption of rights

The discussion of 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 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." (Taylor 1989:11)

The perspective of rights – or even "natural rights" – fits in nicely with 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, 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. It is the aptness of such a picture for biobank research which is the subject matter of this chapter.

Principled autonomy

The perspective of Onora O'Neill on the assumption of rights is to emphasise that duties precede rights.[1] 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. Current epidemiological research is a way to better healthcare tomorrow, from which anyone can benefit. 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 individualism and self-expression, and may heighten rather than reduce public mistrust in medicine, science and biotechnology." (O'Neill 2002:73) 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." (O'Neill 2002:78) 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.[2] 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." (O'Neill 2002:83-4) 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 know 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 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." (O'Neill 2002:92)

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.

Justifying consent by principled autonomy

Giving consent to become a patient or research participant based on principled autonomy is thus about preventing coercion and abuse, rather than about promoting personal 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?* by Sigurdur Kristinsson. Kristinsson takes the *Belmont Report* as his point of departure. 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 in this way:

> 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. (The Belmont Report 1979: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." (The Belmont Report 1979:Sec. C1) The report states, in other words, 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". (The Belmont Report 1979:Sec. B1) 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 Humanity[3] 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 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." (Kristinsson 2007:257)[4]

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." (Manson and O'Neill 2007:149)

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* 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.

A Millian kind of justification for advancing the autonomy of biobank participants 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. According to Mill, it is crucial that people are left alone to be able to exercise their liberty, because it is essential to self-realization (Mill 1977:277) essential to promoting self-esteem and an ability to exercise mature choice (Mill 1977:277) and even essential to developing a more prosperous State. (Mill 1977:310)

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 personal 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" (Kristinsson 2007:258) 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.[5] In opposition to the comprehensive principle, which holds that state neutrality should extend both to the basic framework and the 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.

Research participants and policy makers all agree that the relationship between the state and its citizens in a liberal society 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." (Kristjánsson 1996:142) 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 a 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.[6] 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.[7]

Trust and negatively informed consent

The perspective of principled autonomy emphasise the genuine trustworthiness of the institutions. Sometimes an individual might want to give up her personal 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". (Kihlbom 2008:147) The assumption alluded to, and which Kihlbom finds illustrated in Beauchamp and Childress' *Principles of Biomedical Ethics* (Beauchamp and Childress: 2001), 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 presupposition that this can only be the case if you understand and are aware of what is happening to you." (Kihlbom 2008:146)

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."[8]

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 aims[9], which indeed might be enhanced by someone else. He does not argue 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 we are not familiar with. These states of ignorance do not threaten our autonomy." (Kihlbom 2008:148) 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.[10]

Now, if personal autonomy is promoted as an ideal, an individual should learn to see the personal significance of more choices. This creates a paradox 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.*[11]

Authorisation and voluntariness

The perspective of principled autonomy emphasise the voluntariness of participants. 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[12] biobank in Norway 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*.[13]

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.[14] 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." (Kristinsson and Árnason 2007:206)

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."(Kristinsson and Árnason 2007:205) 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" (Kristinsson and Árnason 2007:212) 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." (Olsaretti 2008:114) For Olsaretti, the existence of *acceptable alternatives* is essential to voluntariness. This distinguishes voluntariness from freedom: I might be free to leave an island, but since I will die if I try to 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.[15]

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, which means that not taking part is a real and acceptable alternative. On the other hand 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 Árnason.

Patients' duties and privacy rights

The main potential for harm to biobank participants is not in terms of inappropriate physical invasions but in terms of inappropriate use of personal information. Such inappropriate use of information might be a matter of breaches of confidentiality that might lead to stigmatization, discrimination, and existential or familial complications. In the biobank context, it might also be a matter of proprietary privacy concerns regarding the kinds of research to which the information is put by the biobank researchers. It might be ethical concerns of the participants like avoiding research contrary to human dignity, or political concerns like promoting research for the benefit of special groups. It might also be economic concerns, if profits might be gained by the biobank in selling the information, or from products or services developed from research on the biobank information provided by the participants.

According to David Wendler "(…) involvement in research includes three distinct elements: 1. exposure to risks; 2. performance of research mandated behaviours; 3. contribution to answering a

research question. (…) To consider a specific example, the standard drug trial involves individuals facing risks (risk element) as a result of taking an experimental drug (performance element) in a way that helps investigators determine whether the drug might be clinically useful (contribution element)." (Wendler 2002:33-4)

In biobank research, Wendler's case in point, risk elements "involve unwanted information flow". (Wendler 2002:35) Performance elements involve medical tests, giving biological samples, and completing questionnaires. Finally, contribution elements involve the participation in pursuing specific research aims. In biobank research with de-identified information, both the risk and the performance elements are negligible, according to Wendler. He then goes on to ask "what reason could there be to solicit sources' informed consent for research that poses no risk for them, and does not affect them personally? What is left for sources to consent to?" (Wendler 2002:38)The answer is that the contribution element is the sole part left to consent to here. This calls for a balancing individual and collective interests: Firstly our interest in enabling the participants autonomous decisions on which projects to contribute to, and secondly the burdens of obtaining such consent – which may hamper our interest in make beneficial research done.

Biobank legislation in different countries qualifies the individuals' right to autonomy over biobank information by making specific uses of biobank information permissible in ways stated by law or with approval from research ethics committees.[16] Most often, however, the right to autonomy over biobank information must be waived by the individuals themselves in terms of giving their informed consent to placing the information at disposal for research purposes. 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. [17]

What unites 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 de-identified data about various groups for the benefit of public health in general, with any feedback in terms of personal health information being given to the individual. The discussion about the legislation of biobank research in Norway is illustrates this.

The participation of every citizen receiving treatment at a Norwegian hospital in the Norwegian Patient Register (NPR) is mandatory. In 2006, the Norwegian Parliament decided that entries in the formerly anonymous should be linked with every patient's personal ID number. This was in February 2007 sanctioned by law. By having identifiable (pseudonymised) patient entries, the

NPR can now be used for the purposes of research, since it enables cross-references and linkages to other registers.

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. (Datatilsynet (The Norwegian Data Inspectorate) 2005)

The arguments of the NDI partly echoes the reasons for judgement given by the European Court of Human Rights (ECHR) in the case Z v. Finland:

> 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).[18] 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. (European Court of Human Rights 1997)

The arguments of the NDI and the ECHR are partly based on matters of principle and partly on matters of empirical consequence. The principled 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 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." (Korn 2000:964) Korn's "pragmatic" root and the "empirical" arguments of the NDI both highlight a right to privacy which is based on 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 arguments of principle 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. 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 principled and the empirical arguments mentioned by the NDI in their statement above.

Onora 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. (O'Neill 2002:38)

In order to promote the specific privacy interests of participants in biobank research, it is according to the perspective of principled autonomy important to situate and value these interests in their proper contexts. As pointed out by the 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 of confidential rather than in the sense of ownership. Rather than implying a duty to secure an interest of the individual of controlling this information, it implies a duty to secure that the information should be handled with respect, that it should not be passed on, and that it should be ensured that its usage does not adversely affect or otherwise compromise participants in the system. The personal origin of any information is not a sufficient condition for requiring consent to any use made of it. 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." (Manson and O'Neill 2007:82) The relevant research here concerns group level phenomena rather than the health status of the individual. It might thus be viewed to be of no concern to individuals' rights of privacy at all. This would imply that to require the informed consent of the participants in these kinds of research must be justified by other concerns that a right to privacy.

Conclusion

Rather than 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 be voluntary participants, and to waive rights to privacy. A crucial question raised by this perspective, however, is when and whether biobank participants have any privacy rights to be waived. The perspective of privacy endorsed here was 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, and thus that the need for requiring consent for these kinds of biobank research falls away.

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Notes

[1] See O'Neill 2002

[2] *See* Schneewind 1998, esp. ch. 22 and 23.

[3] 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.

[4] Cf. Kristinsson and Árnason 2007

[5] *See* Wall and Klosko 2003:6

[6] *Compare* Hill 1991

[7] *See* Guyer 2003

[8] 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.

[9] *See* Kihlbom 2008:148: "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."

[10] For an elaboration on this point, see Ursin 2008

[11] For an elaboration on this point, *see* Ursin et al. 2008

[12] HUNT is an acronym for *Helseundersøkelsen i Nord-Trøndelag*, which translates as *The Nord-Trøndelag Health Study*. For a further description of HUNT, *see* the chapter of this book with the title "The Health Dugnad: Biobank participation as the solidary pursuit of the common good"

[13] Cf. Kristinsson and Árnason 2007 and also Árnason 2004

[14] 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.

[15] S*ee* Colburn 2008. 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.

[16] 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 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. 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.

[17] 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 information about personal finances? Or is it more as Alexander Rosenberg suggests (In Rosenberg 2000): 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.

[18] In paragraph 1 of Article 8 of the European Convention on Human Rights the Council of Europe it is stated that "Everyone has the right to respect for his private and family life, his home and his correspondence." (The European Convention on Human Rights, available at http://conventions.coe.int) Paragraph 2 of the Convention , however, qualifies the right to privacy of paragraph 1 rather strongly: "There shall be no interference by a public authority with the exercise

of this right except such as is in accordance with the law and is necessary in a democratic society in the interests of national security, public safety or the economic well-being of the country, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others." (The European Convention on Human Rights, available at http://conventions.coe.int)