

## **Informed consent and biobanks**

Stefan Eriksson

*Research Program Ethics in Biomedicine, Uppsala University*

### **Introduction**

This is a philosophical study of the *normative* question as to how regulation of informed consent should be constructed with reference to biobanking. In this first interim study I shall try to answer three questions. Firstly, *what* does a person consent to when permitting a tissue specimen to be taken for use in research? In order to assess procedures of information and consent, we have to be clear in our minds concerning *what happens* when somebody takes part in research of this kind. Secondly, we have to know what informed consent *is* and what its *function* is to be. In the following pages I propose a model of informed consent and formulate three principles which can be used in working out guidelines. Thirdly, I shall be addressing the more specific question of what possibility donors should have of withdrawing their specimens and having them destroyed, my purpose being to test the possibility of giving a preliminary answer compatible with these principles.

### **Donation of biological specimens**

It is sometimes claimed that specimens delivered to national authorities or institutions become State property. An alternative idea is that researchers own the specimens they collect. The National Board of Health and Welfare, for example, wrote in its general recommendations on routines for the preservation of sample material in pathology departments (1995:9), that “unless otherwise agreed, ownership of the sample material formally accrues to the party that has taken it”.<sup>1</sup> The question of whether the ownership model is suitable for biobank material is exhaustively addressed in a legal perspective elsewhere in this project, where it is answered in the negative. I would like, however, to say a few words on this subject without bringing law into it.

To many people, the thought comes naturally that their body belongs to them and that, accordingly, a state, a business enterprise or a researcher cannot claim to own part of it. Is it not fair to say that this is *my* blood and no one else’s? The newspaper Aftonbladet wrote that scientists are experimenting on parts of “*your body*” and that “they’re after *your DNA*” (my italics).<sup>2</sup> On closer reflection, though, this idea seems peculiar. Do we as a general rule lay claim to our blood, our body tissue or our body fluids? When somebody says, “This is my blood,” can we, for example, imagine the statement being made in the following setting? Some friends are seated together. When the dinner is being got ready, one of them suddenly notices blood on the floor. Someone of the company says: “That’s my blood.” Now the

important thing here is the fact that he or she is performing an act of reference – pointing out that the blood is really his and no one else's. In other words, he says that it *comes from* him and not from any of the others. Perhaps while saying this he holds up a hand which he has cut. Nothing is said concerning who *owns* the blood. I imagine the same to apply concerning body fluids and tissue. In normal circumstances there is no talk of ownership. When I go to get my hair cut, I don't decide what the hairdresser is to do with the clippings, any more than I tell the doctor what to do with the skin sample from my birthmark after he has examined me. Possession simply isn't an issue.

Now of course, this is not to say that the hairdresser or the doctor are entitled to do whatever they like with parts of my body. But the questionable things they could *conceivably* do would not inspire misgivings because of my right of ownership being infringed but rather, for example, because they did not show proper respect, because they disregarded a symbolic value (the placenta, for example, may be of great value to someone) or because they violate cultural taboos (especially as regards research among foreign civilisations). Arguably, then, scientists and doctors are entitled to use human biological material for research so long as the person supplying the material or people close to them are not harmed as a result. Arguments for this are easy enough to find. Either you can maintain, on grounds of consequential ethics, that, considering how greatly we all benefit from this research, we should do everything to encourage it so long as it does not entail risks or injuries of unjustifiable magnitude. Or else we can express ourselves in value terms. Scientific research has an intrinsic value, and so long as human biological material is of interest to no one but the research scientist, the latter ought clearly to have access to it. The circumscriptions to which this right should be subject are concerned more with matters of personal privacy and integrity than with questions of ownership.

This, of course, does not entirely settle the complex issue of ownership. If someone actually has an interest in their biological material, perhaps a court of law will have to decide the matter, and perhaps it will even choose to make reference to property rights. It would not, however, be a good idea to make this a dominant model, because that would imply a right on the owner's part to do all sorts of things which would prejudice vital interests. Is a scientist, a hospital or a state to have property rights in sensitive information about me and people close to me? As a general rule, whatever is owned can be freely sold, which in the case of biobanks would be disastrous. Attaching over-much importance to the waste character of the material would not be so felicitous either. The problem, above all, is that where abandoned material is concerned, findings is normally keepings, which brings us back to the difficulties already remarked on.

Non-ownership of the specimen one provides does not, of course, mean that one should have no say in the subsequent handling of that specimen. If a specimen contains potential information (information extractable from the material) about me and about my nearest and dearest – which, in principle, is the case with all biological samples – my rights and interests ought still to be acknowledged in some measure. This is what informed consent is meant to provide for. But this begs the question: *what* does a person consent to? To answer this question, one can either search descriptively for knowledge of what people actually consider themselves to be doing when they donate a sample, or else one can constructively design a suitable model. My purpose being normative, I shall be opting for the latter. The purpose of this project is to suggest appropriate guidelines for the management of biobanks, and I want to find a model for what the giving of samples implies, a model representing as faithfully as possible the values which are at stake, regardless of what people actually believe themselves to be doing.

One possible model would be *deposition* – entrusting something to another person for a time. The advantages of this variant are that the party in whose hands the material is

deposited does not own it, and it is made clear that what happens is in the nature of an agreement being concluded. One drawback, though, is that material deposited can always be withdrawn, added to which there is the implication of the person depositing the material still having some kind of title in it.

Can the giving of material instead be construed as a *gift*? A gift is a voluntary transfer of something with no consideration expected in return. This model certainly corresponds to a vital feature of certain biobanks; consider, for example, the donation of blood to blood banks. The British Medical Research Council (MRC) has proposed that donated tissue samples be treated as gifts: “This is preferable from a moral and ethical point of view, as it promotes the ‘gift relationship’ between participants and scientists, and underlines the altruistic motivation for participation in research.”<sup>3</sup> The main problem with this proposal is that we generally give our samples on certain conditions, which is not the case with a gift. One such condition occurs when people expect something in return for their gift – perhaps information about illnesses running in the family or about their descent. One specially important condition is that we sometimes reserve the right to request the return or destruction of the biological specimen, which seems to be a highly relevant interest. In connection with the 1997 Council of Europe Convention, the National Board of Health and Welfare has even proposed that this right be guaranteed by law.<sup>4</sup> Gifts, of course, cannot usually be retracted, so the gift model is not altogether successful either. It needs to be supplemented by a contractual element. Is the *donation procedure* which has evolved concerning the collection of organs for transplant surgery a serviceable model?

Organs may only be taken from a person consenting thereto (see Section 6 of the Transplant Surgery Act, 1995:831). Donation cards have been devised on which the conditions of donation can be indicated, and it is the physician’s duty to check for such conditions by examining the card or by several other means (see Provisions and General Recommendations of the National Board of Health and Welfare. Collection of organs and tissue for transplant surgery or for other medical purposes, 1997:4). A person may choose to donate all their organs and body tissue for transplant surgery and other medical purposes, limit the donation to transplant surgery, exclude certain organs and tissues, or refuse entirely.

The Transplant Surgery Act makes no distinction between biological materials and it also applies to medical research. Yet, for several reasons, perhaps donation would not be an ideal model where biobanks are concerned. Reference to donation in this context is liable to give the impression that biobanking can be regulated exclusively through the above mentioned statutory texts, which would not be without its problems. The donation procedure governs an activity whereby organs are collected mainly from deceased persons, whereas biobanks are mainly interested in specimens from living donors (preferably from initially healthy persons, a biobank with specimens of this kind being judged more interesting for research purposes than banks containing specimens from sick persons only). So the ethical issues at the centre of attention are somewhat different. Another difference between the donation procedure and biobanks is that discussion in the former instance has primarily focused on affective material (material charged with a special emotional significance and importance, which for present purposes means such large and vital organs as the heart), whereas the biobanks often deal in “leftovers” or comparable material. And whereas the ethical problems attending the removal of such large organs have generally concerned respect for the views of the individual on the subject of donation, it is above all questions of integrity that have been the moot point where biobanks are concerned. From this it follows that when the General Recommendations of the National Board of Health and Welfare (1997:4) state that next-of-kin cannot oppose the wishes of the individual donor, this is not fully applicable to biobanks. Genetic information from banked specimens *can* have a highly critical bearing on the privacy and integrity of next-of-kin, in which case it seems vital that they should have

some say in the matter. What is more, several burning issues with regard to biobanks – the possibility of withdrawing specimens and the feasible obligation of obtaining renewed consent before using the specimen for a new purpose – never arise where donation is concerned.

Thus there are palpable differences, but it is sufficient to observe that in the donation procedure we have a parallel to biobanks which, for all the differences involved, points to the possibility of biological material being conditionally donated. To avoid confusing the donation procedure with the giving of samples to biobanks, we can refer to the latter as a *conditional gift*.<sup>5</sup> As the MRC remarks, it is part of our understanding of the nature of a gift that the making and reception of it confirm a special relationship between donor and donee. Accordingly, the person accepting a gift has certain obligations towards the person making it – above all, the obligation of using the gift in a way which will not harm the giver, which brings us back to the previously noted requirement of the rights and interests of the donor of the sample being acknowledged in some measure. The donor can also make stipulations, just as he may decide not to state any conditions in a particular instance. Our model, then, can incorporate both instances of specimens being given subject to vital reservations, and instances where someone makes it clear that the gift is unconditional. It should, of course, be noted that it is the task of the biobank and the examining committee on research ethics to formulate the conditions applying in a particular instance. It is the donor who *makes* conditions, but not necessarily the donor who formulates them.

The institution of inter-personal gifts, however, differs from the giving of biological specimens for research, in that gifts of this latter kind do not establish a relationship between individuals. True, the MRC writes that a relationship exists between the providers of specimens and *scientists*, but donation here most often takes place on a more abstract level, from an individual to what can best be termed the welfare state.<sup>6</sup> In this respect the donation of biological specimens for research resembles the giving of blood: the ultimate beneficiary of your gift is not directly present but exists as an anonymous recipient beyond the institutional intermediary. And the relationship which can be said to exist in connection with the giving of biological specimens for research has as much to do with that remote individual as with the person who is the direct recipient.

Now it may be objected: Surely you can't give away what doesn't belong to you? But this is not necessarily true. Consider the following example, which comes quite close to the actual case (supposing that the gift can be said to comprise information, no less than it comprises the tissue carrying that information). If I entrust somebody with a secret, perhaps I am giving them something which, like a biological sample, has a delicate bearing on personal privacy. Before imparting the secret, perhaps I assure myself of the other person's discretion and stipulate certain conditions. But it would be absurd to maintain that I *own* the information which I then, of my own free will, entrust to the other person. It seems, then, as if in the *conditional gift* we have a model which can avoid all mention of ownership but can incorporate the elements of free will, assumption of responsibility and contract which seem to be of importance when discussing biological specimens.

## **Informed consent**

To answer the question of the role and structure of informed consent in relation to biobanks, we need to define our view concerning the nature of informed consent and its role in relation to biobanks. Informed consent can be briefly termed an autonomous act by a patient or experimental subject (for present purposes, the donor of a specimen) who expressly permits a

professional person (in this case, the person taking the sample) to perform a medical action on the patient or to include the patient in a research project. The use of “expressly permits” instead of “consents” is prompted by the following observation. A person can consent to something without expressly permitting it. For example, a child can consent to a punishment without thereby accepting the actual introduction of the punishment. The same applies, of course, in medicine. For example, Robert M. Veatch maintains that the act of extending one’s arm in order for a blood sample to be taken is, if not explicit consent, then at any rate an adequate form of consent.<sup>7</sup> But a patient thus consenting to a doctor’s authoritarian proposal is not exercising his autonomy. That requires something more, namely *express permission* for what is to happen.<sup>8</sup>

This, then, is what informed consent *means*. But from this meaning we can separate what informed consent is *good for*. In the latter case we enquire after the *values* which informed consent exists to safeguard, and those values bear a direct relation to the stipulations made concerning the process which exists to guarantee informed consent. Participation in the making of decisions, for example, is a value expressed in stipulations of this kind. Those stipulations may, for example, concern the *elements* to be included in procedures of information and consent. Stipulations of this kind are made with a view of attaining or protecting the value concerned. If the stipulations made are satisfied, we can say that informed consent *actually exists*.

What values is informed consent meant to safeguard? Ethicists writing about informed consent have defined it in many different ways, according to which values they find important. The literature includes, for example, the following views. Informed consent is a procedure or mechanism which<sup>9</sup>

- prevents damage from occurring,
- maximises the benefit which should accrue to the patient/experimental subject,
- respectfully provides an individual or a group with knowledge concerning risks/benefit, with a view to protecting them from exploitation,<sup>10</sup>
- expresses the freedom of the individual to decide matters relating to his own person,
- gives effect to the right of the patient/experimental subject
  - to responsibly decide his own concerns,
  - to be treated as a person,
  - to autonomously consent to measures affecting his own person,
  - to have a private life.
- expresses the relationship of credibility and mutual loyalty which should characterise medical practices,
- is meant to bridge the difference in power and knowledge between the physician/scientist and the patient/experimental subject.<sup>11</sup>

All this amounts at the same time to a *legitimation* of informed consent. Because informed consent gives effect to these values, fulfils these functions, it is a mechanism which we find it important to implement and defend.<sup>12</sup>

### Three principles of informed consent

In order to discuss the difficult ethical issues surrounding biobanks, it is not enough to say that consent must express autonomy and to identify the general values which consent defends. Those values must also be *concretised* in the context in which they are to be promoted, and *defined* in a number of more manageable principles. In this section I shall propose three concrete principles which together encompass the values enumerated above. They function in

the main heuristically. Thus, through them informed consent acquires a more manageable form. Insofar, then, as stipulations of informed consent exist, it is according to these three principles that our procedures and guidelines should be tested. Similarly, exceptions to these three principles should always be specifically justified.

*Principle one:* Each individual is *entitled* to decide for himself whether, by furnishing a biological specimen, he is to undergo an examination or take part in a study. This rests on the more general principle that no person should be used for any purpose formulated by others without himself having consented thereto. If we take the *conditional gift* model as our starting point, then of course no one should be forced to make a gift but should always be allowed to decide for themselves when the gift is to be made, to whom and subject to what conditions. In this respect, participation through the giving of samples clearly amounts to entering into a contract or agreement.<sup>13</sup>

This is a so-called negative right which cannot be lightly overridden by reference to another benefit. A cure for cancer would, it is true, be of inestimable benefit, but the researching of a cure is nobody's right.<sup>14</sup> In ordinary circumstances, the negative right of determination over one's own person overrides the benefit which various common projects are capable of producing.

This first principle also means that the person should be allowed to decide the form in which the sample is to be used. By permitting researchers or others to use the sample together with identifying data means that I as a person am actually taking part in the research. If, then, a person is only willing to permit research using coded or depersonalised samples (or the corresponding data), this is to be equated with the same person setting a limit to what she is prepared to take part in *as a person*. Every person should be allowed to make this decision for herself.

The right of the individual, however, should not be automatically viewed in contradistinction to the public interest or to various social projects, for the self-same individuals said here to be invested with rights can also obtain provision for their interests indirectly, through social institutions. The prime distinction to be made, therefore, is between a direct and an indirect *form* of individual interests. As an individual, I can directly assert my interests by exercising my autonomy in various ways, but I can also obtain provision for them indirectly, through elected or appointed representatives. When a law thus impinges on my right as an individual to influence a particular matter, this need not necessarily be deemed prejudicial to my interests. After all, as a democratic subject I have elected a certain order of things in order to bring about legislation which provides both for my interests and for other people's. But this is no reason for denying the possibility of conflicts between the two levels.<sup>15</sup>

Three basic limitations of principle one are conceivable. Firstly, this principle does not address the question of every kind of material. Principle B21 of the Helsinki Declaration lays down that "[e]very precaution should be taken to respect the privacy of the subject, the confidentiality of the patient's information and to minimize the impact of the study on the subject's physical and mental integrity and on the personality of the subject".<sup>16</sup> But who exactly is a subject in a DNA study? Research ethics attempts to safeguard the privacy and self-determination of individuals, but who is the person subjected to an experiment when the research scientist studies a genetic sequence? The newspaper Aftonbladet wrote that "nobody knows who owns *you*," but is it really *me* they see in the experiment?<sup>17</sup> So long as a material is identifiable, there is a question of me being a subject in a more palpable sense. When on the other hand the material lacks any identifying information, the fact remains that I am the *source* or the *origin* of the material, but it seems far-fetched to say that it is *me* the experiment is being performed on. The question is, what sort of facts can emerge from the processing of the material. The research scientist can elicit a fact about me from the material he or she

possesses, but it may also be a fact about me and my family or relatives, just as much as a fact about my ethnic group, my sex or the human race in general. From this point of view, describing genetic research as the concern of the individual is an over-simplification. Thus it is not really surprising that several organisations have chosen to speak of genes as belonging to “the public domain” or of the human genome as being “common heritage of humanity”.<sup>18</sup> Let us conclude that not all research using biobank material can be automatically equated with research on persons.

Secondly, just as in other research contexts, situations may arise when, for example, the interest of the general public or groups of patients in the materialisation of a certain kind of research may be so great as to justify restrictions on the scope of direct individual influence. This can be instanced with register research of the kind which is actually based on a statutory duty of reporting to registers, whatever the individual person’s attitude to the research in question.<sup>19</sup> Research using biobank material, of course, can also be of such dignity that a research ethics committee sanctions a project dispensing with a consent procedure so extensive and expensive that the research would otherwise be rendered impossible or its scientific value seriously jeopardised.

Thirdly, and finally, sometimes it is not even in the individual person’s interests to be contacted. The risk that person is exposed to may be greater in the event of contact than when taking part in the study. In the assessment, for example, of a study of later consequences of legal abortion, contact was judged to be such a psychological strain on many women that the research ethics committee appraising the study judged it unethical to ask the women for their consent.<sup>20</sup> If the rights of the individual are to be infringed in any of these ways, it should be done with great restraint and following careful ethical assessment (by both researchers and research ethics committee).

*Principle two:* If a person is exposed to more than a *minimal risk*<sup>21</sup> as a result of his banked sample being used for some purpose, he should be apprised of this and allowed to decide for himself whether or not he wishes to take such a risk. A person who takes a risk by making a gift – and therefore wishes to make conditions – must of course know about the risks involved in order to be capable of stipulating conditions which are adequate in relation to the risk. The risks can be of various kinds. The nature of them is more precisely expressed in the stipulations made concerning informed consent, i.e. the stipulations regarding what is to be included in information and may possibly be a subject of choice make clear which risks have been identified and perceived as significant. The risks included in principle two are those which a research ethics committee can foresee and can balance against the benefit or the gains of which research holds out a prospect. This means that the donor of a specimen is presumed to accept that certain information will not be communicated and that, for example, an ethics committee can make certain decisions in her stead. (On this point, see what Hansson in his contribution terms the “second meaning” of “integrity”.)

Thus the term “risk” presents us with a difficulty. It is often pointed out that many laymen and members of the profession have different ways of judging risk, not only in the sense of frequently rating the degree of risk differently, but also as regards *what* constitutes a risk. In this respect, “risk” is a value-charged concept. It is possible that documents of consent etc., will above all reflect the professional interpretation of risk. Close attention should therefore be paid to current ethical and political debate and to what pressure and interest groups have to say. This can help us to identify the values which are liable to be infringed and to initiate a discussion of ways in which these risks can be balanced with a maximum of moral sensitivity.

*Principle three:* One should always supply the kind of information which a rational person<sup>22</sup> could normally be presumed to require concerning the use of a biological specimen. This principle is based on respect for people’s *integrity*: a person’s opinions, wishes and

values should be respected by those who interact with him. The principle also acknowledges the privileged situation in which the sampler's knowledge and power place him in relation to the donor. Like principle two, this principle expresses a positively formulated right, in that a balance should be struck between the importance of supplying information and the cost and trouble which this entails. A rational person, after all, will probably agree that a certain kind of information does not justify unlimited effort.

Referring back to the contractual nature of the gift model, this principle means that you can require "the contract" to contain the information which has an essential bearing on your desire to sign it and which it is practically feasible to include. In this way, principle three, like principle two, is contextual in a way which our first principle is not. That which a "rational" person would like to know is of course not the same in every context, depending as it does both on the person herself and on the circumstances.

The information which principle three refers to is of course frequently, though not exclusively, information about risks. But the term "risk" here has a wider meaning. Not all risks are of such a kind that one can predict whether individual sample donors will experience them as risks. A sample can, for example, be used in a type of research which the donor finds morally reprehensible, even if she is not directly harmed by it. This can be the case with research in a field which the donor, as an animal rights sympathiser, cannot accept. And yet, through the sample she has given, she becomes a party to the research. Another example is the case of her specimen being delivered to a business enterprise of which she disapproves and whose work she does not wish to support. In addition, there are conditions attaching to research which can interest individuals or groups but not primarily because they entail risks. The point at issue may, for example, be the role of research in social change or matters which, scientifically speaking, cannot be confirmed as risks but which, for various reasons, are nevertheless open to question. Information capable of shedding light on conditions like these may also be of interest to participants in research.

These principles ought primarily to be considered complementary. All three indicate *when* informed consent should be obtained, namely when the question is one of individual participation, when the person concerned takes a more than negligible risk by participating or if there are other reasons for supposing that the individual or the group to which she belongs would like to know what use their specimens are going to be put to. In this way, all three have something to say concerning the *content* of the information: each individual is informed concerning her participation, the risks she is taking and other relevant matters. How, then, are these principles to be balanced against each other? This is a hard question to answer *a priori*. Principle one has a logical head start on the other two: a non-participant cannot take risks or desire information concerning his participation. Otherwise I see them as mutually supportive. Should an experiment with biobank material mean that a person can be said to take part in the experiment, and then take a risk and, for other reasons, desire information, then there will have to be very good reasons indeed for not obtaining informed consent for the experiment.

### **Can the sample donor ask for the sample to be returned or destroyed?**

The Medical Research Council<sup>23</sup>, the National Board of Health and Welfare<sup>24</sup> and the Biotechnology Committee<sup>25</sup> all wish to make the donor fully entitled to revoke her consent. Their standpoint tallies with Section 12 of the Personal Data Act (1998:204), which provides that in cases where processing of personal data is only permitted when the person registered has given consent as the Act provides, the person registered is entitled at any time to revoke the consent he has given. On the other hand, a right of this kind runs contrary to the established practice of research ethics in connection with register research. If individuals

could recall the data/samples they had supplied to registers, this would detract from the scientific value of the register concerned. This unfortunate consequence is not only negative in itself: setting up a good-quality biobank, with adequate security etc., costs large sums of money, and so failure to use it as effectively as possible would be a waste of resources. It should further be noted that, if the specimen has been made a subject of research, destruction of the specimen eliminates the possibility of subsequently verifying and otherwise following up the research, which without doubt is a palpable deficiency.

How can we resolve the dilemma of desiring for the future both to safeguard the individual person's power of decision over his participation in research and, on the other hand, to make effective use of biobanks? Let us first of all distinguish between (1) revoking consent to further research and (2) retrospectively asking for samples, data and results to be destroyed or returned. When, in connection with (1), we are referring to unidentifiable material, then of course revocation/recall is impossible, and so in a case of this kind the question is irrelevant. (The legislation proposed by the National Board of Health and Welfare refers solely to biobanks containing biological material whose origin is traceable to a certain individual.) If instead we mean coded or identified specimens, then the first part of the dilemma outlined above will come into play (no research yet having taken place, there can be no problems of verification in this instance.) As a starting point we can observe that the possibility, in keeping with our principle one, of revoking consent to further research using coded or identified specimens, is an important right for donors. One should be able to choose whether or not to participate in research. And since not all the undesirable consequences enumerated above apply to this instance, that right carries considerable weight. But, as was stated in our discussion of principle one, that right cannot be absolute: there are occasions when good reasons can be given for departing from the principle. So even though, in the great majority of instances, it is natural for a donor to be entitled to revoke his consent and ask for the sample to be destroyed or returned, there seems to be a problem involved in denying the possibility of situations where exceptions would be ethically desirable.

The dilemma is still more forcibly manifested in relation to (2), above. Here the person has already taken part in the research and still greater values are at stake. The natural solution is to be very careful indeed as to what is agreed on through the informed consent procedure. Hopefully the majority of participants, on the strength of information supplied to them concerning these values, can accept the passing of control over the specimens to the biobank. From an efficiency viewpoint this should be the normal course of things. It is also perfectly possible to anticipate this in the conditions but to give anyone wishing to do so the possibility of making a written proviso. Otherwise, of course, it may sometimes be possible to only take specimens from those accepting the biobank's full right of disposal, without prejudicing the success of the research. In other cases, perhaps the possibility of verification does not require the specimens to be retained, and the donor's right of recovering the samples or having them destroyed can be part of the initial conditions. The circumstances of the individual case should be allowed to decide this. But the proposal from the National Board of Health and Welfare, in which revocation of consent includes destruction of the tissue specimen, has the effect of establishing by law the donor's right to have the specimen destroyed, an arrangement which, in the light of our previous discussion, seems rather ill-advised and ought not to be recommended. There is no precedent for any such inalienable right. As we have already seen, it is abandoned in the statutory requirements, imposed previously by the National Board of Health and Welfare and other authorities, concerning the supply of data to various registers. Research with the aid of these registers has been judged so valuable as to warrant a circumscription of the individual person's right of direct control over her participation. Similarly, research with the aid of biobanks appears to be of such great

interest to broad groups of patients and to society as to make it reasonable for donors at least to be able to consent to control over the specimens in this respect passing to the biobank.

Finally, a problem of demarcation. Both in case (1) and case (2) it appears reasonable that special circumstances and the donors' preferences should be allowed to influence the possibilities of revocation agreed on. Arguments in favour of control for the biobank appear to carry slightly more weight in case (2), while the donors' right is more accentuated in case (1). So where should the line be drawn between the right of deciding on one's participation in further research and retrospective requirements? There may be cause here to observe the stipulations concerning registers in Section 9 of the Personal Data Act (1998:204). That section lays down that the personal data protection official shall among other things see to it that personal data are collected only for special, expressly indicated and justified purposes, that the personal data processed are adequate and relevant in relation to the purposes of the processing, and that no more personal data are processed than are necessary having regard to the purposes of the processing. Insofar, then, as the samples supplied to a biobank are to be regarded as or equated with personal data, these stipulations are a safeguard against excessive conferment of rights on the biobanks. This, in other words, is a possible definition of "further research" as referred to in (1), above. So long as Section 9 of the Personal Data Act is complied with, there is no question of "further research", only of "special, expressly indicated and justified purposes". Research within these frames should be able to proceed on the conditions agreed on by donor and researcher, while research which can be termed "further research", i.e. is no longer confined within the original, expressly indicated purposes, should normally (a) be preceded by the procurement of fresh consent, with specific indication of the control which the donor is to have, or (b) be based on the premise of the donor in future being entitled to recall consent and specimen (for possible exceptions, see the discussion concerning principle one).

## References:

<sup>1</sup> In this paper words of Acts, rules and regulations are unofficially translated to English, and the wording of the translations is not in any way to be regarded as authoritative.

<sup>2</sup> Aftonbladet carried a series of articles on biobanks between 10th and 15th April 1999. The authors, journalists Maria Trädgårdh and Magnus Ringman, were later rewarded with *Stora Journalistpriset* (a prestigious journalist prize).

<sup>3</sup> *Human Tissue and Biological Samples for use in Research*, Interim Operational and Ethical Guidelines issued by the Medical Research Council. 1999. Section 2.1.

<sup>4</sup> *Biobanker i hälso- och sjukvården m.m.* (including a draft special enactment on biobanks in medical care etc. – *en särskild lag om biobanker i hälso- och sjukvården m.m.*), Socialstyrelsen, 2000, published exclusively on the Internet, see <http://www.sos.se/sos/publ/REFERAT/0077-011.htm> (010106). See Section 3 of the draft legislation. See also the Council of Europe *Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine*, Article 5, <http://conventions.coe.int> (010301).

<sup>5</sup> A proposal of this kind will be found in Knoppers, B. M., Human Genetic Material: Commodity or Gift? in Weir, R. F. (ed.) *Stored Tissue Samples. Ethical, Legal, and Public Policy Implications*. University of Iowa Press. Iowa City 1998, pp. 226–235.

<sup>6</sup> This point is made in an unpublished lecture by Richard Tutton (Lancaster University) entitled *Participation in Human Genetics Research: Gifts, Identities, and Genetic Difference*. 2000.

<sup>7</sup> Veatch, R. M., Abandoning Informed Consent in: Kuhse, H. & Singer, P. (eds.), *Bioethics. An Anthology* Blackwell, Oxford 1999, p. 524.

<sup>8</sup> Faden, R. & Beauchamp, T., *A History and Theory of Informed Consent*, Oxford University Press, New York 1986, pp. 278. They, however, use the expression “actively authorizes”.

<sup>9</sup> Several of these possibilities are stated in Dworkin, G., *Autonomy and Informed Consent*, in President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research *Making Health Care Decisions, Volume Three: Appendices (Studies on the Foundations of Informed Consent)*. Washington, D.C. 1982, pp. 63-81.

<sup>10</sup> This, more or less, is how informed consent is construed in the Human Genome Diversity Project, see HGDP North American Regional Committee. Proposed Model Ethical Protocol for Collecting DNA Samples. *Houston Law Review* 1997. vol. 33, pp. 1431-1473.

<sup>11</sup> Freeman, W. L., *The Role of Community in Research with Stored Tissue Samples in: Weir, R. F. (ed.) Stored Tissue Samples. Ethical, Legal, and Public Policy Implications*, University of Iowa Press. Iowa City 1998. p. 281.

<sup>12</sup> This legitimisation also applies to the three principles derived from these values and elaborated in the next section. This legitimisation can be termed *initial*. As Dworkin observes, the ensuing *test* of a proposed general principle is for it to be accepted in practice by other well-informed, rational and free agents. From Dworkin's (contract-ethical) viewpoint it makes no difference whether they justify their acceptance by utilitarian, deontological, virtue-ethical or care-ethical deliberations. Dworkin, G., *Autonomy and Informed Consent. in President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research Making Health Care Decisions, Volume Three: Appendices (Studies on the Foundations of Informed Consent)*. Washington, D.C. 1982, p. 76.

<sup>13</sup> An argument for the great advantages of a contractual model for biobanking will be found in Sass, H-M., *Genotyping in Clinical Trials: Towards a Principle of Informed Request. Journal of Medicine and Philosophy*. 1998. vol. 23, pp. 288-296.

<sup>14</sup> Naser, C. R., *Researcher Obligations to Tissue and DNA Sample Sources. in Robert F. Weir (ed.) Stored Tissue Samples. Ethical, Legal, and Public Policy Implications*, University of Iowa Press. Iowa City 1998, p. 170.

<sup>15</sup> These conflicts, of course, can be of various kinds. It may sometimes happen that an individual's personal interests are incompatible with that same individual's interests at societal level. If so, we have a conflict which, in a sense, takes place within that person himself. In other cases the conflict may be between my interests and the rightful interests of other groups or individuals.

<sup>16</sup> World Medical Association, *Declaration of Helsinki. Ethical Principles for Medical Research Involving Human Subjects*. October 2000, see [http://www.wma.net/e/policy/17-c\\_e.html](http://www.wma.net/e/policy/17-c_e.html) (010301) .

<sup>17</sup> See *Aftonbladet*, Saturday 10th April, p. 6.

<sup>18</sup> Cf. The Danish Council of Ethics. *Ethics and Mapping of the Human Genome*, 1993; Hugo Ethics Committee – Statement on Benefit Sharing, *Eubios Journal of Asian and International Bioethics*, vol. 10. 2000, pp. 70-72; UNESCO, *Universal Declaration on the Human Genome and Human Rights*, 1997.

<sup>19</sup> The *Epidemiology Centre of the National Board of Health and Welfare* maintains a number of such registers, e.g. the Abortions Register, the Cancer Register and the Patients Register. The importance of register research is discussed in Smedby, B., Westin, C-G., Adami, H-O., *Forskningsens behov av centrala register, Rapport till utredningen om informationsstrukturen för hälso- och sjukvården, in SOU 1991:17, Forskning och utveckling – epidemiologi, kvalitetssäkring och Spris utvecklingsprojekt*.

<sup>20</sup> Information booklet by Medicinska forskningsrådet. *Registerdata i forskningen*. Stockholm 1987, p. 15.

<sup>21</sup> “Minimal risk” being taken to imply approximately the risk which people normally take in their everyday lives and which is then deemed acceptable.

<sup>22</sup> The definition of a rational person is best described in a formulation which has several times been used by the ECJ. Concerning, for example, the supply of information on packagings, it has spoken of considering “the presumed expectations of an average consumer who is reasonably well-informed and reasonably observant and circumspect” (European Court of Justice 16 July 1998, Case C-210/96). Unlike the ECJ, however, I would rather not stress the “average” aspect, one point of the principle being its contextuality, i.e. that it is meant to draw our attention to the wishes which this particular person may conceivably entertain when approached, in a concrete situation, on the subject of taking part in research.

<sup>23</sup> Medicinska forskningsrådet, *Research Ethics Guidelines for Using Biobanks, Especially Projects Involving Genome Research*. 1999.

<sup>24</sup> *Biobanker i hälso- och sjukvården m.m.* (including a draft special enactment on biobanks in medical care etc. – *en särskild lag om biobanker i hälso- och sjukvården m.m.*), Socialstyrelsen, 2000, published exclusively on the Internet, see <http://www.sos.se/sos/publ/REFERAT/0077-011.htm> (010106).

<sup>25</sup> Bioteknikkommitténs slutbetänkande SOU 2000:103: *Att spränga gränser. Bioteknikens möjligheter och risker*, Stockholm 2000.