

PAPER

Turning residual human biological materials into research collections: playing with consent

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ABSTRACT

This article focuses on three scenarios in which residual biological materials are turned into research collections during the procedure of procuring these materials for diagnostic, therapeutic or other non-research purposes. These three scenarios differ from each other primarily because they employ different models of consent: (a) precautionary consent, which may be secured during the collecting procedure; (b) the presumed consent model, which may be applied during the collection of materials; and (c) consent for research use of identifiable human biological materials, which may be skipped entirely. These scenarios offer additional sources of biological samples for research purposes and at the same time seem to offer even more flexibility in terms of stringency of consent as compared with the more traditional models of broad consent in prospective research collections and the waiver of consent in retrospective research. Our discussion leads us to think that precautionary consent is preferable to presumed consent and no consent when handling issues of consent in the use of residual human biological materials for research. However, such precautionary consent should not be construed as blanket, unrestricted consent for any future use.

INTRODUCTION

One of the main features of the post-World War II research ethics paradigm has been the emphasis on stringent consent requirements in the field of human experimentation. However, different strategies to soften these stringent requirements have been developed in the field of research on human biological materials. Two of these strategies have been discussed extensively in scholarly literature and addressed in both international and national regulations. The first strategy is to use broad consent in prospective research collections of human biological materials.^{1–3} By ‘broad consent’, we mean any consent that is broader than specific consent, that is, permission to use samples in a particular research project. It may come in degrees, ranging from consent to conduct research in a specific field of biomedicine or on specific disease to unrestricted consent for any future research use, as is usually the case in population-based biobank projects. This type of consent is advocated as acceptable by a number of international organisations, such as the Council of Europe and the Organisation for Economic Co-operation and Development.^{4 5} A typical example of employing the strategy of broad consent in practice would be

a population-based biobank which strives to collect blood specimens from a representative sample of people in a given region. In this case, potential donors can be approached by the general practitioners with a request to take a small additional quantity of blood during regular examinations and asked to give a broad consent for any future research use of these samples.

The second strategy of softening, or rather making exceptions to the consent requirement, comes as a possibility to waive the requirement of consent in secondary use of already existing collections of biological materials taken for non-research purposes during different types of diagnostic or therapeutic procedures. Such collections may be found in a variety of healthcare institutions including hospitals, pathology laboratories, tissue banks, blood banks or genetic laboratories. Re-contacting of donors is regarded as a preferable ethical policy in the case of secondary use of biological materials. However, it is often recognised that in research on large-scale collections of identifiable archived human biological materials, re-contacting might not always be practicable and waiving of consent by research ethics committees (RECs) under certain conditions is considered as an acceptable policy.^{5–9} A typical example of this scenario would be the following: a scientist approaches a pathology laboratory, which has a collection of tumour samples used for diagnosis, with a request to provide him with a number of samples of a particular type of pancreatic cancer tissue. The laboratory agrees to cooperate, but since no consent for research was secured during the collection of samples, the scientist approaches the local REC with a request to waive the requirement for consent.

We will concentrate on the third possible strategy to collect biological samples for research purposes, which seems to offer even more flexibility in terms of supply of biological materials and stringency of consent. This alternative strategy is based on turning residual biological materials into the research collections of biological materials during the collection procedure. Residual human biological materials can be defined as materials taken from the patient in the course of a diagnostic or therapeutic procedure, which can be stored and subsequently used for research (cf. Van Veen *et al*, p2915).¹⁰ Three categories of residual materials can be distinguished for the purposes of this paper. The first category is leftover materials, such as biological materials removed during surgical treatment or biological material left over after diagnostic testing.

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If not used for research, leftover materials are supposed to be processed as medical waste. Leftover materials may also be referred to as 'residues from medical procedures', 'surplus materials', 'body waste', 'medical waste', 'excess clinical material', 'redundant tissue', etc. In addition to the leftover materials, we will also use the term 'residual' to refer to the archived biological materials, for example, diagnostic collections of pathology samples. In most countries, such archived materials must be kept in storage for a certain period of time, usually at least 10 years. Since storage during this period implies a duty to keep the original lesion intact when the materials are used for research purposes, we can distinguish between two categories of such archived materials: before and after the compulsory period of storage of these samples expires.¹¹ The distinction between archived materials before and after the end of the compulsory storage period is usually not specified in legal regulations. However, this distinction is very important since patients' interests in diagnosis seem to prevail over any research interests and the end of the compulsory storage period may indicate that further use of the material will not impede these diagnostic interests. It seems that our use of the term 'residual' to cover both leftover and archived biological materials corresponds with that by the Council of Europe (Art. 12).⁹

The solution to turn residual biological materials into research collections differs significantly from the usual case of the secondary use. In the latter case, if the issue of consent for research use is not resolved during the collection procedure, it arises when research use occurs (and then the issue of consent has to be resolved by seeking either additional consent or waiver of the consent). Turning residual materials (including the materials anonymous to the researcher or 'linked anonymised materials', to use the term of the Recommendation Rec(2006)4 by the Council of Europe on Research on Biological Materials of Human Origin⁹) into collections of identifiable human biological materials stored for research purposes can be achieved in at least three ways: (a) precautionary consent, which may be secured during the collection of materials; (b) the presumed consent model, which may be applied during the collection of materials; and (c) consent for research use of identifiable human biological materials, which may be skipped entirely. As we will see, in different countries, these three scenarios may apply to either leftover materials or archived diagnostic materials, or both these types of residual biological materials.

PRECAUTIONARY CONSENT

By precautionary consent we mean the consent sought for research use of residual materials where the specifics of the future research projects are unknown. Such precautionary measures are thought to solve the issue of consent, should a need arise in future research for the use of such materials. This option seems to be an extension of the strategy of broad consent in the case of prospective research collections of human biological materials mentioned in the Introduction.

The term 'precautionary consent' is used by the German Ethics Committee when it states that seeking consent for research use of bodily substances collected for diagnostic or therapeutic purposes in the absence of any concrete future research plans precludes the need and the trouble to seek re-consent or the waiver of consent if the need to conduct research arises anytime in the future (p12).¹² Although the phrase 'precautionary consent' is not employed in the Council of Europe Rec(2006)4,⁹ this scenario is also envisaged in its Explanatory Memorandum: 'When biological material is removed for other purposes than storage for research [i.e. diagnostics or therapy], it is best practice

to ask the sources for their consent to future use, even where the specifics of the future research projects are unknown' (Sec. 48).⁴ Similarly, the Irish Council for Bioethics found it acceptable to routinely ask the patients for consent for the possible future research use of 'tissue or organs removed during surgical treatment or surplus biological material left over after diagnostic testing' (p31–2).¹³ The Council took into consideration that 'such consent by its nature would have to be a broad consent, as the type of the research is totally unknown at the time [when it's taken from the subject]' (p31).¹³ However, precautionary consent does not need to be totally unrestricted in terms of potential research uses. This is also recognised by the Council of Europe, which states that 'Consent to future research should not be framed too broadly in order to prevent unconditional "blanket" consent' (Sec. 48).⁴ Precautionary consent may differ in breadth in the same way that broad consent does in the case of prospective collections. In addition, it can be implemented as multi-layered consent, allowing donors to choose from a number of different options.^{13 14} For example, the Council of Europe states that such options 'should include the possibility of refusing use of their biological materials and data in any research project, the possibility of consenting only to unlinked anonymised use of their biological materials and data, the possibility of consenting only to specific research and the possibility of being re-contacted or not being re-contacted before engaging in further research' (Sec. 42).⁴ An example of such a multi-layered consent form developed in one Italian healthcare institution can be found in the article by Salvaterra *et al.*¹⁵

PRESUMED CONSENT

In some countries, it is possible to retain identifiable biological materials removed during diagnostic or therapeutic procedures without explicit consent for research use and later treat these collections as already-existing research collections. For this purpose, some countries have introduced opt-out schemes for use of residual materials. This scenario relies on an assumption that members of society are sufficiently knowledgeable of the fact that residual materials are routinely used for biomedical research. As an additional safeguard, hospital patients may be informed during their registration (or through posters or the patients' brochure) that their residual biological materials may be used for research purposes and that they have a right to opt-out. For example, Hens *et al* state that in Belgium 'Many hospitals [...] use a notification policy for [...] leftover tissue such as surgical waste. They distribute folders explaining the fact that such tissue may be reused for research' (p278).¹⁶

Such a system may also be said to operate in the Netherlands. This country introduced a general opt-out scheme for the use of residual tissues anonymous to the researcher. The Dutch Code for Proper Secondary Use of Human Tissue describes mechanisms of presumed consent: 'For the use of coded or anonymous material (for scientific research) it is sufficient if the subject (donor) has not objected to this use.' (Art. 4.2).¹⁷ It is important to note that 'coded' here means 'linked-anonymised' in a sense provided by Rec(2006)4.⁹ The Dutch Code explains that 'The choice system assumes that considerable informative material will be made available in the institution where the human material is collected for original use. The informative material states that "further use" of human material does occur, in particular for scientific research' (Art. 4).¹⁷ This system was introduced by means of an internal code of a professional association. The Code applies to 'scientific research for the purpose of healthcare using human material that first became available for purposes other than for this investigation', which means

that the opt-out system is available for both leftover and archived materials, provided these materials are anonymous to the researcher (Art. 2.1).¹⁷ In addition, Schmidt *et al* suggest that this model can be applied in order to make materials collected prior to the introduction of the opt-out system available for research by informing patients of plans to conduct research through major newspapers and giving them the possibility to opt-out from the research project.¹⁸

A similar system has recently been introduced in Belgium, where the Act on the Procurement and Use of Human Bodily Materials for Human Medical Applications and for Scientific Research states that consent to research use of leftover human biological material is considered to be given if the donor did not communicate an objection to such use (Art. 20.2).¹⁹ Presumed consent for research use of leftover materials is also recommended in Austria where the Bioethics Commission at the Federal Chancellery states: 'In the case of a medical procedure the patient has only consented to the medical procedure. However, it can be presumed that he or she generally has no interest in body waste and that he or she has given presumed consent, unless he or she has explicitly lodged an objection' (Sec. 70).²⁰ Explicit written consent is needed when samples are derived solely for research or where additional quantity of materials that would not be ordinarily taken for diagnostic or therapeutic purposes is taken (Sec. 71).²⁰ In Iceland, the Biobanks Act states that consent can be 'assumed' for storage and research use of biological specimens taken for clinical tests. The Act also states that information in writing on the possibility to opt-out should be available to the donor.²¹

NO CONSENT

The third scenario would be not to require consent for research use of identifiable human biological materials at all. The most straightforward example of this scenario is the US, where the Office for Human Research Protections at the Department of Health and Human Services issued guidelines that treat research on residual tissue anonymous to the researcher as not being human research.²² As a result, such research is exempted from both the ethical review and the consent requirements. We are unaware of any European examples that would fully fit this scheme. Perhaps the closest one is the UK Human Tissue Act (2004) which does not require consent for storage and research use of materials removed from the body of a living person if '(a) it is ethically approved in accordance with regulations made by the Secretary of State, and (b) it is to be, or is, carried out in circumstances such that the person carrying it out is not in possession, and not likely to come into possession, of information from which the person from whose body the material has come can be identified' (Art. 1.7–9).²³ Similarly, the Code of Practice issued by the Human Tissue Authority in the UK in 2009 also allows research on the materials 'taken from the living for diagnosis and subsequently stored in a diagnostic archive' without the patient's consent, provided the samples are not identifiable to the researcher and a specific research project has been approved by a REC. However, it is important to note that the mentioned Code of Practice still calls the situation where the consent is secured 'the preferable scenario' (Para 26).²⁴

COMPARATIVE PERSPECTIVES

While discussing the justification of different strategies of handling human tissue research, it is important to take into account not only different options of consent but also overall levels of risks to which the tissue donors can be exposed. A broader perspective onto the regulatory frameworks of balancing

the softening of the requirement of consent should be taken into account. For example, in some cases, regulatory frameworks dealing with prospective collections are very comprehensive and detailed as they aim to balance or compensate the broadening of informed consent with specific legislation and sophisticated project management and personal data protection systems. In the case of large-scale population biobanks, these systems can even include specially assigned ethics bodies. Secondary research use of biological materials is often regulated less strictly and systematically, especially taking into account that waiving of informed consent is usually only balanced by the requirement of an ethical review of a particular project and that waiving of the consent may be increasingly becoming the default policy among RECs. Finally, the alternative scenarios of secondary use described in this article sometimes provide even more relaxed regulations. These regulations may even be based on policies prescribed by the guidelines of professional organisations rather than legal regulations.

The strategy of turning the residual biological materials into research collections during the collecting procedure seems to have an advantage over the traditional method of the secondary use of biological materials, because it leaves the scientists and RECs free from rather demanding decisions about the requirement of re-consenting and allows them to collect large numbers of biological samples that could otherwise simply vanish. In addition, in contrast to the prospective research collections, it does not require any justification of the intervention to obtain the biological materials since these materials are being removed for non-research purposes—as this strategy utilises interventions whose primary goal is a diagnostic or therapeutic one. Therefore, the strategy of turning the residual biological materials into research collections during the collecting procedure may serve as a useful resource, alleviating the need for biological materials available for research purposes.

Although the availability of this strategy brings significant advantages in terms of supply of biological materials, it also raises important ethical concerns with regard to the autonomy and privacy of the donor.²⁵ In addition, the donors may be concerned with possible commercial exploitation of the samples and the primary use of their biological materials may be hampered (eg, where no or not enough pathology material is left for the diagnosis due to the fact that samples given out for research are not returned or no longer contain the original lesion (Riegman *et al*, p219)).¹¹ Therefore, it is important to make sure that these concerns are assessed and taken into account when discussing whether such a strategy may offer sufficient protection to the donors and a favourable risk/benefit ratio. For example, it is important to ensure that pathology laboratories and healthcare institutions in general, that are responsible for the proper storage of residual tissues, maintain their role in safeguarding donors' interests. One of the most important mechanisms needed to balance this softening of requirements for consent is an approval by the REC, which is usually required for every research project, to ensure, among other things, the compliance with privacy regulations and storage policies of the samples that do not compromise donors' interests in diagnosis and treatment. This is probably the reason why some documents mentioned in the paper^{13 19 20} extend the strategy of turning residual biological material into research collections only to the leftover materials.

Although these three alternative scenarios (presumed consent, precautionary consent, no consent) may appear to be acceptable or even preferable over the traditional ones, we still have to consider which out of these possible options is the most

suitable. One of the most obvious concerns raised by the availability of these scenarios is the validity of consent, especially in cases of presumed consent and no consent models. It may also be questioned whether the assumption on which opt-out systems are based—namely, that the population is sufficiently aware that research use occurs—is realistic. For example, a study conducted at the Vanderbilt University Medical Center in order to assess the efficiency of posters in conducting information on future research uses and possibility to opt-out, showed that posters are not sufficient.²⁶ On the other hand, it may be asked whether precautionary consent for any future research use can be considered informed consent—it seems to be very similar to so-called ‘blanket’ or ‘overall prior’ consent that is being warned against by a number of international documents.^{4 27} We may ask whether this provides the donors with sufficient measures to control the materials. Precautionary consent shares this problem with any sort of broad consent. The problem becomes especially pressing when precautionary consent is secured routinely at the time of admission to the healthcare institution. However, as was mentioned before, the precautionary consent does not need to be construed as totally unrestricted, as it may include certain specifications concerning the possible future use of the samples collected for non-research purposes. Such precautionary consent seems to be preferable to no consent, presumed consent or blanket precautionary consent, since it gives the donors a significant level of control over what happens to their materials and offers enough flexibility to the researchers (it is based on the emerging consensus on the use of broad consent to collect the materials) without relying on a doubtful assumption that donors are aware of possible research use and therefore may control what happens with their samples by means of any opt-out mechanisms. This consideration can also be supported by the recent document ‘Opinion 15/2011 on the definition of consent’ prepared by the Article 29 Data Protection Working Party of the Directive 95/46.²⁸ The Opinion claims that in the context of electronic health records, the opt-out solutions do not meet the requirement of ‘explicit consent’, which is the requirement to be applied on such sensitive categories of data as health data. Therefore, in case of research on biological materials associated with personal health data, the model of presumed consent to take and use the sample for future research would not be in line with the provisions of the Directive.

Recognising that theoretical analysis of these questions is of great significance, it is also important to take into account attitudes and preferences of various interested parties. A number of empirical studies were conducted during which patients were asked about their preferences concerning consent procedures in donating tissues for human tissue research.^{1 29–31} These studies tend to show that, in general, patients highly endorse tissue research and agree that their samples should be used for future studies. However, it is also important to study which consent mechanisms are perceived to be of the patients’ best interests. For example, Vermeulen *et al* report a study in the Netherlands in which 56% of the respondents favoured a ‘one-time general consent’ (which could be regarded as a mode of the precautionary consent) and only 23% preferred the current ‘opt-out’ procedure.³¹

CONCLUDING REMARKS

Our aim in this paper was not to present a thorough analysis of practices of consent from the legal point of view in different European countries, but rather, to describe a number of alternative strategies to soften the stringent requirements of consent inherent in the post-World War II paradigm of research ethics as

applied to research on human biological materials. We hope to initiate a discussion as to what extent such divergences from this paradigm are justifiable. It seems desirable to tune different levels of regulatory stringency (including regulations on acceptable types of consent) to different types of biological materials according to the interests of the donors involved. Special protection should be given to archived diagnostic materials, especially during the compulsory storage period: research use should not hamper the original purpose, that is, diagnosis. Otherwise, remarkable differences in regulatory stringency associated with different types of human tissue research are hardly justifiable, bearing in mind that all these types fall within the broad field of non-interventional and minimal-risk research. Our discussion leads us to think that precautionary consent is preferable to presumed consent and no consent when handling the issues of consent in the use of residual human biological materials for research. However, such precautionary consent should not be construed as blanket, unrestricted consent, for any future use.

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