

‘Mirroring’ the Ethics of Biobanking: What Analysis of Consent Documents Can Tell Us?

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Abstract Biobanks have been recognized as a key research infrastructure and how to approach ethical questions has been a topic of discussion for at least a decade by now. This article explores the characteristics of donors’ participation in European biobanks as reflected in the consent documents of a selection of different biobanks from various European countries. The primary aim of this study is to understand how donors are informed about their participation in biobanking. Also the paper discusses what the most important thematic issues of information are to be given to the biobank participants and how this information should be presented in the consent documents. For these purposes, we analyse consent documents from 14 biobanks in 11 countries for six ethically relevant issues: (1) model of consent, (2) scope of future research, (3) access to medical data, (4) feedback to the participants, (5) consent withdrawal, and (6) role of research ethics committee. In order to compare different trends of informing donors of human biological material and medical data, we interpret the six analysed issues in the context of respect to donor’s autonomy paradigm. Although the results of the paper reflect the heterogeneity of biobank consent document policies applied in different European countries, we uncovered some trends and suggested several examples of good practices to balance the interests of the donors with those of the researchers and future patients.

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Introduction

In the last 10 years biobanks have attracted considerable attention worldwide as a key research infrastructure. Several years ago the “Time” magazine has listed biobanks as one of the “*top ten ideas changing the world right now*” (Park 2009). However, developments in the field of biobanking also raise important ethical and human rights concerns. One of the most visible issues emerging in the ethical debate on biobanking has been the type of consent to collect human biological material (HBM) and personal medical data as well as the need to transform the post-Nuremberg ethical framework for biomedical research. This transformation of research ethics has been mainly related to the introduction of the concept of „broad consent“ as contrasted to a specific consent describing a particular research project in detail. It has been argued that specific consent was very relevant in the post-Nuremberg context of research ethics, emphasizing the importance of specific consent in interventional clinical trials, which in many cases carry significant level of risk. This type of consent has been, however, not suitable for the large scale biobanking initiatives, which require collecting HBM and personal medical data without a possibility to indicate in a sufficiently specified way (at least comparable to that of clinical trials) the future research activities where HBM and data could potentially be used. At first sight the recourse towards a “broad consent” model can be seen as a weakening of the fundamental requirement of the post-Nuremberg ethical framework based on the principle of respect for personal autonomy and specific consent. On the other hand, it should be noted that this type of consent has only been proposed for the activities which do not involve any high risk interventions and significantly contribute to biomedical developments. In addition, the alternative ethical framework of biobanking attempts to balance the modification of a “specific consent” model with such ethical principles as solidarity (participation in research for the common good), sharing of research benefits (Chadwick and Bere 2001), citizenry, and reciprocity (Knoppers and Chadwick 2005).

It should be stressed that in the biobanking debate it is not only important to set the rules for procurement of HBM as such but also, and perhaps even more importantly, to think about the ways personal medical information is going to accompany the HBM in all the future research activities. This information is usually collected during the enrolment into the biobank, but very often the donor of HBM is also asked to grant access to his or her personal medical information in the future. It makes biobanking a type of a life-long repository of regularly updated sensitive health related data to be used in different research projects without a specific prior notification of a donor. The situation becomes even more complex when the presumed consent model to collect residual HBM and to use associated personal medical information are proposed and promoted in some countries (e.g., Federation of Medical Scientific Societies 2003). This is why biobanking activities are only ethically justifiable if people understand and agree with this type of robust

use of their HBM and, even more importantly, their health related information. Therefore, despite of the broadening of the research ethics framework with such principles as solidarity, sharing of research results, reciprocity, and citizenry, respect to personal autonomy retains its importance in protecting the interests of the biobank participants. Ensurance that adequate information crucial for the decision making is provided to the participants of biobanking initiatives retains its fundamental importance. This also explains the aims of this paper. First, to explore how the donors are informed about their participation in biobanking. Second, to suggest what the most important thematic issues of information are to be given to the biobank participants and how this information should be presented in the biobank consent documents.

The analysis of biobank consent documents enables us to compare practices of informing donors about their participation in different biobanks, and even picture some specific patterns of informing donors in different types of biobanks. For the purposes of our study we have distinguished six thematic issues of information, which can be regarded as the most relevant from the respect for participants' autonomy point of view. These are (1) model of consent, (2) scope of future research, (3) access to medical data, (4) feedback to the participants, (5) consent withdrawal and (6) role of research ethics committee (REC). We consider them as ethically relevant issues in the context of biobanking since these topics are crucial for the decision making at different stages of participation in the biobanks. It could also be claimed that they in some way compensate the lack of 'specificity' of consent to biobanking and therefore could be regarded as ethically relevant from the respect for personal autonomy perspective. It is also no surprise therefore why national bodies/ethics committees¹ pay much attention to them while discussing the issues of informing the participants about biobanking.

For the purposes of our paper we raise the following basic ethical questions: how much do the analyzed practices match the interests of the donor and how congruent they are with the donor's autonomy based approach? If we follow the six thematic issues described above, it seems that the donor's autonomy based approach should:

1. Employ some form of explicit rather than presumed consent for collection, storage and research use of HBM and medical data. It should be noted, however, that an exception can be made for collecting residual HBM in case this is followed by an explicit consent for the use of related personal data;
2. Define the scope of future research in a reasonable detail;
3. Explain a possibility for the biobank to access personal medical data in the future;
4. Offer different options of feedback regarding findings discovered in the course of research along with appropriate personal counselling;

¹ Swiss Academy of Medical Sciences, German Ethics Council (two opinions), Austrian Bioethics Commission at the Federal Chancellery (two opinions), UK Medical Research Council, Cyprus National Bioethics Committee, Federation of Medical Scientific Societies, Belgian Advisory Committee on Bioethics, French National Consultative Ethics Committee for Health and Life Sciences, Irish Council for Bioethics, National Bioethics Commission of Greece, Organisation of European Cancer Institutes (Milano), Nuffield Council.

5. Explain the consequences of and offer different options for disposal of HBM and medical data in the case of withdrawal;
6. Ensure REC's review for every research project which involves biobanked HBM and medical data.

Materials Collected and Types of Biobanks

To obtain consent documents, we contacted colleagues who are engaged in biobanking in various European countries. In addition, several consent documents were received by navigating biobanks' websites which appeared on internet searches. In total we collected 14 consent documents (both consent/objection forms and/or informational leaflets) from biobanks in 11 European countries: three from the United Kingdom (UK biobank, biobanks from Cambridge and Oxford), two from Italy (biobanks from Padova and Milano), one biobank each from Norway (Oslo), Austria (Graz), Estonia, Latvia, Portugal (Lisbon), Germany (Munich), Belgium (Brussels), the Netherlands (Rotterdam), and Luxemburg. All non-English language biobank consent documents were translated into English by professional translators. The analysis presented in this paper refers to both—the consent forms and information sheets.

Eleven out of 14 biobank consent documents consisted of two separate documents: informational leaflet and consent/objection form. The extent of the informational leaflet varied between 2 and 12 pages (957–3,780 words, average 1,750 words), consent/objection forms were 1–4 pages long (330–5,046 words, average 1,062 words). However, if the information on biobanking was integrated into a larger consent document of a particular research project or consent form for a diagnostic procedure which was not specifically designed to address biobanking issues, the amount of information provided to the participants was smaller (81–1,109 words, average 503 words).

The consent documents collected came from three types of research biobank: population biobanks² (Latvia, Estonia, UK biobank), disease biobanks³ (Rotterdam, Luxembourg, Oslo, Cambridge, Brussels, Munich, Milano, Padova, Lisbon), and 'mixed' biobanks comprising both population and disease collections of HBM (Graz, Oxford).

Most of the consent documents that we obtained were from disease biobanks focused on the collection, storage and use of HBM in cancer research since this field is very active in biobanking. Several consent documents from disease biobanks were

² A population biobank primarily aims to obtain biomarkers of susceptibility and population identity, and their operational substrate is germinal-line DNA from a huge number of healthy donors, representative of a concrete country/region or ethnic cohort (Riegman et al. 2008).

³ A disease biobank's (i.e. tumour banks) aims correspond to biomarkers of disease through prospective and/or retrospective collections of tumour and non-tumour samples and their derivatives (DNA/RNA/proteins), usually associated with clinical data and sometimes associated with clinical trials. Those data are usually not collected for a concrete research project, except the case of clinical trials, but from the healthcare clinical records. The amount of clinical data linked to the sample determines the availability and biological value of the sample (Riegman et al. 2008).

not solely designed for the purpose of biobanking, but rather the biobanking section was included in consent documents which were primarily designed for diagnostic and treatment purposes or such a section was a part of a specific research project consent document. The majority of the disease biobanks were collecting HBM left over after diagnosis or treatment. In some cases additional HBM was also collected (usually a small amount of blood) specifically for biobanking purposes (e.g., Rotterdam, Lisbon, Milano, Brussels, Munich, Cambridge). It is also interesting to point out that we encountered two specific types of disease biobanks. First—the pathology archive that stores HBM for diagnostic purposes and that may also allow a small part of HBM to be used for future research following a prior consent from the donors (Padova) and second—biobank containing HBM that was collected mainly for the purposes of a specific research project and future unspecified research (template of consent document provided by Oslo).

Analysis of Consent Documents

In this section the findings related to the analysis using the six thematic issues referred to in the introduction will be presented. Notably, nine out of 14 biobank consent documents included at least some information on all six issues.

Consent Model

We found that the majority of biobanks we analysed used an opt-in (explicit) consent model for collection, storage and research use of HBM and medical data. This is clear in the context of population biobanks given that the way a potential donor is recruited implies an explicit consent procedure. However, this trend was also prevalent in the case of ‘mixed’ and disease biobanks. These consent documents also asked for an explicit written consent provided by a person with basic information and with an option to agree or disagree with participation. The only exceptions were two disease biobanks (in Brussels and Rotterdam) where a presumed or ‘mixed’ (presumed/explicit) consent approach was observed, which reflects the national laws and guidelines in those countries. The Brussels biobank applied an opt-out consent model for collection, storage and use of leftover HBM from clinical care in research, however it did ask for an explicit written consent, provided separately for additional interventions performed in order to obtain extra HBM, e.g., a blood sample and for accessing personal medical data. The Rotterdam biobank is noted to be an example of a “pure” opt-out model, whereby automatic storage was applied, not only for the leftover HBM from clinical care, but also access to personal medical data for future biomedical research without a separate consent regarding medical data.

Scope of Future Research

We noted that the consent information regarding the scope of future research was tailored to the type of biobank. For instance, all three population biobank consent

documents emphasized their general aim to improve prevention, diagnosis and treatment of various illnesses that can be seen in the population. All population biobanks clearly stated their specific focus on genetic research, however they gave rather broad and general information about what they aim to achieve through conducting future research (e.g., “*to determine genes that influence the development of diseases*”). The UK biobank and Estonian biobank specifically stated that future research may involve genetic analysis of participants’ DNA. The UK biobank additionally provided an example list of diseases which may be investigated, whilst the Latvian biobank allowed donors to restrict the extent of genome research by writing into the consent documents what they disagree with. The two ‘mixed’ biobanks formulated the possible future research use of donated HBM similarly to population biobanks with additional explanations regarding the future use of disease collections. For instance, one aim of the Oxford biobank is “*to look at the mechanisms which make cells grow and also what makes them sensitive or resistant to treatment*”.

As for the disease biobanks, in addition to employing such phrases like “*for medical scientific research*”, “*for biomedical research*”, five out of 9 biobanks also provided other specifications. For instance, the Munich and Cambridge biobank consent documents particularly stressed the possible use of HBM for genetic research e.g., “*for ethically approved research which may include genetic research*”, “*for future scientific research (especially gene analysis)*”. The Padova biobank consent document mentioned that stored HBM may be used for research which includes DNA analysis. The rest of the disease biobanks do not specifically mention the use of DNA. One biobank that we reviewed gave the possibility to place restrictions by providing a separate consent specifically for use in genetic research (Luxembourg). Another biobank provided an option to choose between research on the specific disease group, e.g., tumour diseases, and other diseases (Milano). However, it is also worth pointing out that, in some cases, although the scope of future research is not specifically mentioned in the disease biobank consent documents it may be inferred from the biobank name (e.g., ‘Tumour Bank’ in the Brussels example).

Access to Medical Data

In all population and ‘mixed’ biobank consent documents, consent to agree or disagree with participation in the biobank explicitly included accessing medical records (or also other databases). The Latvian and Graz biobanks elaborated the consent requirement even further. In the Latvian case, the biobank asked for a separate consent for elaboration, renewal and verification of donor’s health condition description in the genome database, while the Graz biobank asked for a separate consent for accessing personal medical data stored in other health institutions (general practice, other hospitals) but not for accessing data stored in health institutions where the HBM is obtained. All population biobanks specifically mentioned restricted access to personal medical data for insurance companies (because of potentially adverse effects on insurance status) and/or family members

(though medical data may also be clinically relevant for them, especially if the donor is found to have a serious genetic disorder).

As for the disease biobanks, five of them explicitly endorsed the access to personal medical data in the future. Two (Brussels and Cambridge) asked for a separate consent for this reason. In the other four disease biobanks this is not explicitly mentioned but generally the use of medical data as well as access to it in the future could probably be implied from other provisions in the consent documents like “*Privacy of the donors of residual tissue must be protected*” or “*The processing of your data will be managed according to the provisions of the Legislative Decree 196/2003*”.

All biobanks that mentioned the use of medical data and HBM outside of the biobank institution put an emphasis on protection of participant’s privacy by ensuring that HBM and data will be anonymous for researchers (i.e., that researchers will not have direct access to personal identifiers like name, surname, date of birth, place of birth, etc. of donors). Certain biobanks in their consent documents explained what kind of rules they apply with regard to coding of personal medical data within the biobank itself (e.g., chief processor or chief of the biobank is in charge of coding of HBM and personal data (Estonia, Padova)).

Feedback to the Participants

In the consent documents, ten out of 14 biobanks (all population and ‘mixed’ biobanks as well as many disease biobanks) specifically addressed the issue of managing findings discovered in the course of research that might affect the donor’s health (e.g., Estonia, Luxemburg, Oxford) or also the health of relatives (e.g., Latvia, Cambridge) or direct descendants (Graz). Two population biobanks, three disease biobanks and both ‘mixed’ biobanks offered an option for participants to receive this information. However, the amount of information offered and the subjects to whom the information may be conveyed varied. The Estonian biobank consent document stressed that all health related information of the donors or their relatives (genetic data, hereditary characteristic and genetic risks, except for donor’s genealogy) may be reported. Others offered to disclose medically relevant information only, i.e., the information which may be used for donors’ health care (Luxemburg); which may be useful for the health of the donors or their family members (Padova); or which is considered medically important (Oxford). In the meantime the Latvian biobank consent documents combined all three choices together and let the donor choose either to receive all information, only medically relevant information (which may help to avert health risks) or to refuse to receive any information in general. It is also interesting to point out that biobanks which provided information relevant to the donor’s family members or relatives, usually gave this information to the donor only, except for the Padova biobank which did not give this information to the donor, but upon donor’s request may contact family members and inform them with the donor’s previous consultation, whenever possible.

The issue of how findings are returned to the donors (or relatives) also varied in the analysed consent documents. For example, the Estonian biobank suggested that

participants access the biobank themselves along with the support of genetic counselling, although the participant may entitle a general practitioner to access the data at the biobank as well. A few biobank consent documents explained that this may be done by the research group contacting the donor's clinical team (Cambridge), hospital consultant or general practitioner (Oxford). The Luxembourg biobank states that in the case of there being findings, appropriate specialists would reassess them in order to decide whether to report results to the donor through the donor's doctor or not. The Latvian biobank suggested that in emergency cases, access may be granted without the written consent of the participant. The rest of the consent documents provided no specification of the scope and method of feedback apart from the statement that such information is accessible.

Consent Withdrawal

All consent documents, except for those of two disease biobanks (Munich and Oslo), explicitly stated that consented individuals are still free to withdraw from the biobank at any time. However, not all specified the extent or consequences of such a withdrawal. Three of those specifying offered destruction of HBM, and destruction or "no further research use" of medical data (Brussels, Latvia, Luxembourg). A few only endorsed destruction of HBM (Rotterdam, Lisbon, Cambridge) without explicitly mentioning whether there will be any restriction on further research use of medical data. A couple of biobanks offered destruction of information enabling personal identification (Estonia), or both destruction of information enabling personal identification and destruction of HBM (Graz). Tiered options were provided in the UK biobank example, where withdrawal was allowed at three levels: "no further contact" (allowing continued use of information and HBM, and further obtaining of information from medical records), "no further access" (allowing continued use of already collected information and HBM) and destruction of HBM plus no further research use of medical data. Similar options of "no further access" were also additionally provided in the Estonian and Latvian consent documents. In the case where a biobank participant does not withdraw, the Luxembourg biobank, the UK biobank and the biobank from Lisbon explicitly stated that the consent of participants remains valid also after a person's death.

Role of REC

All consent documents, except for Lisbon and Estonia, specifically explained to the participants that all research studies involving HBM and data stored in a biobank will be conducted only if ethical approval (ethical approval or notification in the Padova example) is issued by an appropriate REC. In the UK biobank's case, consent documents did not specifically mention the REC, however, it is emphasized that HBM and data from the UK biobank "will be available only to researchers who have the relevant scientific and ethics approval for their planned research." Some other important obligations are placed on the RECs as well: e.g., obligation to approve the transfer of HBM to other research institutions (also commercial companies) for research purposes (Munich); to approve the biobank (Oxford); to

review it periodically (Luxemburg); and to approve the updating, supplementing or checking information of the gene donor and collection of additional data (Estonia).

Discussion

In this section the most important thematic issues of consent documents will be analysed from the donor’s autonomy based approach. The problematic aspects of the structure and design of consent documents as well as the practice of using the archives of pathology specimens for research purposes will be raised as well.

Prevalence of the ‘Opt-in’ Model

It should be noted that the opt-in model of consent prevailed not only in population and ‘mixed’ biobanks, but also in the disease biobanks which mainly collect residual HBM. In seven out of nine reviewed consent documents from disease biobanks, opt-in was the dominant consent model for collection, storage and future research use of HBM and personal medical data. The opt-out consent model was found in Brussels and Rotterdam and was only fully applied to both leftover HBM and data in Rotterdam under certain conditions. One of the arguments against the use of the presumed consent model in disease biobanking is that it involves collecting and (or) accessing sensitive personal data. When people participate in biobank based research, questions of privacy and data protection are of the greatest concern (European Commission 2010). The Brussels biobank is a good example of combining an autonomy based approach to deal with personal data and a flexible model of collecting HBM: this biobank used two different consent models for the leftover HBM (presumed consent) and for the data (explicit consent). It should be noted that this option worked well for this biobank since very few patients tend to choose to participate in biobanking but disagree to grant access to the medical data.

Broadly Defined Future Research Use

Several disease biobanks define the scope of future research in very broad terms by using such phrases like “*for biomedical research*” or “*for ethically approved research which may include genetic research*”. Even those who try to describe this issue more specifically do not explicitly provide the exhaustive list of diseases for which the biobanked HBM and data may be used. One could argue that under such circumstances the understanding of biobank participants regarding the scope of use of HBM and data may be regarded as insufficient. Biobank participants receiving so little information in this regard may hardly understand what kind of studies future research use may imply, what their HBM and data will be used for and therefore may be reluctant to participate in biobanking activities. However, the question also arises whether it is even possible to provide more specific guidelines on this issue. For example, the Nuffield Council (2011) in its report mentions that sometimes “*it is difficult, if not impossible, to formulate a research question for participants to consent to, or even name the diseases and conditions in the context of which the*

samples and data will be used in the future". Therefore, in such cases, using a system similar to that presented by the Milano biobank, which provides options to choose between research on the specific disease groups (e.g., tumour diseases) and other diseases, could be a good example of a combination between the donor's interests and the limited current knowledge of scientific and technological development of future medicine. It is also worth noting that emerging new models such as 'dynamic consent' could offer a way forward to help overcoming this challenge and help bridge the gap between broad consent and patient understanding, as discussed in the European Commission Report on Biobanking (2012). For example, this type of approach is being used in the ENCORE project which employs modern information technologies to allow biobank participants to continuously show their preferences on the use of their HBM and data through the easy-to-use computer interfaces (EnCoRe 2012).

Importance of Clarification of Accessing Medical Data and Involvement of RECs

Due to the difficulties in providing a detailed description of future research use, people who are concerned about their personal data may hesitate to be enrolled in little-understood activities of biobanking. Therefore while encouraging people to participate in biobanks, it is also important to inform them about the biobank's need to access their medical data. All the analysed biobank consent documents, except for several disease biobanks, explicitly endorsed the access to personal medical data of the participants in the future, however, only a few biobanks provided more details in this regard. The Graz biobank seems to be a good example of how to elaborate this further. This biobank asks for a separate consent to access personal medical data stored in health institutions (general practice, other hospitals) other than the health institution where HBM is obtained.

RECs also play an important role in encouraging people to take part in biobanking activities and compensating for the lack of knowledge of biobank participants about future research use of biobanked HBM and data. Therefore most national bodies/ethics committees⁴ in their opinions regarding biobanking indicate that RECs should be involved in biobanking activities while reviewing particular research projects on HBM and data stored in biobanks. This information is also provided in most biobank consent documents that we analysed. This allows us to believe that involvement of RECs is considered to be a good practice of biobank research in assessing whether all specific projects are in line with the initial consent of biobank participant, whether the scientific and practical value of research projects satisfy the common good, etc. Whether other obligations should be placed for the RECs, e.g., the transfer of HBM to other research institutions for research purposes, the authorisation of the biobank, much depends on the national biobanking models, competence of RECs, type of data transferred, the existing national regulations on data protection and other legal and ethical aspects.

⁴ See the note 1.

Diversity of Biobank Consent Document Policies on Feedback to the Donors

Feedback to participants is another interesting issue for debate. There has been extensive discussion in the literature during recent years whether biobanks should return research results which may have personal significance to biobank participants and whether it is really possible to do so and if so, how and when to make this happen (Bredenoord et al. 2011; Brothers 2011; Hoeyer 2010; Knoppers et al. 2006; Miller et al. 2008). Many biobanks have focused on a precautionary position not to promise feedback to patients (Belgian Advisory Committee on Bioethics 2009). In addition, difficulties regarding the practical and financial feasibility of delivering this service may be raised. Arguments against providing the feedback include: results may *‘have not yet been validated in terms of their medical relevance so that the sample donor cannot be adequately advised with regard to the informative value and implications of the results’* (Austrian Bioethics Commission at the Federal Chancellery 2007); *‘anonymisation or coding of the samples and data makes it difficult to go back to the patient’* (Belgian Advisory Committee on Bioethics 2009). However, our analysis showed that biobanks tend to ‘therapeutise’ themselves. Half of the biobank consent documents explicitly state that they would return results to the biobank participants that may be of potential relevance to their health or even to the health of their relatives. The feedback of such findings is likely to enhance public support. However one may wonder how realistic this “therapeutic promise” of biobanking really is?

If we relied on the concept that feedback is needed, then other questions could be raised—for example, how much information should be reported to the donors and in which way? The analysed biobanks offer a variety of ways to tackle this issue. However, it seems that the combination of the Estonian and Latvian biobanks is the closest match to the donor centred ethical approach. The Latvian biobank allows the donor to choose for himself either to receive all available information, or only medically relevant information (which may help to avert health risks), or to refuse to receive any information in general. An important feature of the Estonian biobank is that it offers feedback along with the support of genetic counselling.

Withdrawal: Unclear ‘Fate’ of Medical Data

Withdrawal is another important issue while exploring biobank consent document policy. Our analysis showed that most biobanks specify the extent or consequences of withdrawal in case of HBM disposal and offer the strictest scenario—destruction of HBM. However, several of these biobanks do not clearly state whether withdrawal restricts the future research use of personal medical data which may be of particular concern to the donor. Considering this issue from the broader perspective, the UK biobank seems to favour donor’s interests most of all, as it gives the option to the donors to decide between several types of withdrawal, that include the destruction of HBM and no further use of medical data.

Structure and Design of Consent Documents

As mentioned before, the length of biobank consent documents varies significantly among different biobanks. The documents from some disease biobanks are quite short (e.g., average of 503 words), which may raise the question whether this much information is sufficient to be provided in the consent documents? While evaluating this kind of practice from the donor's autonomy approach, it seems that the amount of information provided in the documents should be put in the context of alternative ways of communication, e.g., by face to face explanation, other general information or websites. Also, the length of explanation may also be shorter if people are generally more aware and educated about biobanking. On the other hand, it must be taken into consideration that the total information load presented to the person at one time cannot be overwhelming or it will not be well understood. Interestingly, one study (Helgesson et al. 2005) revealed that most of the participants even in specific research studies may be satisfied with less detailed information than that with which they were provided. In such cases, it may be helpful to work together with patient groups in order to reach a good balance of information that is also accessible.

Although the length of the consent document is important, the structure and design of the consent document influencing the way information is provided to the potential donors of HBM seems to be no less problematic. Though the majority of consent documents which came from disease biobanks were specifically designed for biobanking, there were several biobank consent documents that were integrated into consent documents for diagnostic or treatment procedures. Consequently, the question arises whether all disease biobanks should have separate documents for biobanking next to the consent for clinical interventions? Consent for clinical interventions which also include a biobanking section may better explain the integral role of biobanking in the provision of healthcare and the advancement of diagnostic and treatment technologies. This would also be convenient for biobanks from a practical point of view. However, such consent design may induce a misconception that biobanking is primarily aimed at the healthcare of participants. It can be noted that this important issue does not seem to raise concern for most of the national bodies/ethics committees, expressing their opinions about biobanking, except in the case of Ireland. From our reviewed 14 opinions of various national bodies/ethics committees on biobanking issues⁵ only Irish opinion specifically discusses a similar issue and recommends introducing a separate consent for research in order to avoid therapeutic misconception (Irish Council for Bioethics 2005). An example of a potential solution could be the Cambridge biobank which provides a consent form which is primarily dedicated to the diagnostic procedure and includes the possibility of consenting to the use of HBM and medical data in research. In addition, patients are provided with a separate informational leaflet that specifically addresses the details of research biobanking.

Finally, the regulatory framework and consent procedures for use of pathological archives for research purposes should also be mentioned in this discussion. Pathology archives usually contain HBM retained from diagnostic procedures which

⁵ See the note 1.

could also be partially used for future research. In many European countries, an explicit consent to use a diagnostic sample for future research is not usually obtained during routine medical HBM collection. In terms of consent, “*the waiving of consent is considered as an acceptable policy*” (Gefenas et al. 2011). Therefore, a question can be raised in this context of whether the pathological archives should develop consent documents for the use of HBM similar to the example of the Padova biobank described in this paper. On the one hand, this could avoid a perceived double standard in collecting, storing and future research use of HBM and data, and protect the donor’s autonomy. On the other hand, if pathology archives contain large collections of HBM and only a small fraction of them is used to provide HBM for research (e.g., if 1 or 2 % of HBM stored in archive is used for research), it could be debatable by biobanks and/or researchers whether it is feasible and proportional to impose such a burden of the collection of the consents on the pathology centre.

Concluding Remarks

In conclusion, our analysis reflects the heterogeneity of biobank consent document policies applied in different European countries. It shows some trends how ethically relevant issues characterizing biobanks are described in consent documents from different types of selected European biobanks and their different level of compliance with the donor’s autonomy centered approach. We acknowledge that our analysis does not imply the bottom line of how biobanking system should be organized in any given country which is establishing biobanks or updating biobanking regulations, as this will also depend on differing social and cultural environments amongst the countries. However in our analysis we raised some specific questions and suggested some examples of good practices to balance the interests of the donors with those of the researchers and future patients: in particular we have emphasized the diversification of consent models for HBM and personal medical data in the case of Brussels, the specificity of defining the scope of future research in Milano, flexible solutions of consent withdrawal from biobanking in the case of UK biobank, as well as flexible solutions of management of feedback to the participants in case of the combination of both Estonia and Latvia; explicit mentioning of the REC’s function to assess every research project in case of most biobanks we analysed, as well as clarification of accessing medical data in the case of Graz. We believe that these good practice examples help to maintain the respect for personal autonomy as a guiding principle when potential biobank participants are informed about the most important thematic issues related to participation in biobanking activities as well as to satisfy the expectation of scientists, biobanks and future patients, since all these examples come from the existing biobanking practise.

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