# A serviceable Research Biobank model: Charter of Principles and Biobank Ethics Consultation Service (BECS) as a formal toolkit to promote an expert ethical guidance to biobank research

**Elena Ferioli**

*Center for Clinical Ethics (CREC), Department of Biotechnology and Life Science, University of Insubria, Varese, Italy.*

Corrispondenza: Elena Ferioli, Center for Clinical Ethics, Department of Biotechnology and Life Sciences, University of Insubria, Via O. Rossi 9, Varese, Italy; e-mail: elena.ferioli@uninsubria.it.

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*ABSTRACT*

*The complexity of biobank research has recently increased generating a number of novel ethical issues. In recent years the University of Insubria is committed to provide specific training programs in Bioethics, Applied Ethics and Clinical Ethics aimed to face to critical topics related to medicine, research and biobanking. Actually we design the Insubria Biobank as a research infrastructure with an appropriate Ethical Framework and responsible for the custody of biospecimens and data according to a model of Charitable Trust. So to answer certain questions is crucial: How could biobank respect the trust placed in it? What resources could promote the goals of the biobank? Do professionals require a specific ethical training?*
*This credit of trust must be fed and confirmed by the ethical choices of the biobank and ensuring maximum transparency and traceability of decisions. The aim of the Insubria Biobank is to become an ethical subject to secure the public trust and to define the ethics criteria to be made public and to which the biobank will comply. In our model we propose the prospective involved parties that could guarantee the achievement of this goal: Informed Consent, Charter of Principles and Biobank Ethics Consultation Services (BECS).*
*Our purpose is to offer a Charter of Principles and BECS to help scientists, health care professionals, patients, donors, institutional review board and policymakers, better navigate the ethical issues in biobanking. An exploratory survey to identify the willingness to use BECS represent our future research plan.*

*RIASSUNTO*

Un utile modello di biobanca di ricerca: Carta dei principi e Servizio di Consulenza Etica per le Biobanche (BECS) come kit formale di strumenti per promuovere una guida etica esperta alla ricerca sulle biobanche.

*La crescente complessità delle biobanche di ricerca ha recentemente generato la necessità di affrontare le nuove implicazioni etiche e sociali sottese. Negli ultimi anni l'Università degli Studi dell'Insubria si è vista impegnata nella erogazione di programmi di formazione nell'ambito della Bioetica, Etica applicata ed Etica Clinica al fine di affrontare argomenti critici nell'ambito della medicina, della ricerca e delle biobanche. Attualmente si vuole istituire una biobanca di ricerca come una infrastruttura caratterizzata da una appropriata cornice etica e quindi responsabile della custodia dei campioni biologici e dei dati correlati in accordo con un modello di fiducia caritatevole. Quindi diventa cruciale rispondere ad alcune inevitabili domande: come la biobanca può rispettare la fiducia in essa riposta? Quali risorse possono promuovere questa finalità? I professionisti che lavorano nell'ambito delle biobanche di ricerca necessitano di una formazione specifica?*
*Questo credito di fiducia deve essere alimentato e confermato dalle scelte etiche della biobanca, assicurando la*

*massima trasparenza e tracciabilità delle decisioni. Lo scopo della biobanca è divenire un soggetto etico che assicuri la fiducia pubblica e che definisca i criteri etici a cui si ispira rendendoli pubblici. Nel nostro modello proponiamo le potenziali parti coinvolte che siano in grado di garantire il raggiungimernto di questo scopo: il consenso informato, un codice etico della biobanca e un servizio di consulenza etica specifico per le biobanche di ricerca (BECS). Il nostro scopo è quindi offrire una Carta dei Principi e un servizio BECS per aiutare scienziati, ricercatori, operatori sanitari, pazienti, donatori, politici, comitati etici a riconoscere e gestire le implicazioni etiche delle biobanche di ricerca. Un questionario di esplorazione finalizzato ad identificare la propensione ad utilizzare un servizio BECS rappresenta una nostra futura e successiva ricerca.*

*Keywords*: biobank, trust, Charter of principles, ethics consultation.

*Parole-chiave*: biobanca, fiducia, Carta dei principi, consulenza etica.

## 1. Current and future power of Research Biobanks

Biobanks play a crucial role in biomedical research and their constitution derived from a number of situations that have occurred in recent decades and that regard them as one of the most innovative and up-to-date in the field of biomedical research [1; 2].

Biobanks are large-scale repositories of biological samples and associated data and this unique combination of dissimilar sets makes biobanks very special regarding their position in biomedical research, in ethical requirements, multidisciplinarity and international collaboration.

For the success and development of biomedical research studies, it is currently of great importance to have large quantities of representative samples of biological tissues, tumors, cells, proteins, DNA and other vital fluids including blood, serum, urine, etc. Advances in the different techniques called 'omics' (genomics, proteomics, etc.) [3] help in obtaining a large amount of data and high samples quality preserved in excellent condition and readily available.

The importance of biospecimens in health research and the expansion of biobanks have risen steadily as research demand has increased. At the same time, there has also been a gradual appreciation of the need for not just more biospecimens but also better quality biospecimens [4; 5].

The last decade has seen tremendous improvements in the collection and storage of human samples, allowing the worldwide scientifc community to obtain very important results in the feld of medical research and to discover new frontiers within life science and patient care. Biobanks are one of the pillars in personalised medicine tackling all its aspects such as prevention, diagnosis, treatment and monitoring closely the specific characteristics of an individual patient [6].

Therefore the current power of biobanks is the amount of samples of high-quality and related information available for current and future research of diseases, for optimising patients´ prevention, diagnosis, treatment and monitoring. The material stored in biobanks is a treasure for future technologies that will be able to utilise the currently uncovered information and knowledge infact in the next decades new

research methods, approaches and technological achievements will be discovered and there will be enough material for new discoveries [7; 8]. As biobank samples are increasingly used for translational research and clinical implementation projects, questions about appropriate means to have ongoing engagement with participants, what are the best consenting methods, returning personal results and other policy issues must be addressed by each biobank.

## 2. Recent ethical issues concerning biobanks

We believe that research biobank is associated with specificities that justify a dedicated analysis of the ethical implications. The increasing number of publications reporting advances in post-genomics and biobanking has been paralleled, over the past few years, by an increasing number of studies dealing with the numerous related ethical aspects [9; 10].

The understanding of the research, as well as the awareness of the ethical implications and the public's attitude to the participation in a biobank for research purposes is a fairly unknown field and the scientific community has struggled with a number of ethical and legal conflicts related to the collection and use of biospecimens in research [11].

For some biobanks offer the possibility of unprecedented advances which will revolutionize research and improve the health of future generations; for others they are worring repositories of personal information and tissue which will be used without sufficient respect of autonomy.

The idea of a biobank to facilitate medical research would appear to be a worthwhile and commendable activity to most people. However, the establishment of such archives raise not only many of the same ethical problems that face the medical community (particularly those involved in organ donations and procurement), but also some unique questions of their own [12; 13].

Therefore it is necessary to find appropriate responses to a series of questions concerning the proper approach to ethical dilemmas that may arise from research biobanks: what resources and/or specialists are advisable to resolve ethical issues and to promote the goals of the biobank? What is the role and the sensitivity of the researcher faced with ethical dilemmas? Do professionals require a specific training? How practically can the biobank respect the truth placed in it? How can volunteers provide fully informed consent when neither they nor the biobank have any idea about the nature of future research which will be performed on the donated sample? Who actually owns the collected sample? Does a stored biosample have a commercial value and can it be sold? What happens if research discovers that a volunteer has a potentially deadly disease?

In recent years the Research Center of Clinical Ethics (CREC) of the University of Insubria is committed to provide specific training programs in Bioethics, Applied Ethics and Clinical Ethics aimed to face to critical topics related to medicine, research and biobanking [14].

On the basis of the current situation, CREC consider that it would be interesting to design an accademic "Insubria Biobank"

as an unique key research infrastructure which must respond to high quality levels, safety and skills as required by the international community in accordance with guidelines for scientific and technological infrastructure, and to set up an appropriate "Ethical Framework" identifying sufficient and well-established ethical instruments avaible for regulating biobank research [15].

Considering the complexity of ethical issues, we believe that the patient's and partecipant's trust is the main matter. The Biobank would become subject responsible for the custody and management of biological materials and the protection of data confidentiality, acting as a filter between the public and the research community. So in our biobank model the researchers would only be licensed for use and not for ownership the biological samples collected, which are an heritage of the community, according to a model of "Charitable Trust", in which the donor gives his powers devices to a trustee, which has a legal duty to use them in the public interest [16] and to make people understand the research process that is activated through that specific biobanking, as the article 29 Working Party statutes [17]. This model would allow an effective balance between freedom of scientific research, individual rights and collective needs in the name of the principle of sociality [18]. 'Trusted' implies that participants recognize the competence, expertise and moral integrity of the researchers involved and of the biobank governance [19; 20].

### 2.1 Biobank consent debate

Allocating a sample to a research biobank means giving something whose current research uses are known, but whose future research uses cannot be predicted, as these will depend on future technologies and discoveries. This implies that the biobank should avoid the risk that the only communicable information concerns the scientific knowledge available at the time the sample is taken.

Appropriate informed consent is one of the most intensely and widespread discussed topics within the context of biobank research [21-23]. Most of the research results related to biobanks are achieved with the collaboration of healthy subjects or patients who give their consent to use biological samples for research, but are these subjects informed about the study that will be conducted on their samples? are they really sure to understand the purpose of the study? Are they interested to know the modalities of their participation?

Classical informed consent that is focused on a specific research project is considered insufficient in biobanking, infact what characterizes and distinguishes the research carried out on samples and informations stored in a biobank is not only its enduring without a defined timing, but also the use of biospecimens for a range of research areas that can not be defined, if not in general, when asked to patient/participant the authorization to use them. There is an inevitably gap of information with obvious repercussions on decision-making skills, but it could not be otherwise to avoid penalizing the true meaning of the biobank.

The controversial themes that involve

biobank participants include the type of consent form, the right of withdrawal, personal benefit, returning research results, and protection of privacy [24].

Numerous studies have investigated these issues highlighting the common wish of the participants to be able to express an opinion independently only after receiving an exhaustive explanation of the research and understanding their real involvement. Another important fact emerged from these studies reveals how is particularly important for the final decision of the participants, the confidence in researchers and institutions offering the study and their credibility at the time of the request for consent [25].

Within the context of biobanking consent, it is important to define what information must be understood for a prospective participant's consent to be considered valid. Literature indicated significant uncertainty about defining a threshold of understanding and what should happen when prospective participants are unable to grasp key information. These findings have important implications for urgently needed discussion of whether consent comprehension is an ethical requirement or an ethical aspiration [26].

We argue that, in the case of research biobanks, there is a need to replace the currently used informed consent with a broad trusted consent. The model of broad informed consent seems to prevail considering a necessary balance amoung the individual autonomy, the collective interest and research requirements. Effectively confronted with the challenges facing the study-specific consent model, many biobanks have opted for a broad consent approach [27-29] through which the research subject may be asked for permission concerning three types of activity: the extraction of their biological sample and the collection of relevant associated data – including genomic, health and lifestyle data; the storage of their biological sample and any associated data for use in research; the future use of their collected biological sample and associated data for unspecified research purposes.

We defend the broad model by arguing that it is the best way to make large-scale biobank research feasible [30]. When this model is applied, general consent is gathered at the time of enrolment and subsequently, samples stored in the biobank can be reused for new studies without re-obtaining consent from participants as long as the use fulfills regulatory requirements such as approval from an ethics committee so that participants' values will not be inadvertently violated by future research. This requires the broad consent to identify the core values that will guide decision-making about future research projects as well as any potential research areas that are excluded from the scope.

We defend a value criterion for which the consent model should offer participants the opportunity to assess whether the research to be conducted with biobank materials is in line with their personal values, and to make consent decisions based on this and also we propose the duration criterion which afford ethical protection for the duration of the subject's participation in the biobank, and give the subject a real and actionable right of withdrawal [31].

The broad informed consent model for prospective samples was regarded as justi-

fied, because it was seen to merit both research and the autonomy of individuals. This followed a general European and international trend to regard broad consent as a valid and preferred model for biobanking [32].

Having been informed about the general scope of the biobank, participants are able to evaluate whether they wish to consent to the overall biobank policy and to the types of research that the biobank permits upon any samples according, for example, to its charter of principles.

We conclude that, as long as it is combined with strong institutional protections and provides long-term protection for participants, the broad consent model is best suited to meet the stated aims of informed consent in biobank research.

With the development of information technology tools, a novel consent model has been proposed termed *dynamic consent* which uses modern communication strategies to inform, involve and obtain consent for every research project based on biobank resources [33; 34]. This approach focuses on new possibilities for constant communication and has the potential to increasingly involve participants in the use of their biological samples, but it also reveals several weaknesses such as therapeutic misconception.

Dynamic consent is employed as a delivery system for study-specific consent, therefore it must initially be assumed that it will also suffer from the problems besetting study-specific consent.

Clearly this would have a substantial impact on the ability of biobanks to carry out research, and would place a particular burden on disease-specific biobanks that work with end-of-life patients or competence-limiting diseases such as dementia.

Study-specific consent probably also fails to meet the information criterion, as it is structured to focus on information about the risks of a particular study, while the relevant risks in biobanks, are a consequence of general biobank governance, policy, and competence. In addition it runs the risk of failing to protect the autonomy of the participants sufficiently, as dynamic consent is unable to ensure that potential participants make decisions about participation that are based on a high level of information and understanding without external influence or coercion. Dynamic consent intentionally differs from traditional consent by allowing participants to provide consent in uncontrolled conditions.

In recent articles some authors have developed an alternative to consent what they call a meta-consent framework on which, participants can choose the type of consent framework they require, for different kinds of use, different types of user and so on. Meta-consent involves a distinctive kind of design of the consent process and probably is not the solution to perennial debate on the ethics of biobank participation [35; 36].

Comparing dynamic, meta and broad consent, for us the latter still implies a higher order of ethical mediation among the autonomy of biobank participants, the competence, expertise and moral integrity of scientists, the biobank governance and the approval from an ethics committee.

### 2.2 The important position of the General Data Protection Regulation on biobanking

Biobanks are large-scale repositories of highly sensitive medical and biological data about individual human beings and, different from databases used in hospitals, it is the very mission of biobanks to make these data broadly available to research users, therefore the importance of data protection cannot be overstated. Enforcing rigorous and credible data protection, as well as anonymity will be vital for the future of biobanks that must strife to continuously improve technical, legal, and organizational means to protect, and safeguard, medical and biomedical data.

Principles that govern access to biospecimens and their associated data set(s) are an important component of the biobank management model, particularly if a broad use of the collection is anticipated [37]. Advancing digitalization in biobanking raises various privacy and data protection issues. First it must be ensured that the management and use of comprehensive, biosample-related data is embedded into appropriate organizational information technology infrastructures that comply with the country-specific legal and ethical frameworks [38].

A key element of appropriate data management in biobanks should be that clinical data, sample-related data, and identifying data are physically stored in separate databases under different administrative power and using different identifiers. All data set(s) should be protected by coding and accessible only by authorized persons [39].

Moreover, it is crucial to set up guidelines for the distribution and sharing of specimens and related data that comply with local, national and international laws, ethical norms and security of intellectual property rights, as well as to ensure the availability of data and materials to the wider scientific community and provide equal right of access to researchers.

According to the recent literature, we approve the concept of solidarity which consider all samples and information at full disposal of the entire community and which indicates the biobank as the key infrastructure building on relationship of trust in research . Those concerns lead to a great emphasis on biobanking principles of transparency, trust and partnership [40].

The General Data Protection Regulation (GDPR) 2016/679 of the European Parliament and of the Council seeks to ensure the free movement of data throughout the European Union (EU) and give expression to the right to personal data protection within and beyond the EU [41]. It details, the lawful basis of the processing of data (Article 6) and delineates prohibitions for processing special categories of data, such as health and genetic data (Article 9), sets out the conditions for consent (Article 7), outlines the individual rights of data subjects (Articles 13-22), and provides data subjects with a mechanism to enforce their rights (Articles 77-84).

The recent introduction of the GDPR has been an area of significant concern for personal data engaged in biobanking research. The aspiration of providing for a high level of protection to individuals' personal data risked placing considerable constraints on scientific research [42; 43].

The GDPR provides data subjects with a number of rights which are of key importance: right to information (in particular, Art. 12-14), access rights (Art. 15), right to rectification (Art. 16), right to erasure (Art. 17), right to restriction of processing (Art. 18), right to data portability (Art. 20), right to object (Art. 21).

A distinction can be drawn between primary and secondary biomedical research based on data and samples. While lawful basis of primary research could be consent based, which might not necessarily be so for secondary use of personal data or research using residual biological material. In the latter cases, the claim of legitimate interest is of particular importance [44]. When data are not processed based on the individual's consent, the requirements set in Article 6(4)[1] shall be met, which includes the existence of appropriate safeguards.

In addition EU or Member State law may provide for exceptions and national derogations to a law that otherwise is committed to paying great attention to human rights and as specified in article 89(2)[2] GDPR, the derogations can be applied if they are necessary for research purposes [45].

Article 9(1)[3] prohibits the processing of special information that includes genetic information, but Article 9(2)(j) allows for processing the genetic data as part of a special category of data if 'processing is necessary for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes'. When applying Article 9(2)(j), this processing must be in accordance with Article 89(1) based on Union or Member State law, which shall be proportionate to the aim pursued, respect the essence of the right to data protection and provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject. In other words a Member State may attribute particular value to biobank research limiting data subjects right to control the use of their data in research by removing

1 Where the processing for a purpose other than that for which the personal data have been collected is not based on the data subject's consent or on a Union or Member State law which constitutes a necessary and proportionate measure in a democratic society to safeguard the objectives referred to in Article 23(1), the controller shall, in order to ascertain whether processing for another purpose is compatible with the purpose for which the personal data are initially collected, take into account, inter alia: (a) any link between the purposes for which the personal data have been collected and the purposes of the intended further processing; (b) the context in which the personal data have been collected, in particular regarding the relationship between data subjects and the controller; (c) the nature of the personal data, in particular whether special categories of personal data are processed, pursuant to Article 9, or whether personal data related to criminal convictions and offences are processed, pursuant to Article 10; (d) the possible consequences of the intended further processing for data subjects; (e) the existence of appropriate safeguards, which may include encryption or pseudonymisation.

2 Where personal data are processed for scientific or historical research purposes or statistical purposes, Union or Member State law may provide for derogations from the rights referred to in Articles 15, 16, 18 and 21 subject to the conditions and safeguards referred to in paragraph 1 of this Article in so far as such rights are likely to render impossible or seriously impair the achievement of the specific purposes, and such derogations are necessary for the fulfilment of those purposes.

3 Processing of personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, and the processing of genetic data, biometric data for the purpose of uniquely identifying a natural person, data concerning health or data concerning a natural person's sex life or sexual orientation shall be prohibited.

the consent requirement according to a principle of proportionality. Consequently the GDPR creates new exemptions for research and leaves member states to specify their own rules [46] reviewing national regulations governing data protection in research areas in which flexibility is permitted.

On the other hand a full implementation of the derogations may render the research unethical and not in line with individuals interests. For our biobank model an ethics committee may be faced with a situation whereby a study under review meets the requirements and derogations under the GDPR, but have ethical concerns about the research. Ethics committees are not necessarily under the obligation to approve research that meets this legal threshold, but fails to meet ethical criteria.

A coherent and robust governance structure, based on commonly adopted strategies (communication, compliance, expert advice, external review, internal procedures, and partnership) [47], is key in fostering trust and trustworthiness that is so important in biobanking and including policies on access, information, use and reuse of data, transfer to third parties, feedback of findings, storage of data, withdrawal of consent, re-contact of data subjects, access requests from third parties, access requests of data subjects, intellectual property and commercial use. These policies must be made publically available and submitted to a local ethics committee as part of the research protocol.

Finally is also important that prior to commencing a processing operation, a biobank researcher should assess the following starting points: what kind of information is being processed (sensitive or general)? What is your purpose ? Do you have a choice over whether or not to process the data? Who does the processing benefit? What kind of impact could processing have on the data subject? Are they vulnerable? Would individuals expect this processing to take place? Are you able to stop the processing at any time on request? It is not an exaggeration to state that the arrival of the GDPR has been accompanied by uncertainty and unease in the biobanking research community [48; 49]. However the final text of the GDPR includes provisions which seem to offer clear support for our biobank model and its ethical framework [50].

## 3. Expressing ethical principles of biobank in a Charter

Biobank governance is broadly defined as the organization spectrum under which a large set of interacting components meet, including decision-makers, institutions and policies, procedures and practicioners. The advantages of a successful biobank governance system is uniformity and quality assurance, efficiency of predefined rules, practice of research according to ethics and laws and transparency in decision making [51], and the successful management ensures longterm establishment of public trust.

In our opinion one method to develop trust is to implement fair and transparent practices that are based on ethical, rather than strictly legal, principles to govern the collection and use of biospecimens in research and confirmed by the ethical choices of the biobank.

The aim of biobank is to become an ethical subject to secure this public trust and to define the ethics criteria to be made public and to which the biobank will comply. In our model we porpose to define not only guidelines but also a charter that explain the principles of conduct and the purpose of the Biobank and then to translate the complexity of biobanking into locally relevant evidence-based messages and materials to support increased knowledge and understanding in the local community [52].

### 3.1 From communication of facts to communication of values

Over the past few decades, outstanding progress in the field of biomedicine has increased awareness of ethical issues and scientific research has rooted in the quest for truths and knowledge that serve humanity and fits into a vision of a progressive and caring society. Actually electronic databases and internet searching helps us to identify articles, reviews, editorials, books or any related content in academic journals that refer to research ethics, a charter for ethics in biomedical research and research integrity. The analysis included international [53], national and ethical charters drafted by learned societies which stimulate researchers and institutions to think about their responsibility for research [54; 55].

A Charter of Principles could constitute an enabling tool to improve the ethical governance of the biobank and could outline the mission and values of the biobank, how professionals are supposed to approach problems, the ethical principles based on the biobank's core values, and the standards to which the professional is held. It must be written in simplified language to make it accessible and usable by scientists and other stakeholders, and must provide a consistent set of principles that will improve interoperability nationally and internationally.

This charter could create messages and materials to generate opportunities for meaningful conversations between community members, patients, providers, and researchers about the complex scientific and ethical information about biobanking, leading to improved understanding of and possible enrollment in biobank.

The general principles of autonomy, beneficence/non-maleficence and justice, frequently appear in the literature on ethics of biobanking [56] and constitute core values, but in our opinion also the following principles could constitute the common premise for the charter: respect for privacy (custodianship), reciprocity (feedback of results should be channelled to institutions and patients), freedom of scientific enquiry (custodianship should encourage openness of scientific enquiry and should maximize data and biospecimen use and sharing so as to exploit their full potential to promote health), respect for intellectual property, promotion of the common good and responsibility (optimize the benefits of collaborative research for the benefit of all).

The charter should describes also the principles that can be translated into actions during the different steps in the research process, from the initial working hypothesis to publication and dissemination of the results and consideration of opportunities for further research: integrity, honesty, impartiality, transparency, compe-

tence, accuracy, rigorousness, precision and verifiability, caution, carefulness, respect, confidentiality, reliability, creativity, open-mindedness and altruism.

Finally it is also important to evaluate if biobanking may include research procedures that violate the religious values and preferences of some patients [57] and to encourage biobank to explore new forms of communication, including internet and web-based technologies, as a means to better, and more directly, engage with the public and stimulating its participation as a potentially very powerful means of building trust.

### 3.2 The moral concerns of participants: knowledge, attitude and opinions

The long-term storage of ever increasing amounts of human biological materials and biomedical data for research purposes in the form of broadly accessible biobanks is a reality in present day biomedical research and create a growing interest on the part of many governments in the creation of biobanks [58]. Nevertheless, this would be impossible without participation of many donors who offer samples of their biological material for scientific research. Biobanks are not only an issue of biomedical research, but are becoming a public issue involving citizens and patients, to actively participate in biobanking with respect to ethical, legal and social issues [59; 60].

As each biobank exists in a unique geographical, social, and historical context, donation is a complex process determined by people's knowledge about biobanking, public views on biobanking, willingness to donate, donors' motivations, perceived benefits and risks of biobanking, preferred type of consent, trust toward biobanks [61].

Although biobanks exist in many countries, an eurobarometer study on biotechnology has demonstrated that two-thirds of europeans have never heard about biobanks and less than 2% search for information about biobanking [62]. Despite the deficits in knowledge, most research showed that public opinion on biobanking is generally positive and supports the idea of creating local biobanks.

Better knowledge, trust toward biobanks, preference for broad consent, and decreases perception of the risks related to the privacy and confidentiality of samples correlates positively with the willingness to participate. Respondents' willingness to donate particularly depend on access to the information about the research, as many participants wanted to know who was conducting the research and where the research was being conducted, what was its purpose, who would have access to research results, and where and how the samples would be stored. Public's attitudes on participation in a biobank may be further encouraged by the anonymization of samples and the possibility to withdraw from the research and by the positive recommendation of an ethical committee, religious assent, and the conviction about the simplicity and safety of procurement of tissues.

In contrast, participants may be discouraged by inadequate knowledge on biobanking, disapproval of the research, concerns over the safety of the data, fear over the invasive nature of the sampling procedure, detection of genetic predispositions, and

use of the sample in line with donors' values. Many respondents were afraid of stigmatization and discrimination, and commercial use of their samples and finally geographical distance from the biobank also discouraged some donors [63].

Other donors are also driven by altruistic motives, feeling of duty, desire to contribute to the common good and helping others and future generations through the creation of new knowledge and the development of new therapies. Others expected benefits to their families, relatives or ethnic groups [64].

Data derived from public interviews underline original interpretations of biosamples as gifts [65]. For most people biobanking seemed simple to do (*unreserved gift*) and sample may be very easy to give; many said they had not considered their donation as a gift until explicitly questioned about it, a gift not routinely thought of as such, but for a few this resonated. This view seemed more common amongst people with a specific health condition, perhaps reflecting a shared sense of identity with others who experience the same illness and future beneficiaries of the research. For some people, the notion of a direct relationship with past or future beneficiaries of health care and medical research was explicit, not just in terms of an illness community but also sometimes one's own family (*reciprocal gift*). The notion of a *collective gift,* where one's own contribution has little intrinsic value until combined with others is also widespread.

Some people also considered it at best a low value or *unwanted gift* and others consider that the use of the word 'gift' was overstating the value of biosamples, an exaggeration. This view was particularly associated with tumour and urine samples, although for some people it applied equally to blood, even if others saw blood as something different and this may partly reflect the more invasive nature of donating blood samples, compared to something which is excreted or is being removed anyway.

Some participants who focused on the nature of a donation as a gift believe that, once a consent is signed and a donation is made, donors no longer have the right to say how their sample is used. Some went further, noting that once the donation is given the donor is no longer responsible for how it is used by others. Those who trusted researchers thought biobanks should be free to use donations with few restrictions while participants who were skeptical wanted to see donors have more control over their donations.

Some participants insisted that biospecimens remain a part of the donor who is culpable for the way they are used, while others felt that once given, a gift is no longer one's property and thus the biobank is responsible for any and all uses of the donation. We found differences in attitudes about the ethics of gift giving and the moral responsibility for uses of the donated biospecimens. What we learn from these conversations is that members of the public are not ethical rubes: biobanks can and should make their case for donation using ethical arguments that address the values of potential donors and prevent unethical research practices. Biobanks need to assure potential donors that research done with their biospecimens will not be "like Dr. Frankenstein's lab" and will not ignore the moral values of donors.

Currently, biobanks do not typically compensate donors for their contributions [66]. The majority of donors were motivated by altruism and viewed their donation as a gift, payment might be counterproductive as well as unwanted, since it signals that the donation is a transaction, not a gift. This distinction resonates with our findings and helps explain why 'gift' can seem a troubling or inappropriate word for biosamples. The gift – the value – is in the giving, in the collective contribution to research, rather than in the sample itself. Focusing on the value of participation and the information derived rather than the value of the physical sample might have more intuitive appeal to potential participants. Governing bodies should exercise caution when setting discourses around donation, whilst recognizing that the public holds positive attitudes towards helping others and donating biosamples.

## 4. The establishment of Biobanks Ethics Consultation Service (BECS)

The complexity of biomedical research has generated a number of novel ethical issues for clinical investigators, institutional review boards (IRBs), and other oversight committees. In response, many academic medical centers have created formal research ethics consultation (REC) services to help investigators and IRBs navigate ethical issues in biomedical research. Research ethics consultation programs are being established with a goal of addressing the ethical, societal, and policy considerations associated with biomedical research and a number of these programs are modelled on institutionalized clinical ethics consultation services [67-69].

The REC could therefore need a more specific progress direct to biomedical research increasingly carried out in biobanking. Emphasis on biobank translational research to facilitate progression from the laboratory into the community also creates a dynamic in which ethics and social policy questions and solutions are ever pressing. Accordingly, we sought to gain an updated perspective on the current role and current practices of ethics consultations in research settings.

For this reason we intend to create an institutional Biobank Ethics Consultation Services (BECS) to help scientists, health care professionals, patients, donors, institutional review board and policymakers, navigate the specific ethical issues in biobanking management and research, such as: respect for privacy and autonomy, reciprocity, freedom of scientific enquiry, respect for intellectual property, promotion of the common good and responsibility [70].

Consequently BECS could assist investigators before and after the regulatory review; investigators, IRBs, and other research administrators facing challenging and novel ethical issues; IRBs and investigators with the increasing challenges particularly related to informed consent and secondary uses of biospecimens and data.

It is important that our BECS should work to raise the visibility of its service and engage in open communication with existing clinical ethics consultation services as well as the IRB.

The major ethical and professional practice challenges associated with the pro-

vision of BECS include: i) managing multiple institutional roles and responsabilities, ii) supplementing regulatory oversight, iii) managing sensitive information, and iv) communicating with consultation requestors about how these issues are managed and providing a forum for deliberative exploration of ethical issues, iv) training researchers in the field of bioethics [71-73].

Our project is also going to present several practical strategies for addressing these challenges and enhancing the quality of BECS services. The consultant's special clinical skills include the ability to identify and analyze ethical problems; use reasonable clinical judgment; communicate effectively; negotiate and facilitate negotiations; and teach others how to construct their own ethical frameworks for a relevant research decision making. Hopefully BECS should be integrated into a bioethics service, with a single ethical consultant or a small team, and should be a useful tool for enhancing the quality and legitimacy of biobank research, emphasizing the researcher's individual responsibility, promoting personal consideration and collective debate on research ethics, facilitating interactions between research groups and biobank institutions and finally encouraging the proper supervision of young researchers, fostering their awareness of ethics and introducing them to biobank research ethics [74].

Such services can increase sensitivity among researchers to the ethical implications of biobanking, result in better institutional research policies, and facilitate the development of an organizational culture that is receptive to the identification of specific ethical issues for biobanking reserach.

An exploratory survey to identify the willingness to use BECS represent our future research plan. It is desiderable that the creation of BECS takes into consideration the possible indications given by the potential stakeholders, in addition to the experiences coming from others countries [75].

## 5. Training the next generation of biobankers

The growing complexity of biobanking requires dedicated professional staff who are trained in multiple aspects of the biobanking process, including technical, managerial, regulatory, and ethical aspects, and who have a good understanding of the challenges of biospecimen research, but also of the challenges related to the sustainability of future biobanks.

These factors made the idea of a "biobanker" career acceptable to the community but finding a collaborator capable of conducting all these activities may be like looking for a needle in a haystack. Consequently with the development and professionalization of biobanks, the training of biobank personnel has become critical and up to the present, biobanking staff need to be trained in an *ad-hoc* manner, usually through specific international or national programs and courses [76; 77].

The objective of some training program is to specifically train students as professional biobankers, thus supporting the emergence of a new curriculum and job definition for individuals who will devote their careers to biobanking and the management of biospecimen resources.

The recent multidisciplinary teaching program developed combines understan-

ding of biospecimen sciences, methodological knowledge (epidemiology, statistics, clinical research, and health economy), familiarity with legal, regulatory, and ethical issues and development of personal capacity in management of teams, projects, budgets, and organizations. [78; 79].

It will be essential that such training programs become an integral part of international recommendations and standards for biobanks [80].

Biobanking is becoming more and more professional, which is why we have a specific need for further education and training. In the near future, the management and organization of biobanks will evolve to adopt organizational domains similar to those of "big data" systems, emphasizing the interoperability between specimen and data science [81]. This will require the introduction of more sophisticated education programs in data sciences, as well as the development of education in ethical and regulatory issues. Infact BBMRI-ERIC, the research infrastructure for biobanks and biomolecular resources, systematically scans the horizon for upcoming debates and questions surrounding ethical, legal, and societal aspects of biobanking, and provides professional support to biobanks through the ELSI Services and Research Unit [82].

We believe that the next step will be to develop and offer training programs to create professionals to be included in BECS through university level courses which typically involve multiyear, multiweek, or single-/multiday commitments. Credentialing of biobank staff will become important as biobanking becomes professionalized and the presence of a biobank ethicist will be essential to support such credentialing and to offer practical, tangible and hands-on ethical and legal guidance.

We also believe that the credibility and effectiveness of biobank ethicists depend upon their knowledge of ethics, their practical experience, and personal abilities, not one form of abstract knowledge. Competence, quality and functional effectiveness are the foundamental areas needed for serving on BECS.

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