

Biobank External Ethics Committees (BEEC) in Spain. Nature, functions and operating procedures

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BIOBANK EXTERNAL ETHICS COMMITTEES (BEEC) IN SPAIN. NATURE, FUNCTIONS AND OPERATING PROCEDURES

ABSTRACT: Law 14/2007, of July 3, on Biomedical Research established the legal regimen for the use of human biological samples for biomedical research purposes. This regimen was subsequently implemented by Royal Decree 1716/2011, of November 18, which establishes the basic requirements of authorisation and operation of biobanks with biomedical research goals and the treatment of biological samples of human origin and regulates the operation and organisation of the National Biobank Registry for biomedical research.

According with this legal regime, consent for donation samples to biobanks can be given in very broad terms as these institutions guarantee the respect to the donors rights through the implementation of particular policies.

Biobanks must have two external committees: the Scientific External Committee and the Ethical External Committee (BEEC). The BEEC verifies compliance with the applicable ethical and legal requirements regarding research projects, for which the samples are aimed, the procurement of the donors' informed consent, the sample storage conditions and the guarantee of confidentiality of the obtained information.

The BEEC must advise the Biobank's Scientific Manager on the appropriateness of the management procedures for samples and associated data and on other ethical and legal aspects of the biobank's good practices document. Moreover, the committees must confirm whether the donors' rights regarding the information obtained, used or stored during the research are respected: the right to; know the overall results of the research, access to personal information and the right to the information that is relevant to the donor's health that could arise during the research.

KEYWORDS: Research ethics committees; biobanks; biomedical research; biological sample; informed consent

SUMMARY: 1. Introduction. 2. The functions of the Biobank External Ethics Committees (BEEC). 2.1. Assessing the requests for the transfer of samples and data associated. 2.2. Advising the Biobank's Scientific Manager about

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Reviews

the biobank good practices document. 2.2.1 Draft and/or approve the information and consent forms models. 2.2.2 Assess requests for the incorporation of samples into the biobank. 2.2.3. Ensure donors' rights on the resulting research data. 2.2.4. Advise on the quality policy of the biobanks from an ethical perspective. 2.3. Ensure that information about the use of samples is given to donors. 2.4. Assist the Biobank's Scientific Manager on other issues submitted for consideration. 3. Conclusions.

1. Introduction

Law 14/2007, of July 3, on Biomedical Research established the legal regimen for the use of human biological samples for biomedical research purposes in Spain. This regimen was subsequently implemented by Royal Decree 1716/2011, of November 18, which establishes the basic requirements for the authorisation and operation of biobanks with biomedical research goals and the treatment of biological samples of human origin, and regulates the operation and organization of the National Biobank Registry for biomedical research.

Royal Decree 1716/2011 differentiates three options for managing samples, which, with different requirements, reconciles the respect for donors' rights, the researcher's ones and those of society in general. It is within this framework that the donation for research projects, collections and/or biobanks fits.

The regulation defines a biobank as a public or private, non-profit institution that houses one or several collections of biological samples of human origin with biomedical research goals, organised as a technical unit with quality, order and destination criteria. These institutions are conceived as tools that facilitate the availability of samples for research based on broad consent and on enhanced guarantees for the management of the samples. Therefore, given the biobanks' vocation of public service, the donors' consent is granted in broader terms than for specific projects or for collections limited to a research line. The samples are made available to all investigators who justify the importance of their research, whose project is approved by a research ethics committee and who ensure the legitimate use of the samples. These transfers from the biobank do not require the specific consent of the donor, who was informed of this management system.

This way, the terms of broad consent in Spain are consistent with the recent European texts dealing with data protection in general and sample donation for research in particular¹.

¹ Article 9 of Regulation 2016/679 of 27 April 2016, General Data Protection Regulation (GDPR), establishes that 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. This shall not apply if, among other reasons, the data subject has given explicit consent to the processing of those personal data for one or more specified purposes, or when processing is necessary for scientific purposes 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. Recital 33 of the GDPR establishes that data subjects should be allowed to give their consent to certain areas of scientific research when in keeping with recognised ethical standards for scientific research. Data subjects should have the opportunity to give their consent only to certain areas of research or parts of research projects to the extent allowed by the intended purpose.

The flexibility in the transfer and use of samples in the biobank model, results in a complex structure that operates as a guarantee of the donors' rights and their sustainability. The biobank must be authorised by the corresponding administrative authority and will be registered in a public registry. The biobank will have a holder (responsible for its operation), a scientific BSM, a head of data storage (who will address the requests for the exercise of the rights of access to personal data, rectification, cancellation or opposition made by patients) and two external committees: the BSEC and the BEEC. These committees will consist of at least 4 members with sufficient expertise in matters related to the functions performed and will have internal operating procedures, which will establish the appropriate mechanisms that ensure the independence and absence of conflicts of interests in the decision-making process.

Article 15.3 of Royal Decree 1716/2011 covers the functions of the BEEC, which in most cases have been assumed by an already established research ethics committee (REC). The REC have applied their procedures to operate to these effects, although they have adapted some aspects to conduct these new tasks.

There is no binding international standard regarding the obligation to have an ethics committee in the structure of the biobanks, with competencies in its management. However, several international institutions have directly or indirectly recommended the implementation of one².

The aim of this paper is to analyse the significance and scope of the functions attributed to the BEEC in order to clarify the issues that might arise in its interpretation and to clarify the operational guidelines.

2. The functions of the Biobank External Ethics Committee (BEEC)

Following the provisions of article, 15.3 of Royal Decree 1716/2011 mentioned above, the functions that Royal Decree 1716/2011 attributes to BEEC are analysed below.

2.1. Assessing the requests for the transfer of samples and data associated

As established by Art. 34 of Royal Decree 1716/2011, the transfer of samples from a biobank requires an application by the principal investigator of the research, which must describe the project to be

GDPR describes in article 15 the Right of access by the data subject. This article establishes that the data subject shall have the right to obtain from the controller confirmation as to whether or not personal data concerning him or her is being processed.

Chapter IV of the Recommendation CM/Rec(2016)6 of the Committee of Ministers of the Council of Europe, on research on biological materials of human origin, foresees the need to implement governance systems of collections when samples are intended to be used for future research, and not just to be used in a particular and already known project.

² See Governance principles set in article 16 of the Recommendation CM/Rec(2016)6 of the Committee of Ministers to member States on research on biological materials of human origin. See also Best practice 1.2 of the OECD Guidelines on Human Biobanks and Genetic Research Databases, 2014: "The establishment, governance, management, operation, access to, and use of the HBGRD and its protocols and processes for research activities, should be approved or reviewed, as applicable, by an independent research ethics committee".

developed, includes the favourable opinion of the REC regarding the project and the explicit commitment not to use the requested material for some other purpose.

The application must be examined by the Biobank's External Committees that will issue the corresponding reports. These reports are required for the approval or refusal of the request and are binding if the opinion is negative (Art. 15.2a and 15.3a of Royal Decree 1716/2011).

The BSM is responsible for the decision regarding the transfer, who will have to justify ruling against it (Art. 13i of Royal Decree 1716/2011). The transfer agreement is formalised in a document signed by both the principal investigator and the biobank.

To conduct its evaluation, the BEEC will verify compliance with the following ethical and legal demands:

A. The BEEC must check that a procedure has been followed to check that the consent fits the transfer provisions (it should be underlined that consent has been given in broad terms, but including options for restrictions). This procedure could involve the effective revision by BEEC or by another authority or staff of the biobank; the creation of registries including consent restriction or classifications of samples by research lines; or could involve other mechanisms that allow this verification.

B. Samples will only be transferred for requests from scientifically approved research projects. The BEEC should not reassess the project as it has already been approved by the REC of the centre where the study will be conducted. However, the BEEC should assess the ethical and legal requirements to give its approval to the transfer of samples and their use in the specific project approved by the REC. To this end, the protocol should be one of the documents provided to BEEC who will assess the transfer.

C. Verification will be conducted to ensure there is no discrepancy between the project objectives and the number of samples requested. As stated above, the biobank must establish mechanisms that help verify the lack of discrepancies, and one mechanism could be a review by BEEC, in all or in particular cases.

D. Respect for the right to data protection will be ensured. The samples and associated data should only be transferred after anonymization or dissociation. The request application should indicate the specific measures that will be applied to ensure the confidentiality and security in the data management.

E. The individuals' rights concerning their data shall be ensured: data access, return (or not) of results and, if necessary, the availability of genetic counselling. This assurance will be verified by confirming that the investigator knows and assumes the obligations laid out in the biobank policies in this regard (see epigraph 2.2.3), and that this is reflected in the sample material transfer agreement (MTA).

F. The same evaluation must be done if the application comes from other country. It should be mentioned that the need of the revision of the project will be satisfied when it is carried out by a foreign accredited ethics committee³.

Table 1 lists the documentation that the BEEC can manage in order to conduct the evaluation of the transfers and the aspects that can be reviewed based on each document. Each BEEC, along with the

³ I. ALFONSO, P. NICOLÁS, E. FERNÁNDEZ DE UZQUIANO, *Ethical and legal aspects related to the management of human biological samples in clinical trials. Proposal of evaluation criteria for clinical research ethics committees*, in *Rev Esp Med Legal*, 42(3), 2016, 105-119.

BSM, must decide through which particular medium, procedure or document they will review the aspects that must be assessed (whether all those that appear in the left column are necessary or not) and to what points their examination must refer.

Table 1. Documentation that a BEEC could manage in order to assess the transfers

Document	Review
Request from the principal investigator of the study research	The request is justified by the project's needs/objectives. The purpose is consistent with the terms under which the consent was granted.
Project protocol	The request is justified by the project's needs/objectives. The purpose is consistent with the terms under which the consent was granted. There is no discrepancy between the project objectives and the quantity of sample requested.
REC's approval for the research project	The opinion refers to the same project (and version) for which the samples are requested.
Technical and availability report of the biobank samples signed by the Scientific Director of the biobank.	The samples are available for this transfer. The purpose is consistent with the terms under which the consent was granted.
Favourable opinion of the BESC	The BESC has positively evaluated the transfer.
MTA Model (not necessary if already examined on other occasions)	There is a commitment not to use the samples for other purposes. There is a commitment regarding the destination of the remaining samples. There are commitments regarding data protection and confidentiality.

2.2. Advising the Biobank's Scientific Manager about the biobank good practices document

The Code of Good Practices, as defined in the document prepared by the Working Group of the Good Practice Guide of the National Biobank Network⁴, is an agreement guide of procedures which aims to provide guidelines for proper functioning of human biobanks for research.

The BEEC must know both the good practice document of the biobank and the standard operating procedures which define the existence of quality controls in the storage and transfer of samples or the application of the corresponding security measures in the data archives.

⁴ Code of good practices. Working group of good practice guide 2012. Spanish national biobank network.

The law does not establish when this advice should be carried out. What is reasonable, and in fact is the most common practice, is that either it can be given after a request of the biobank institutions, or as an initiative of the BEEC itself.

Advice the BSM, in relation to the content of the good practice document and standard operating procedures, can be described, among others, in the following functions.

2.2.1. Draft and/or approve the information and consent forms models

Although RD 1716/2011 does not require the BEEC to draft and/or approve the of information and consent forms models, the fact is that this is a fundamental aspect in the management of samples⁵. Therefore, the advisory function in this area must necessarily include that task. The BEEC must ensure compliance with legal provisions regarding the aspects to be included in the information sheets, but also the addition of other specific information about the biobank or the future research (e.g. that the biobank is limited to a particular research area, or if it is foreseeable a whole genome sequencing).

2.2.2. Assess requests for the incorporation of samples into the biobank

Biobanks may collect samples that had been obtained during standard diagnostic, therapeutic or screening procedures; that had been obtained for a research project; that are direct donations to the biobank; samples of deceased persons; or samples from other biobanks or collections.

In the ethical evaluation of incorporation of samples into biobanks, the following aspects must be taken into account:

- It will be necessary to check the conditions under which the samples were donated, through the evaluation of the corresponding model of informed consent, to verify that they correspond to the destination that is to be given.
- The conditions of the transfer are described in the corresponding MTA.
- In the case of obtaining and using biological samples of deceased persons, BEEC must verify that the subjects agreed in life or did not expressly record their opposition; to this end, the existence of said instructions must be verified and, in their absence, his closest relatives and professionals who assisted him at the health center should be consulted. All consultations should be recorded. A prior documented agreement between the biobank and the establishment of origin of the samples must exist, as established in Art. 33 of RD 1716.
- One of the most challenging issue is the stored samples that have been obtained for healthcare purposes, without the source subject having consented to its use for biomedical research purposes⁶. The actions to follow will depend on the moment at which the samples were obtained. To this end,

⁵ I. ALFONSO FARNÓS, A. HERNÁNDEZ GIL, M. RODRÍGUEZ VELASCO, *Update the Research Ethics Committees work in the evaluation of genetic research and as Biobank external ethics Committees*, in *Revista de Derecho y Genoma Humano*, 39, 2013, 173-203.

⁶ M.C. MARTÍN-ARRIBAS, E. FERNÁNDEZ-DE UZQUIANO, L. DE SOLA PEREA, J. ARIAS-DÍAZ, *Storage of human samples for research: Autonomy and genomic data*, in *Medicina clínica (Barc)*, 144(10), 2015, 465-469.

the fulfillment of the requirements of the exceptional regime (Art.58) or the transitional provision of the BRL should be reviewed⁷.

- Although legislation includes as an option the use of identified samples, as a general rule, samples should be coded, unidentified, as is set out in the UNESCO's International Declaration on Human Genetic Data⁸.
- It must be noted that the aforementioned points shall be applicable when the samples are collected in another country. Moreover, according to article 31 of the RD1716/2011, biological samples from other countries may only be used for biomedical research if the guarantees provided in the Spanish regulations have been observed for the collection, donation and storage. It should be understood that this requirement refers to the supervision of the procedure in the country of origin by an accredited ethics committee, whose report should be valid in Spain. Rules about import/export of human materials will also be taken into account.

2.2.3. Ensure donors' rights on the resulting research data

The law recognizes three nearby but differentiated rights over the data collected, used or kept in the context of scientific research: the right to know the overall results of the research, the right to access to personal data and the right to know the relevant information concerning health. The subject must be informed about these rights, although in the last two cases if the samples are anonymized the object of the rights does not exist anymore⁹. In the following lines it will be described the content of each of these three rights and the role of the BEEC in the process of their exercise.

The first of these rights is developed exclusively in the area of scientific research and its object is the general outcome of a research project (so no data concerning the donor or any identified person). This right refers to the access that the subject who has participated in an investigation has, under request, to the information about the benefits or results of the project or projects. The investigators, the person responsible for collections and the biobanks as institutions, must ensure the availability of

⁷ In exceptional cases, codified or identified samples for biomedical research may be used without the consent of the subject source when the obtaining of said consent is not possible or it entails a nonreasonable effort. In these cases, the favourable opinion of the corresponding Research Ethics Committee shall be necessary, which must take into account, at least, the following requisites: a) That the research is of general interest; b) That the research is undertaken by the same institution that requested the consent for the obtaining of samples; c) that the research is less effective or not possible without the identifying data of the subject source; d) that there is no record of an express objection of the subject source; e) that personal data is guaranteed confidentiality. Besides this, it is also possible to use samples for biomedical research purposes, obtained before the LIB, without consent (for use in research), in some circumstances after the favorable opinion of the Research Ethics Committee.

⁸ Article 14. Privacy and confidentiality. (c) Human genetic data, human proteomic data and biological samples collected for the purposes of scientific research should not normally be linked to an identifiable person. Even when such data or biological samples are unlinked to an identifiable person, the necessary precautions should be taken to ensure the security of the data or biological samples.

⁹ For further analysis of the issues of anonimisation see M SARIYAR, I. SCHLÜNDER, *Reconsidering Anonymization-Related Concepts and the Term "Identification" Against the Backdrop of the European Legal Framework, Biopreservation and biobanking*, 14(5), 2016, 367–374.

this information. This faculty is provided in general in Art. 27 of the LBRL¹⁰ and in particular in Art. 32 of RD 1716/2011¹¹.

The BEEC has no specific powers or obligations in relation to this right expressly defined in the law. Article 27.1 BRL says that the investigator must send a summary of the research, once it has finished, to the "corresponding" ethics committee, but there is no indication to a subsequent obligation for this committee. This is because the purpose of this article is just to facilitate the monitoring function of the projects. However, it must be taken into account that the biobank must guarantee the availability of information concerning the results of the projects in which samples have been used, in case the donor request it (article 32.1 of the RD mentions in this sense the expected and achieved benefits), so it seems reasonable to argue that the BEEC should, in this regard, be involved in this duty and check the following items: that a donor application form is available, that the information about this right is included in the informed consent model, that there is a procedure according to which this information is received and stored in the biobank; and that investigators are required to send the general results to the biobank. Its function therefore is related to the revision and assessment of the biobank's policies.

Secondly, the subject has the right to access to personal data as a faculty that emanates from the right to self-determination: the subject can know what personal data are being processed and to whom they have been communicated (Art. 15 Organic Law 15/1999, of 13 December, on the Protection of Personal Data). The object of this right is any information relating to an identified or identifiable person and, in this sense, refers to any results obtained from physical examinations or procedures, analysis of samples or data, etc... This right is expressly recognized concerning data stored in the clinical record (Law 41/2002, of 14 November, regulating patient autonomy and rights and obligations related to information and clinical documentation) and also concerning genetic data archived in the biomedical field in the UNESCO's International Declaration on Human Genetic Data (2003) and in BRL. It would be adequate to take certain precautions when the donor is going to access to this kind of data, such as to provide at the same time information about its relevance, about the importance of its correct interpretation, about the risks of its diffusion, etc.

The role of the BEEC in relation to this right is similar to that described in the previous case: it should assess and examine that mechanisms have been implemented in order to facilitate the exercise of this

¹⁰ Article 27. Information about the results: 1. Once the research is finished the responsible investigator shall forward a summary to the competent authority which issued the authorization and to the corresponding Research Ethics Committee. 2. The results of the research will be communicated to the participants, upon request. 3. Investigators shall public the general results of research once it is finished, taking into account the requirements regarding personal data referred to in Article 5.5 of this Law and without prejudice to the corresponding intellectual property rights that could be derived from the research.

¹¹ Article 32. Availability of information. 1. Without prejudice to the writing information to be received in by the subject before giving consent for the collection and use of the sample, the biobank, the person responsible of the collection and the person responsible for the project using biological samples for biomedical research purposes, shall provide the subject with the availability of information relating to the use of his / her sample by third parties, unless the sample has been anonymized, namely: a) Specific purpose of the research or research for the that the sample was used. b) Expected and achieved benefits. c) Identity of the principal investigator. d) Genetic data duly validated and relevant to health obtained from the analysis of samples transferred. e) Mechanisms to guarantee the confidentiality of the information obtained f) Identity of the persons who have had access to the personal data that have not been dissociated or anonymized.

right (the donors have been informed about this right, there are adequate application procedures, and investigators are aware of the duty to collaborate when required). According to Law 15/1999, the responsible of the data file is the one who has the legal duty to guarantee the right of access, so in the case of biobanks it corresponds to the title holder/owner.

Finally, the subject has the right to get the information relevant for his/her health. This right has some common elements with the one to access personal data, but they differ in others. Regarding the rights to get the information relevant to his/ her health, the research subject has to take a previous position in relation to the communication of the information obtained from the analysis of the samples (article 59.1 and BRL). The duty to communicate arises only if the option is "to know" but in this case, there is no need of a subsequent request by the donor. The recognition of this right, which is also in UNESCO's International Declaration on Human Genetic Data, is a clear example of the permeability of borders that separate research and clinical frameworks. In fact, the direct benefits that could be derived for the health of the subject oblige the investigators to communicate information obtained for another purpose. This obligation to communicate the results is set out as follows in the Spanish regulation:

- It refers to data relevant to health in a broad sense, also for reproductive health, which includes the possibility of preconceptive or pre-implantational diagnoses. The investigator who finds the information is the first professional that has to evaluate its relevance and validity.
- The obligation concerning the subject rises only if he/she has opted for communication.
- If the subject has decided not to know, according to Art. 49 of the BRL, the biological family members or their legally authorized representative "could be" informed. Article 4.5 of the same Act provides an action rule in this case, but related to the clinical context, since it mentions the "responsible physician"¹²; even if, the intervention of the ethics clinical committee (to which this article also refers) seems to be adequate. Another important issue refers to the contradictory provisions in the BRL referring the communication of the results to family members in case the subject doesn't want to know. While article 49 uses the expression "could be reported", article 4.5 indicates that "will be reported". Again, it seems that this last article focuses on a situation of family genetic counseling process in which the relatives are already involved in the analysis. So in the case of "research findings" in a research context, article 49 should be preeminent.

Regarding the role of the BEEC, it has to carry out the review of the biobank policies as previously described for the other two rights, but in this case it also plays another important role. In fact, Art. 15.3 d of the Royal Decree states that this committee is responsible for deciding the cases in which it will be necessary to send individual information to the source subject, in relation to the transfer of samples to be used in a research project, and in relation to the communication of results when they may be relevant for the subject's health.

The procedure for the reporting of these results should therefore follow the following phases:

¹² The right of the person not to know will be respected, including unexpected findings. However, when this information, in the opinion of the responsible physician, is necessary to avoid serious harm to his / her health or that of the biological relatives, a close family member or a representative will be informed, after consulting the clinical ethics committee if any.

- First, the donor must be informed about the possibility of obtaining data that may be relevant to his / her health or that of his / her family and will express his / her will in relation to the communication (article 59.1.i BRL).
- Second, the investigator, or clinician responsible of the request of informed consent, should ensure the availability of genetic counseling in case this information is to be communicated (article 55 BRL).
- Third, if the investigator finds information that in his/her opinion may be relevant to the subject's health, he or she must communicate it to the BEEC.
- Fourth, the BEEC shall check if the donor wanted to know.
- Fifth, the BEEC shall evaluate the need to communicate the results, regarding the implications for health in a broad sense. The BEEC could request expert advice about the clinical relevance of the genetic information that will depend on the penetrance of the variant (probability that the characteristic controlled by a gene is manifested in the carrier), the severity of the disease it produces, and the possibility of intervention¹³. However, not only clinical relevance should be taken into account to evaluate the opportunity to contact the donor, but also the general relevance to take any kind of vital decisions (for example those related to reproduction choices), as health should be understood in a broad sense. If the subject chose to ignore, the opportunity to inform relatives should be evaluated based on these same implications.
- Sixth, the BEEC decision concerning the return of results shall be communicated to the BSM.
- Seventh, the BSM will follow the procedure to contact the donor, the family members or the designated legal representative.

2.2.4. Advise on the quality policy of the biobanks from an ethical perspective

The BRL and the RD 1716/2011 explicitly refer to the need to follow quality criteria and implement the necessary means to guarantee the quality, safety and traceability of samples, data and work protocols of a biobank (articles 3 d and 66 c BRL and 6 h RD).

Article 15.3 of the RD 1716/2011 states that the BEEC shall advise the BSM about the adequacy of these procedures *from an ethical perspective*.

The BEEC shall also verify that the quality policy ensures that the labeling, traceability codification and anonymization procedures, accomplishes with data protection requirements and guarantee the other rights of the donors (as the return of results or the right to have the sample back if it is needed for health reasons).

¹³ To communicate a genetic result, it must meet the requirements of analytical validity and clinical relevance. Only relevant information that has clinical utility should be communicated, when the participant so requests, avoiding to report on the genetic alterations in which it is not possible to intervene. As have been said, required on findings concerning serious diseases against which no intervention is possible, genetic counseling should be reported with the prescriptive information provided that the validity of the results is known. C. AYUSO, J.M. MILLÁN, R. DAL-RE, *Managing unexpected findings in genetic research. When to communicate them?. Lights and shadows in clinical research* (chapter 10). Fundació Víctor Grífols I Lucas, 2013.

2.3. Ensure that information about the use of samples is given to donors

Article 32.2 RD 1716/2011 establishes that BEEC will decide in which cases it will be essential to send the information to the donor individually concerning the points listed in the first section, that include the specific purpose of the research in which the sample is going to be used. The meaning of this obligation is to give the person the opportunity to partially withdraw consent for that purpose, taking into account that consent for biobanks is given in broad terms.

We suggest that the following criteria could be taken into account, among others, to make the decision:

- Donor did not give consent themselves (minor, incapacitated, consent waiver).
- Donor was not informed about relevant aspects (for example that completes genome sequencing would be carried out).
- The purpose of the research is unique (e.g. studies which foresee the use of human samples along with others of animal origin, or the creation of immortalised cell line).
- There is an appreciable and unforeseen risk (e.g. for discrimination, loss of confidentiality, identifiability).
- Data, that could reveal personal information about relatives who did not give their consent, may be obtained.

When one or more of these circumstances are met, BEEC should evaluate the need to contact the subject and ask him for a specific consent for the use of the sample. If the BEEC concludes that the specific consent is needed but the attempt to contact the donor proves unsuccessful, the sample should not be used for that particular purpose.

2.4. Assist the BSM on other issues submitted for consideration

The BEEC may advise on the following issues:

- Communication, dissemination and transparency policies. Biobanks should describe, document and publicize the collections they maintain, as well as the conditions to their access, in order to optimize their use and ensure the transparency of activities. For that, it is recommended that each biobank, through the website, publishes a "catalogue" with a description of each of the collections along with the minimum data associated with each sample and that it will be available to potential users.
- Formative aspects. On occasions the biobank and its BEEC jointly impart training to investigators in order to inform them about the procedures for requesting samples and on ethical and legal requirements.
- Resolution of enquiries. It is common for BEEC to resolve ethical doubts submitted by the biobank and/or by investigators who request biological samples. It is important to keep in mind that the great variability of situations in the different research projects can cause issues that require a fluid communication between those in charge of the biobank, the investigators and the BEEC.

3. Conclusions

The BRL designed the biobanks for research purposes, as tools to ensure the availability of biological samples for all investigators, respecting, as a priority, the rights of donors and guaranteeing the qual-

ity of the material. Biobanks have been developed as institutions that allow the coordination of basic studies with clinicians, encouraging the creation of cooperative models. In Spain, they have been set up, in all autonomous communities, with different models adapted to the needs of each community. The BEEC is a key element in the structure and functioning of biobanks, which is based on policies that guarantee donor rights, flexibility, agility and trust. This way, we should manage the active and dynamic involvement of BEEC to be at the heart of these institutions. For this reason, the content of the powers attributed to it by the legislation has been described in these pages in a very broad sense, with an extensive interpretation. On the other hand, it has also been taken into account that there is scope for each biobank to articulate its particular action procedures.

In order to facilitate the functions of biobanks and investigators, the BEEC should have web pages that would allow access to informed consent models, procedures or evaluation forms.

Finally, for an optimal development of these competences, in order for the BEEC to take part in the biobanks policies, it seems essential that a fluid, trustworthy and cooperative relationship be fostered by the committee and by the scientific board of the biobank, in periodic meetings or other permanent communication channels.