



UNIVERSITAT^{DE}
BARCELONA

By-Laws on the Organization and Functioning of the Bioethics Committee

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BY-LAWS ON THE ORGANIZATION AND FUNCTIONING OF THE BIOETHICS COMMITTEE

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PREAMBLE

Research projects involving experimentation with human subjects or biological samples of human origin, interaction with human participants, or social intervention are essential to the advancement of scientific knowledge. Such projects require particularly careful evaluation of the procedures involved, with special attention to their ethical and legal implications.

In just a few years, the collection, use, storage and transfer of biological samples for diagnostic, research and innovation purposes has taken on great importance. Research involving invasive procedures on human subjects and research involving gametes, embryos and embryonic cells has become essential in the field of cell therapy and regenerative medicine and is increasingly common. However, these scientific advances, and the procedures and tools used to achieve them, raise significant ethical and legal uncertainties that must be properly regulated, with the balance and caution required by a complex issue that directly affects human identity.

At the same time, research in the social sciences, behavioural sciences and digital humanities, as well as developments in artificial intelligence, big data and related fields, provide very powerful tools that have clear implications for the field of bioethics.

Indeed, for this type of research, the vast majority, if not all, of calls for projects require the researchers involved to obtain a favourable report from a research ethics committee authorizing the project, and any publications arising from the project must be approved by the relevant committees. Law 14/2007, of 3 July, on Biomedical Research, establishes the need to create collegial bodies of this type, which are recognized as being particularly qualified to carry out this function due to their impartiality, independence, technical capacity and the professional competence required of their members. Research ethics committees must ensure, at each research site, that the ethical, legal and methodological aspects of research involving human subjects or the use of biological samples of human origin are appropriate.

The Bioethics Committee of the University of Barcelona (hereafter, CBUB) was created in 1996 in response to an evident need to evaluate research projects managed by internal UB units and carried out by UB researchers. The CBUB advises researchers and evaluates their projects to ensure compliance with the ethical standards set out in documents such as the Nuremberg Code, the Declaration of Geneva, the Declaration of Helsinki, the Belmont Report, and the UNESCO Universal Declaration on Bioethics and Human Rights, among others. These requirements include the principle of beneficence, the principle of respect for the autonomy of individuals in giving consent to participate in research, the principle of justice, the principle that the well-being of research participants must take precedence over all other interests, and the protection of non-autonomous persons and vulnerable populations.

The University of Barcelona has been a pioneer in research and dissemination in this field. The CBUB was set up in parallel with the Bioethics and Law Observatory, which was established in 1996 and has done a great deal to disseminate ethical principles in the field of human experimentation. These activities have been recognized with various awards and projects, such as the creation of the UNESCO Chair in Bioethics in 2007.

The need for the CBUB to evaluate projects in this area has increased considerably in recent years, as has social sensitivity and interest in the field of bioethics. It is therefore essential to restructure the CBUB



in order to strengthen its composition, clearly define the responsibilities of its members, and to provide them with adequate technical and administrative support.

In the light of the above and in accordance with Articles 12, 49, 50 and 63 of the Statute of the University of Barcelona, the Governing Council of the University, at the proposal of the Vice-Rector for Research, has approved these **By-Laws on the Organization and Functioning of the Bioethics Committee of the University of Barcelona**.

SECTION I. General provisions

Article 1. Subject

The Bioethics Committee of the University of Barcelona (hereinafter referred to as CBUB) is the organizational structure established by the University to ensure the appropriateness of the methodological, ethical and legal aspects of research involving interventions on human subjects, the use of biological samples of human origin, and the use of personal data, as well as compliance with current legislation and the general principles established in the UB [Code of Ethics on Integrity and Best Practices](#) and in the [UB Code of Conduct for Research Integrity](#).

Article 2. Functions

2.1 The CBUB's mission is to evaluate the research projects and activities of UB researchers that require such evaluation, to reflect on and debate the ethical issues raised by scientific research, and to promote training in bioethics and research integrity for PhD-holding research staff and trainee researchers.

2.2 The CBUB shall have the following functions:

- a) Advising researchers on matters relating to research involving human subjects, including both research directly involving human participants and the collection and analysis of personal data and of biological samples of human origin.
- b) At the request of researchers, preparing project evaluation reports, taking into account the following principles:
 1. Consider the ethical and legal aspects of the material and methodology used in a research project or activity.
 2. Assess whether the process for obtaining, collecting, analysing, storing and, where appropriate, disposing of personal data complies with applicable bioethics codes and regulations.
 3. Assess data privacy and confidentiality measures; anonymization, pseudonymization and coding procedures; and procedures for transferring personal data to third parties for all types of projects, taking into account current legislation on the protection of personal data.
 4. Carefully assess all data and sample collection activities and those involving minors or vulnerable groups, with regard to both informed consent and assent.
 5. Suggest appropriate changes for the improvement and acceptance of research projects submitted for evaluation.



Before issuing reports, the Committee may ask the researchers concerned to clarify and/or amend certain points. Any issues of this kind must be corrected by the researchers.

- c) Reviewing projects that have already been evaluated to determine whether they can be extended or if the researchers concerned need to submit a new application. The Committee may also propose the suspension of any procedure being applied that does not meet the ethical requirements set out in the protocol originally approved.
- d) Developing appropriate forms for requesting approval of projects by the Bioethics Committee, as well as a guide that clearly and systematically explains the requirements and specifies the documents that must accompany applications according to the area in which the research is to be conducted.
- e) Establishing an internal and external operating protocol to clarify circuits and timescales for the submission and approval of projects.
- f) At the request of the Research Integrity Committee or the Ethics Committee, analysing and reporting on possible ethical violations in the CBUB's areas of competence.
- g) Developing codes of good practice, disseminating the principles of bioethics, and promoting discussion of the implications of new scientific and technological discoveries.
- h) Coordinating the CBUB's activity with that of similar committees in other institutions and bodies.
- i) Ensuring confidentiality and compliance with personal data protection regulations.
- j) Any other functions assigned to it by current legislation.

2.3 The CBUB may act as a reference committee for the evaluation of research projects of public and private bodies when so arranged through an agreement, and may provide instruction and training in bioethics and research integrity for researchers of the UB or any other institution when requested to do so.

2.4 The CBUB shall work in coordination with any UB committees related to its functions, such as the Ethics Committee, the Research Integrity Committee, the Animal Experimentation Ethics Committee, the Biosafety Committee, and the Data Protection Office, among others.

SECTION II. Composition

Article 3. Composition

3.1 The CBUB shall be composed of the following members:

- a) the UB's Vice-Rector for Research, or his/her delegate, who shall chair the Committee;
- b) the chair of the UB's Ethics Committee or his/her delegate;
- c) between 10 and 20 academics (from the life sciences; health sciences; human, social and legal sciences; or experimental sciences) or staff with experience in the field of bioethics who work full-time at the UB, appointed by the rector at the proposal of the chair of the Committee;



d) two researchers from institutions in which the UB participates, or with which it has signed a collaboration agreement, appointed by the respective institution at the proposal of the chair of the Committee; and

e) the UB's data protection officer, who shall attend meetings with the right to speak but not to vote.

3.2 The members referred to in points c) and d) above shall be appointed for a period of six years, renewable for a maximum period of four years. In order to ensure the continuity of the Committee, no more than one third of its members may be replaced by new members each year.

3.3 Meetings of the CBUB may be attended by administrative and service staff as necessary to provide technical and administrative support and by any persons invited by the chair based on the items to be discussed. Support staff and invited participants shall have the right to speak but not to vote.

Article 4. Chair and secretary

4.1 The CBUB shall be chaired by the Vice-Rector for Research, or any other vice-rector who may assume his/her functions in the future, or by a person delegated by the Vice-Rector. The chair shall represent the CBUB.

4.2 The chair of the CBUB shall appoint the secretary, who shall perform the duties assigned to him/her by legislation in force. In particular, the secretary shall convene meetings of the Committee, draw up minutes for meetings, issue certificates relating to resolutions adopted, and perform any other functions assigned to him/her by these by-laws. The secretary of the Committee may be a non-member, in which case he/she shall not have the right to vote.

Article 5. Rights and duties of CBUB members

5.1 CBUB members shall have the following rights:

- a) To be notified of and attend meetings.
- b) To have access to the information needed to perform their functions.
- c) To be informed of any complaints and/or information related to the functioning of the CBUB.
- d) To obtain recognition for their work on the Committee on the terms established.
- e) All other rights recognized by the regulations or legislation in force.

5.2 CBUB members shall have the following duties:

- a) To maintain confidentiality with respect to any procedures or projects that they review.
- b) To faithfully follow the University of Barcelona's Code of Ethics on Integrity and Best Practices and all related regulations; local, state and European regulations that apply to human experimentation; and the University of Barcelona's Code of Conduct for Research Integrity.
- c) To abstain from participating in a procedure and/or evaluation if there is a legal reason to do so, in situations of conflict of interest, or if they have been directly or indirectly involved in the project or procedure to be evaluated.



d) Any other duties laid down by the regulations or legislation in force.

SECTION III. Organization and functioning

Article 6. Meetings

6.1 The CBUB shall hold at least one ordinary meeting each quarter. Extraordinary meetings may be convened at any other time at the request of the chair or one third of the members of the Committee.

For meetings, deliberations and resolutions to be valid, a majority of the members must be present on first call, or a third of the members on second call. The chair and/or the secretary, or their authorized representatives, must be present in both cases.

6.2. The Committee shall operate in plenary sessions and through subcommittees. Subcommittees shall be composed of at least three members and shall carry out such functions as may be delegated to them by the Committee. However, the plenary may request that any matter be brought to its attention.

6.3 Resolutions not requiring a qualified majority shall be adopted by simple majority. The chair's vote, if necessary, shall be a casting vote.

Article 7. Additional information and advice

7.1 The CBUB shall, with the utmost diligence, consider the procedures submitted for evaluation and make a determination in each case. Procedures must be submitted electronically.

7.2 The CBUB may request any additional information it deems necessary from the researcher responsible for the project to be evaluated.

7.3 Where appropriate, the CBUB may seek the advice of experts from outside the Committee, who must strictly observe the principle of confidentiality.

7.4 The CBUB shall be supported by administrative and service staff to carry out an initial review of procedures submitted for evaluation and to check that all the necessary information has been included.

7.5 Technical and administrative support staff, who must have sufficient resources to ensure the diligence required, shall be obliged to maintain the confidentiality of the projects and procedures they review and to comply with regulations in force.

Article 8. Evaluations

8.1 Approval to carry out a project or use an experimental procedure shall require an absolute majority vote of members of the plenary of the CBUB. In the case of subcommittees, approval shall require a unanimous vote.

8.2 The CBUB shall issue an individual report on each project or procedure it evaluates, stating whether or not approval is granted and specifying any additional requirements.



8.3 The report referred to in the previous point shall be sent by email to the researcher responsible for the project or procedure.

8.4 In the event that any additional requirements are specified, the researcher responsible shall have one month to make the necessary changes to the project or procedure. If the requested changes are not made, or are not made within the prescribed time limit, the project shall be rejected.

8.5 Documentation related to each project or procedure evaluated, as well as external expert opinions and reports, shall be kept for at least three years after the completion of the project or research activity, unless another rule or provision provides for or requires retention for a longer period.

Article 9. Minutes

9.1 For each meeting of the CBUB, the secretary shall draw up the minutes, which shall include a list of the members present, the agenda, the place where the meeting was held, the start and end time, the main items discussed, and the resolutions adopted.

9.2 The minutes shall be emailed to all members of the Committee to inform those who were unable to attend of the decisions taken and so that any necessary amendments can be made.

9.3 The minutes must be approved at the next meeting of the Committee.

ADDITIONAL PROVISION

The necessary mechanisms shall be established to coordinate the activities of the CBUB with those of other UB committees.

TRANSITIONAL PROVISION

The CBUB shall be constituted in accordance with the amendments to these by-laws within a maximum period of two months after their entry into force.

The CBUB must adapt its internal procedures within six months of the date of entry into force of these by-laws in order to ensure that the data protection officer of the UB fulfils the functions established by Regulation (EU) 2016/678 of 27 April 2016, Organic Law 3/2018 of 5 December, and other regulations on the protection of personal data.

REPEALING PROVISION

The by-laws governing the organization and functioning of the Bioethics Committee, approved by the Governing Council on 7 October 2020, are hereby repealed, as are any previous provisions that are inconsistent with these by-laws.



FINAL PROVISIONS

First. These by-laws shall enter into force on the day following their approval by the Governing Council and shall be published on the UB's Electronic Office and on its Transparency Portal.

Second. The vice-rectors' offices responsible for research and knowledge transfer shall settle any disputes concerning the interpretation of these by-laws.