

REGULATIONS ON THE ORGANIZATION AND FUNCTIONING OF THE BIOETHICS COMMITTEE OF THE UNIVERSITY OF BARCELONA

Approved by decision of the Governing Council on 7 October 2020

Preamble

Research projects that involve experimentation with human subjects or biological samples of human origin, as well as interaction with human participants or social interventions, are essential for the advancement of scientific knowledge. Such projects require particularly careful evaluation of the procedures involved, with special attention to their ethical implications.

In fact, many calls for research projects require that projects obtain a favourable report from a research ethics committee that authorizes the research. Law 14/2007, of 3 July, on biomedical research, states the need to establish collegial bodies of this kind, which are recognized as being particularly qualified to perform this function due to their impartiality, independence, technical capacity, and the professional competence required of their members. At each centre where research is conducted, research ethics committees must ensure the appropriateness of methodological, ethical and legal matters related to research involving interventions on human subjects or the use of biological samples of human origin.

The Bioethics Committee of the University of Barcelona (CBUB) was established in 1996 to address the clear need to evaluate research projects managed by internal units of the UB and carried by UB researchers. The CBUB advises researchers and evaluates their projects in order 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 when 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.

In just a few years, obtaining, using, storing, and disposing of biological samples used for diagnostic and research purposes have gained great significance. Research that involves performing invasive procedures on human subjects and research with gametes, embryos and embryonic cells has become essential in the field of cell therapy and regenerative medicine, and such research is increasingly frequent. But these scientific advances and the procedures and tools used to achieve them generate significant ethical and legal uncertainties that must be properly regulated with the balance and prudence 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 in the field of bioethics.

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 by Dr María Casado, who has made an outstanding contribution to the activities of the CBUB and done a great deal over the years 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 very considerably in recent years, as has social awareness and interest in the field of bioethics. Consequently, it is now essential to undertake a restructuring of the CBUB in order to strengthen its composition, clearly define the responsibilities of its members, and provide them with appropriate technical and administrative support.

In the light of the foregoing considerations, and by virtue of the provisions of Articles 12, 49, 50 and 63 of the Statute of the University of Barcelona, the University's Governing Council, at the proposal of the Vice-Rector for Research, has approved the following **Regulations on the Organization and Functioning of the Bioethics Committee of the University of Barcelona**.

Article 1. Object

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

Article 2. Functions

2.1 The CBUB's mission is to evaluate research projects and doctoral theses of UB researchers when requested to do so, to reflect on and debate ethical issues raised by scientific research, and to promote the training of researchers and doctoral students in bioethics and research integrity.

2.2 The CBUB shall have the following functions:

- a) To advise researchers on matters related to research involving human subjects, including both research that directly involves human participants and the collection and analysis of personal data and biological samples of human origin.
- b) To draw up, at the request of researchers, favourable or unfavourable reports following project evaluation based on:
 1. Evaluation of the qualifications of the principal investigator and the research team, as well as the feasibility of the research project.
 2. Consideration of the methodological, ethical and legal aspects of the research project.
 3. Weighing the balance of anticipated risks and benefits of the research project.
 4. Assessment of procedures for obtaining, collecting, analysing, storing and destroying (if applicable) personal data, particularly but not exclusively data of a sensitive nature, including assessment of informed consent procedures, and considering, in all cases, legislation on the protection of personal data in effect at the state and European level.

5. Assessment of measures to ensure privacy and confidentiality of data; anonymization, pseudo-anonymization and coding procedures; and procedures for the transfer of data to third parties for all types of projects, considering, in all cases, current legislation on the protection of personal data.
- c) To review projects that have been previously assessed and propose the suspension of any procedures being applied that do not meet the requirements set out in the protocol originally approved.
 - d) At the request of the Research Integrity Committee, to study possible ethical violations relating to its areas of competence.
 - e) To develop codes of good practice, disseminate the principles of bioethics, and promote discussion of the implications of new scientific and technological discoveries.
 - f) To coordinate its activity with similar committees in other institutions or bodies.
 - g) To ensure confidentiality and compliance with data protection regulations.
 - h) Any other functions assigned to it by current legislation.
- 2.3 The CBUB may act as a reference committee to evaluate research projects of public and private bodies when so stipulated in 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 UB committees related to its functions, such as the Ethics Committee, the Research Integrity Committee, the Animal Experimentation Ethics Committee and the Biosafety Committee and the Data Protection Office, among others.

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 designated representative, who shall chair the Committee;
 - b) the chair of the UB's Ethics Committee or his/her designated representative;
 - c) ten academics (from the life sciences; health sciences; human, social and legal sciences; or experimental sciences) 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; and
 - 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.
- 3.2 The members referred to in sections c) and d) of the preceding point shall be appointed for a period of four years, renewable for a maximum of four further 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 in accordance with 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 his/her designated representative. The chair shall represent the CBUB.
- 4.2 The chair of the CBUB shall appoint the secretary from among the members of the Committee. The secretary shall have the functions assigned to him/her by legislation in force. In particular, the secretary shall draw up the minutes for meetings, issue certificates related to resolutions adopted, and perform any other functions assigned by these regulations.

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.
- 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; 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 any procedure and/or evaluation when there is a legal reason to do so, in a situation of conflict of interest, or if they have participated, directly or indirectly, in the project or procedure in question.

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.
- 6.2 For meetings, deliberations and the adoption of resolutions to be valid, the majority of members must be present on first call, and the chair and/or secretary, or their delegated representatives, must be present in all cases.
- 6.3 The Committee shall operate in plenary sessions and through subcommittees. Subcommittees shall be composed of at least three members and shall carry out the functions delegated to them by the Committee. However, the plenary may request that any matter be brought to its attention.

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 For the performance of its functions, the CBUB shall receive the support of administrative and service staff, who shall conduct an initial review of procedures to verify that all necessary information is included before submitting them to the CBUB.
- 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 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 produce an individualised report on each project or procedure it evaluates, in which it shall state whether or not approval is granted and specify 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. If the applicant wishes to continue the process of seeking approval, the project must be resubmitted.
- 8.5 The documentation related to each project or procedure evaluated, as well as the opinions and reports of external experts, shall be kept for at least three years.

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 points discussed, and the resolutions adopted.
- 9.2 The minutes shall be sent by email to all members of the Committee to inform those who were unable to attend the meeting of the decisions taken, and so that amendments may be made if necessary.
- 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 regulations, within a maximum period of one month from their entry into force.

Final provisions

1. These regulations shall come into force the day after their publication on the UB Transparency Portal and shall supersede any previous regulations.
2. The vice-rector's offices responsible for research and knowledge transfer shall settle any disputes concerning the interpretation of these regulations.