



Fatebenefratelli Ethics Committee  
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## ETHICAL CODE FOR THE USE OF BIOLOGICAL MATERIAL FOR RESEARCH OR EXPERIMENTAL PURPOSES

*This Ethical Code was elaborated by the Ethics Committee of the Catholic Hospital Institutions of Brescia (Comitato Etico delle Istituzioni Ospedaliere Cattoliche Bresciane - CEIOC), which in its activity draws inspiration from the tradition and teaching of the Catholic Church. As such, the Code should be interpreted in light of this Magisterium.*

*The Ethical Code has been reviewed by the Fatebenefratelli Ethics Committee, established by the Fatebenefratelli Lombardy-Venice Province as the reference committee for its centres.*

1. This Ethical Code applies to the collection and use of biological materials for research or experimental purposes at centres that refer to the Fatebenefratelli Ethics Committee, regardless of whether such materials are stored in a biological bank.

Under this Code, any deposit of biological material for research or experimental purposes is considered a biological bank.

2. Biological material will be collected and used for research or experimental purposes only with the prior informed consent of the individual from whom the material originates to its collection, its use within the scope of a specific research or experimental activity, and, when planned, its storage in a biological bank.

Sampling from a person with a legal representative or court-appointed supporter (“amministratore di sostegno”) responsible for healthcare decisions may only be carried out with the consent of the latter, and only when the research cannot be conducted with other participants. If the person has requested the presence of a family member or a trusted person, this person may sign the consent on behalf of the participant. However, no sampling will take place in the event of dissent from the individual concerned.

Consent for the storage of material in a biological bank may include consent for the use of the same material for further research or experimentation consistent with the objectives and methodologies of the project for which consent has already been granted.

Any eventual subsequent use of the biological material for other research or experimental activities that is not consistent with the previously expressed consent will require a new expression of consent.

3. Consent may also be granted for the storage of material in a biological bank and its use for justified future research or experimental needs, and thus without indicating specific research or experimental activities that are already planned. Consent for the storage of material in a biological bank must indicate the purposes of possible future research and the fundamental methodologies involved, provided that such research complies with the regulations of this Ethical Code.

These provisions also apply to the use for research or experimental purposes of biological materials collected for diagnostic or surgical purposes, or detached from the body of a human individual for any reason.



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4. The biological material and associated data must be pseudonymized in a way that prevents the tracing of the identity of the individual who provided said material, except by the person responsible for the experiment, research, or biological bank, and only for the benefit of the donor.

5. The management and use of biological material must comply with the ethical principles outlined in art. 2 of the Regulation governing the activity of the Fatebenefratelli Ethics Committee.

The approval for the establishment of a biological bank is also subject to the respect of these principles.

The aforementioned article reads as follows:

*2.1 The Fatebenefratelli Ethics Committee operates to ensure respect for human life, from conception to natural death, and, along with it, the protection and promotion of the right to health and of human rights.*

*2.2 The Fatebenefratelli Ethics Committee is inspired by the tradition and teaching of the Catholic Church, in accordance with the constitutive purposes of the promoting institution.*

*2.3 In its activity, the Committee also refers to the documents of the National Committee for Bioethics and to National and International Organisms on the protection of human being in the areas of medicine and biomedical research.*

6. No current or future use of biological material, based on any motivation, is authorized for purposes that are not compatible with the principles of Catholic moral doctrine and the objectives pursued by the Fatebenefratelli Lombardy–Venice Province, which established the Fatebenefratelli Ethics Committee.

7. Every single research project or experimentation involving biological material conducted at the centres referring to the Fatebenefratelli Ethics Committee is subject to the approval of the competent Ethics Committee in accordance with legal regulations in force, to which complete documentation and information must be provided, particularly regarding the rationale, aims, novelty and value of the study, the experimental design, the detailed description of the procedures and methodologies to be used, and the analysis of the risks and benefits for the subjects involved and for the community.

Regarding genetic studies, the methods for the secure storage of DNA samples and the collected or generated data must also be specified, along with the measures intended to protect the subject's right to privacy.

The Centre which the research's principal investigator is affiliated to is required to implement procedures aimed at a preliminary assessment of the research protocol to be submitted to the competent Ethics Committee in accordance with legal regulations in force. This assessment must also address the ethical aspects of the protocol, in accordance with the principles set forth in this Ethical Code.

The opinion of the Fatebenefratelli Ethics Committee shall be requested in advance in cases of particular ethical complexity.

8. The transfer of biological material to other institutions may occur for important and documented reasons and will only be possible if the recipient institutions pursue objectives analogous to those of the centres referring to the Fatebenefratelli Ethics Committee, in accordance with this Ethical Code.



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It is the responsibility of the biological bank or the sending institution to ensure, prior to any transfer of biological material, that no use will be made of the material that is inconsistent with the principles set forth in this Ethical Code. Furthermore, written documentation must be obtained – issued by both the person in charge of research or experimentation on the biological material at the recipient institution and an individual authorized to act on behalf of the institution where the research or experimentation will take place – confirming their commitment to operate strictly within the authorized limits, in accordance with section 9.

9. Any transfer of biological material to institutions other than those referring to the Fatebenefratelli Ethics Committee, as well as any individual research project or experimentation on the same material to be conducted at one of these institutions, is subject to prior authorization from the sending institution, based on criteria that include an assessment of the compatibility of the transfer with the consent given by the donor, an evaluation of the research project as outlined in section 7 and its alignment with the provisions of section 5, the evaluation of the requesting Institution and the curriculum vitae of the principal investigator, and confirmation that the research protocol has been approved by a formally established Ethics Committee.

Upon completion of the research or experimental activities for which the biological samples were transferred, all the transferred biological material, and in any case all the material that remains in any form, must be returned to the centre referring to the Fatebenefratelli Ethics Committee that sent the material.

The transferred biological material may be temporarily retained by the recipient institution solely for the purpose of conducting additional research or experimentation that is consistent with the aims and methodologies of the project for which consent has already been obtained, and which has been authorized by the sending institution. The transferred biological material may not be further transferred or made available, in whole or in part, to recipients not specified in the material and data transfer agreement.

10. Any commercialization of biological material collected and stored in the biological bank is prohibited.

In the event that the results of scientific research conducted on samples stored in the biological bank lead to patent requests with potential commercial applications, the centre holding the patent is required to consider the possibility of sharing the benefits, for example, by investing a percentage of any proceeds into research activities related to the pathology from which the patent has originated. It shall be the responsibility of the centre to request, in the biological material transfer agreement, a similar commitment from third-party Institutions to which the samples have been transferred.

11. In case of cessation of the activity of a biological bank within the centres referring to the Fatebenefratelli Ethics Committee, the biological material and associated data stored therein may be transferred to another biological bank, preferably established at one of the centres referring to the Fatebenefratelli Ethics Committee, or that in any case commits to fully adhere to the principles set forth in this Ethical Code, subject to the consent of the individual concerned or in accordance with the consent previously granted by the individual.



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12. This Ethical Code must be made known to all individuals from whom consent is requested for the collection, use, and eventual storage of biological material and must be attached to the informed consent form.

13. The individual who has given consent for the storage of biological material in a biological bank, or the other individual referred to in paragraph 2 of section 2, may withdraw their authorization for the storage and use of biological samples at any time.

Research or experimentation involving biological materials stored at the centers referring to the Fatebenefratelli Ethics Committee prior to the date of entry into force of this Ethical Code may be conducted, provided that compliance with the provisions outlined in section 7 is ensured, by obtaining the consent of the individual referred to in paragraph 1, or the individual referred to in paragraph 2 of section 2.

In cases where obtaining such consent is not feasible or is deemed difficult to implement, ethical approval for the research or experimentation, as stipulated in section 7, by the competent Ethics Committee in accordance with applicable legal regulations, subject to evaluation by the Centre which the research's principal investigator is affiliated to, as specified in section 7, paragraph 3, is considered sufficient from an ethical point of view.

14. The provisions of this Ethical Code apply, insofar as they are compatible, to any biological materials that have come into possession, for research or experimentation purposes, of the centres referring to the Fatebenefratelli Ethics Committee.

*Date of last revision: October 1, 2024, revised from version March 21, 2002.*

*The official version of this Ethical Code is in Italian.*