

Text approved by the UOC Executive Board on July 10, 2023, and modified by the UOC Executive Board on July 1, 2024

## **REGULATIONS OF THE RESEARCH ETHICS COMMITTEE OF THE UNIVERSITAT OBERTA DE CATALUNYA**

### **PREAMBLE**

Research carried out at the UOC must meet a number of methodological, ethical and legal requirements, in accordance with the highest standards of scientific rigour. In order to facilitate this, the UOC regulates the Research Ethics Committee (CER) and its functioning.

The aim is to provide an assurance of control that is consistent with the requirements of legislators, standards and funding bodies, and an increasing number of journals and other types of scientific publications that accept research papers.

The main role of the CER is to act as an institutional instrument to achieve the above aims, through the preparation of reports that endorse the approach of any research project wholly or partially carried out by the UOC.

The CER also deals with enquiries from the university community on ethics and data protection issues related to research, it assesses research associated with bachelor's or master's degree final projects, and it draws up guidelines or recommendations on specific topics or particularly controversial issues. It also arbitrates enquiries and mediates conflicts arising from research activities at the UOC.

### **CHAPTER I. GENERAL PROVISIONS**

#### **Article 1. Purpose of the regulations**

The purpose of these regulations is to regulate the responsibilities, composition and operating rules of the Universitat Oberta de Catalunya's Research Ethics Committee.

#### **Article 2. The Research Ethics Committee**

The CER is the collegiate body of the UOC responsible for respectfully, confidentially and efficiently assessing the ethical, methodological and legal aspects of the research and teaching research activities carried out at the university.

The CER carries out its responsibilities in accordance with these regulations and in compliance with the current regulations on animal experimentation, biomedical research and the protection of personal data.

The CER is responsible for assessing research activities involving human subjects and their biological samples, as well as those involving the participation and/or involvement of people, especially when their personal data are to be used.

### **Article 3. Responsibilities of the Research Ethics Committee**

The CER is the body responsible for validating research protocols, determining whether or not the assessment is positive, issuing the final decision and safeguarding the documentation generated during the process. The CER acts independently, guaranteeing the anonymity and confidentiality of personal data and ensuring the impartiality and fairness of its decisions.

The main responsibilities entrusted to the CER are:

- a) Assessing and analysing the ethics protocols applicable to research projects and teaching research activities, and ensuring proper compliance with ethics and data protection rules and policies.
- b) Assessing the balance of possible risks in the research project or teaching research activity in order to identify and propose measures and controls to mitigate them.
- c) Analysing, advising on, developing, maintaining and reviewing the UOC's policies and procedures for ensuring that the research projects and teaching research activities carried out at the university are appropriate from a methodological, ethical and legal point of view.
- d) Drawing up recommendations and guides on good scientific practice, as well as carrying out training tasks relating to ethics and data protection in research projects and teaching research activities.
- e) Issuing, as a mandatory requirement, ethical compliance reports (statements) and specific mandatory security and data protection measures.
- f) Liaising with the institutional bodies responsible for research and teaching research activities in order to update or improve the actions to be taken in the assessment of ethics and data protection.
- g) Informing the Compliance Office of any potential conflicts of interest in the area of research prior to the start of the project.
- h) Cooperating with the institutional bodies responsible for research in resolving conflicts relating to research misconduct.
- i) Ensuring that research data are in compliance with the FAIR principles and in accordance with the UOC's Open Knowledge Action Plan and Institutional Policy on Open Access.



## CHAPTER II. COMPOSITION, STRUCTURE AND ORGANIZATION OF THE RESEARCH ETHICS COMMITTEE

### Article 4. Composition of the Research Ethics Committee

The CER has the following composition:

- a) The chair, a member of faculty or researcher, who presides over the Committee.
- b) At least four (4) members of the UOC's teaching and research staff with proven experience or expertise, representing the university's research areas.
- c) The deputy general manager with responsibility for research and knowledge transfer matters or a person to whom this responsibility has been delegated.
- d) The head of the Legal Office or a person competent in data protection matters to whom this responsibility has been delegated.
- e) The technical secretary of the Research Ethics Committee.

Where necessary, the CER may invite experts in specific areas of knowledge, as well as administrative staff competent in the matters to be discussed, to attend its meetings.

The UOC must provide appropriate administrative and technical support mechanisms to enable the CER to carry out its activities.

### Article 5. Appointment of members of the Research Ethics Committee

The members of the CER are appointed by the UOC's Executive Board at the proposal of the vice rector responsible for the field of research.

The term of office of the chair of the Committee is four (4) years.

### Article 6. Responsibilities of the chair of the Research Ethics Committee

The responsibilities entrusted to the chair of the Committee are as follows:

- a) Representing the CER within the university or delegating this task to another member of the Committee.
- b) Convening meetings and setting the agenda.
- c) Presiding over meetings and moderating them or delegating this task to another member of the Committee.
- d) Coordinating, together with the Technical Secretary's Office, the development, maintenance and review of policies and procedures within the CER to guarantee the methodological, ethical and legal suitability of the research projects and teaching research activities carried out at the UOC.

- e) Coordinating, together with the Technical Secretary's Office, the provision of analysis and advice on the ethical protocols of research projects and teaching research activities, as well as ensuring proper compliance with the policies and regulations on ethics and data protection.
- f) Coordinating, planning, developing, organizing and supervising, together with the Technical Secretary's Office, the implementation of processes, tools and other mechanisms appropriate for its purposes.
- g) Signing statements on ethical protocols with favourable or unfavourable reports.
- h) Writing periodic reports to be submitted to the Executive Board or the competent office of the vice rector.

### **Article 7. Technical Secretary's Office for the Research Ethics Committee**

The Technical Secretary's Office is the organizational unit of the CER that supports the assessment of research projects and teaching research activities in order to ensure that they comply with the methodological, ethical and legal requirements established for research activities carried out at the UOC.

It assists the CER as guarantor in activities involving research with human subjects and biological samples, and it ensures compliance with the General Data Protection Regulation (GDPR) in research activities involving the participation and/or involvement of people and the use of their personal data.

### **Article 8. Responsibilities of the Research Ethics Committee's Technical Secretary's Office**

The Technical Secretary's Office is entrusted with the following responsibilities:

- a) Assisting the CER in assessing and analysing the ethical protocols of research projects and teaching research activities, and ensuring proper compliance with ethics and data protection policies and regulations.
- b) Assisting the CER in assessing the balance of potential risks in research projects or teaching research activities in order to identify and propose measures and controls to mitigate them.
- c) Assisting the CER in assessing, advising on, developing, maintaining and reviewing the UOC's policies and procedures for ensuring that the research projects and teaching research activities carried out at the university are appropriate from a methodological, ethical and legal point of view.
- d) Assisting the CER in drawing up recommendations and guides on good scientific practice, and carrying out training tasks on data protection in research projects and teaching research activities.

- e) Advising, supporting and training researchers and students in the proper application of the relevant methodological, ethical and legal standards, so that they can apply them to their research projects and build a culture of compliance.
- f) Coordinating, planning, implementing, organizing and monitoring processes, tools and other mechanisms as defined and prepared by the CER.
- g) Managing the issuance of ethical compliance reports for the correct protocols to be approved and the documents establishing mandatory measures.
- h) Carrying out the relevant processes and responsibilities entrusted by the CER.
- i) Performing such other duties as the chair of the CER deems appropriate or necessary, within the limits of the applicable regulations.

### **Article 9. Duties and obligations of the members of the Research Ethics Committee**

Members of the CER must act independently and autonomously in the performance of their duties.

Members of the CER are bound by secrecy and confidentiality with respect to the substance of deliberations and votes at CER meetings, and with respect to all information and documents to which they have access in the performance of their duties.

Members of the CER must not know about, and may not be involved in deliberations and decisions on, any matters in which their independence, impartiality and objectivity in the performance of their duties may be compromised.

## **CHAPTER III. FUNCTIONING OF THE RESEARCH ETHICS COMMITTEE**

### **Article 10. Schedule**

The CER normally meets once (1) a month, but may meet every fifteen (15) days if its activities so require. The chair of the CER convenes meetings and sets the agenda, but they may delegate this responsibility to the Technical Secretary's Office if they deem it appropriate. In the case of urgent matters, the chair may call an extraordinary meeting at any other time.

Notice of meetings must be given by email at least five (5) days in advance. This notice must state the date, time and place (if the meeting is to be held in person) or the link (if it is to be held online or in hybrid format). It must also include the agenda, the necessary information on the items to be discussed, the list of protocols requiring joint assessment, and the list of protocols proposed for favourable decision by the Technical Secretary's Office.

## Article 11. Ethical review procedure

Any member of the UOC university community requiring an ethical and data protection assessment of their research project or study must submit a request through the appropriate Virtual Campus pages, including all relevant information and documents.

When the Technical Secretary's Office receives the relevant information and documents, the assessment of the project or study will begin. If additional information or corrections are required, it must inform the requesting party, who must comply with the request within a maximum period of two (2) months. After this period, if the required information has not been received, the file will be closed *ex officio* and shelved, and the requesting party will be informed.

The time limit for reviewing the information and documents received is a maximum of one (1) month counting from the date of receipt of the information requested from the requesting party.

When reviewing complex projects and studies, the Technical Secretary's Office must contact the member of the CER who is an expert in the relevant field of research so that they can jointly review and assess it.

The CER may also request an expert in a specific field of knowledge to review the project or study and prepare a report if the field so requires. The report must be sent to the Technical Secretary's Office, which must attach it to the file and present it at the assessment meeting for joint review.

After reviewing the information and documents provided, the Technical Secretary's Office must draw up a document with safety and protection measures for the project or study. This document is mandatory for research projects and doctoral theses, and recommended for bachelor's or master's degree final projects.

The assessed requests must be presented at the CER meeting in order to obtain final approval and a favourable opinion.

## Article 12. Minutes of meetings

The Technical Secretary's Office must present the items on the agenda, which must be presented by the Technical Secretary's Office itself and by the chair of the CER. The Technical Secretary's Office must record the opinions expressed and the agreements reached.

The meetings serve to reach agreements and approve the issuance of favourable statements proposed by the Technical Secretary's Office.

After the meetings, the Technical Secretary's Office draws up the minutes with the content of the session and sign it with the approval of the presidency.

The minutes are sent by email to the members of the Committee to inform them of the decisions taken. CER members have five (5) days to make any changes. After this period, the minutes are considered closed.

The minutes are saved in a place set aside for the CER.

### **Article 13. Deadline for issuing reports**

As soon as a meeting has ended and the issuance of a favourable statement has been approved in the minutes, the Technical Secretary's Office will issue the corresponding statement.

The statement issued will contain the date of issue, the unique file number and the reference of the research project or study requested. The statements issued will be provided to the chair of the CER, who will have two (2) working days to sign them and return them to the Technical Secretary's Office.

Within two (2) days of receiving the signed statement, the Technical Secretary's Office must notify the requesting party via their official UOC email account. The notification must include the signed statement and the document establishing the safety and protection measures tailored to the research project or study in question.

If the requesting party needs proof that the project has been submitted for review before the date of the CER meeting, a certificate signed by the chair may be issued stating that the project has been submitted to the CER and is pending review.

### **Repealing provision**

These regulations of the Research Ethics Committee repeal the *Organizational structure involved in research ethics* document approved by the Executive Board in October 2015.

### **Final provision. Entry into force**

These regulations will come into force as soon as they are published on the UOC's e-Services Portal, subject to approval by the UOC's Executive Board.