



UNIVERSITAT DE VIC  
UNIVERSITAT CENTRAL  
DE CATALUNYA

**UVIC-UCC RESEARCH ETHICS COMMITTEE  
REGULATIONS**

Approved by the Board of Governors of UVic-UCC on 1 December 2015

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## INTRODUCTION

As defined in the statutes of Balmes University Foundation, which owns the University of Vic – Central University of Catalonia (UVic-UCC), one of the University's aims is to promote research and knowledge transfer in all the fields in which it works. This may be undertaken directly or through agreements with other universities, institutions, companies and people from outside the UVic-UCC. It is particularly important to promote links between the University and social actions, particularly those of a cultural or economic nature. To meet this institutional objective, the UVic-UCC aims to attain and promote integrated teaching and high quality scientific and technical research, from a humanising perspective that meets the complex needs of current society and fully respects human rights and the environment. To fulfil its role, the UVic-UCC sets out to undertake open, excellent scientific and technical research to serve society and the region, in coordination with the various disciplines, and disseminate the results of this research through knowledge transfer and translation.

Traditionally, research has been developed within the framework of universities and the academic community, to meet quality criteria and under the supervision and monitoring of their respective bodies. However, in recent years, specific structures have been established at different Spanish universities in the form of research committees or commissions, to further systematize the supervision and monitoring of the research task, as a tool to support and guide researchers from different disciplines. These structures, which have a responsibility to society, must respond quickly and effectively to current and future needs with respect to scientific and technical research, and must protect the basic rights of people, social and economic justice, the environment, respect for the principles and commitments of bioethics adopted by the scientific community, and the necessary sensitivity to animals and living being during experimental research.

Various national and international bodies and authorities have developed guides or codes of good scientific practices<sup>1, 2</sup> for the entire scientific world and for scientific institutions that carry out basic or applied research, such as the UVic-UCC<sup>3</sup>, to

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<sup>1</sup> Código de Buenas Prácticas Científicas del Centro Superior de Investigaciones Científicas (CSIC); 2010. See: <http://www.csic.es/web/guest/etica-en-la-investigacion;jsessionid=0543F6588763FFBF9A6B196601987AFD>

<sup>2</sup> Recomendaciones con relación al impulso e implantación de buenas prácticas científicas en España. Comité de Bioética de España. 2010. See: [http://www.comitedebioetica.es/documentacion/docs/buenas\\_practicas\\_cientificas\\_cbe\\_2011.pdf](http://www.comitedebioetica.es/documentacion/docs/buenas_practicas_cientificas_cbe_2011.pdf)

<sup>3</sup> Codi de bones practiques en recerca de la Universitat de Vic – Universitat Central de Catalunya.

establish a framework of reference that guides all research activity. In these codes and recommendations for good scientific practices, the concern for ethical aspects of research is particularly important, particularly when the research involves human subjects or the use of personal or genetic data, has a considerable impact on social or economic structures, or involves animal experimentation or practices that could harm the environment. In recent years, important international documents have been approved on human rights in the area of scientific, technical and biomedical research (the Declaration of Helsinki, the European Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, UNESCO's Universal Declaration on Bioethics and Human Rights, and others), which particularly highlight the essential role of bodies that oversee ethics.

There is a set of specific legal regulations which must be met in all fields. However, beyond complying with regulations, the analysis of the ethical aspects that a certain research project involves, and respect for the basic rights of participants, are elements that should be analysed by a research ethics committee.

In the same line, for several years all public calls for research grant applications have required that researchers submit their projects along with a favourable report issued by an ethics committee, which could be attached to the university or institute itself or to another leading centre. Therefore, many Spanish universities have created their own research ethics committees, initially only to oversee animal experimentation projects<sup>4,5</sup>, although subsequently they extended their area of responsibility to all research that involves some of the elements that administrative regulations require in official calls for applications such as: experiments with or on people, experiments with embryonic stem cells, the use of personal or genetic data, biological or human samples, animal experimentation, and the use of biological agents or genetically modified organisms. Exceptionally, clinical trials of drugs or health products and other kinds of invasive research involving human subjects are governed by specific legislation and must be supervised by an accredited research ethics committee. However, a university ethics committee may provide additional support in this task of ethical evaluation.

Although the UVic-UCC is not involved in clinical research, which tends to be undertaken by health institutions or biomedical research centres, it does carry out studies that require the approval of an ethics committee. Therefore, there is a clear need to establish a research ethics committee within the University, so that projects do not have to be sent to external ethics committees for approval, as has occurred to date. A research ethics committee within the UVic-UCC would enable

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<sup>4</sup> Decret 214/1997 pel qual es regula la utilització d'animals per experimentació i per altres finalitats científiques (DOGC No. 2450 of 7.08.1997).

<sup>5</sup> Real Decreto 1201/2005 sobre protección de animales utilizados para experimentación y otros fines científicos (BOE no. 252 of 21.10.2005).

any researcher to request information, advice and a statement on the research projects that they are planning. The creation of such a committee would also enable the University to join the “Network of Ethics Committees of Spanish Universities”, and share its experience with that of other universities in Spain.

The Committee will have its own tasks and functions, and will be governed by these Internal Regulations that describe the functioning and dynamics of its work.

The articles included in the Internal Regulations are detailed below.

## Article 1. LEGAL NATURE OF THE RESEARCH ETHICS COMMITTEE

The Research Ethics Committee at the University of Vic – Central University (hereafter CER) is an independent collegiate body designed to assess and classify projects. It will work transparently on issues related to the ethical implications of research. In its activities, the CER may take into consideration other regulations and documents that are relevant in Spain and internationally on the matter.

## Article 2. FUNCTIONS OF THE RESEARCH ETHICS COMMITTEE

CER functions include drawing up and approving reports, proposals, recommendations and other documents. Specifically, the CER will:

- Issue mandatory and binding reports, requested by the University’s faculties and research groups or directly by the researchers, related to research projects that, due to their contents or objectives, will be carried out on people, use personal data, human biological samples or genetically modified organisms, or involve animal experimentation.
- At the request of the principal researcher, tutors of bachelor’s degree and master’s degree final projects, supervisors of doctoral theses, the vice-rector for research, deans, or the director of the doctoral school, assess any other research project. In this case, there may be no obligation to provide a CER report, but the project may have a direct or indirect effect on the fundamental rights of people and their biological, psychological and social dimensions, the welfare of animals, and the defence and protection of the environment, or could have other objectives associated with a commitment to society or the environment.
- When necessary, draw up reports for the University’s governing bodies on the activity of the CER, or on ethical aspects that are relevant to the research carried out at the University.
- Promote training in bioethics for CER members and for the research community in general.
- Any other function that could be delegated to the CER by the University’s

governing bodies, in relation to ethical aspects of research developed by the UVic-UCC.

### Article 3. APPOINTMENT OF MEMBERS AND COMPOSITION OF THE COMMITTEE

Members of the CER will be appointed according to the criteria specified in the following paragraphs.

The CER is comprised of the following people:

- Vice-Rector for Research
- Two members of the Chair in Bioethics
- One person from the Technical Office of Research and Knowledge Transfer (OTRI).
- A representative of each faculty on the UVic Campus and on the Manresa Campus.
- The Coordinator of Chairs
- The Director of the Doctoral School
- A member of the Clinical Research Ethics Committee at the Hospital Consortium of Vic (HPH).
- Any other member who, in the future, could be of interest due to their profile and their contribution to the Committee's tasks.

All members will be appointed by the Rector, although Faculty representatives will be proposed by their respective deans, using criteria that they consider appropriate. The OTRI representative will be proposed by the Vice-Rector for Research; members from the Chair in Bioethics will be nominated by their director; and the member from the CEIC by internal agreement of this body. The aim will be to select as a representative a person with a sound knowledge of the research area to be developed. If possible, he/she should also have some knowledge and training in ethics or bioethics.

The other members are selected because of the position they hold (Vice-Rector for Research, Coordinator of Chairs, and Director of the Doctoral School).

CER members will remain on the Committee for 4 years, and may be appointed for one more period only (a total of 8 years). However, they may also voluntarily withdraw from the Committee or be replaced by an internal decision before their term of office is completed.

#### Article 4. CHAIRPERSON OF THE COMMITTEE AND FUNCTIONS

4.1. CER will be chaired by the University's Vice-Rector for Research or a person delegated by this Vice-Rector.

4.2. The Chairperson, who will be the representative of the CER, will chair meetings and carry out all the corresponding functions of representation. Specifically, he/she will draw up an assessment report for each project that is submitted. Reports will be sent to the researcher or research group that requested them.

4.3. With the exception of the Chairperson, CER members cannot claim to represent the Committee.

#### Article 5. SECRETARY OF THE COMMITTEE AND FUNCTIONS

The CER will have a secretary whose role will be to receive requests made to the Committee, receive documents for review and analysis, write the minutes of meetings, announce calls to meeting, and generally provide support for all the internal tasks of the CER.

The position of Secretary of the Committee will be held by the person designated by the Technical Office of Research and Knowledge Transfer (OTRI), and is therefore also a member of the CER.

#### Article 6. CER MEMBERS

6.1. CER members will remain on the Committee during their term of office, without

limiting the provision in Article 3. They will have full independence in the area of the Committee's tasks.

6.2. CER members must keep confidential their deliberations about the content of debates, and the information that they are provided of this nature or that which is recommended by the CER itself. In addition, Committee members must maintain the confidentiality of all the projects they assess, and the confidentiality of the contents of reports that are issued.

6.3. CER members should refrain from investigating, discussing or making decisions about matters in which their independence, impartiality or objectivity could be compromised. If the CER determines that some of the Committee members may have a conflict of interests in relation to projects submitted for evaluation, even when this is not stated specifically, the project could be discussed initially without this member, if their participation in the evaluation is required, or the member could be asked not to contribute to the discussions.

6.4. Members of CER have the right to participate actively in initiatives, discussions and in the Committee's decisions. They must give their thoughts, opinions and proposals, and take an active part in the tasks, in accordance with the provisions established in these Regulations.

6.5. CER members have the right and the duty to attend sessions. When they accept the role of member, they take on the commitment to attend meetings or to give a reason for their absence.

6.6. CER members shall undertake continuous training activities relating to research ethics and bioethics, in order to meet the standards required in these kinds of bodies. The Chair in Bioethics will be responsible for managing the training of members of the Committee and the scientific community.

## Article 7. GENERAL REGULATIONS ON THE FUNCTIONING OF THE RESEARCH ETHICS COMMITTEE

7.1. The Committee will function as defined in these Regulations, and in any other applicable regulations.

7.2. CER will meet at least once every two months, sufficiently in advance to fit in with calls for research projects, when required. The schedule for ordinary meetings will be announced at the start of the University's academic year. Specifically, researchers and research groups in different areas will be informed by the OTRI, so that they are all aware of the schedule.

CER could hold additional meetings if the demand from researchers is high enough to justify this. Researchers' requests will be grouped together in one meeting when possible, so as not to exceed the frequency of a meeting every month. However, when there is a specific project whose timing requires an extraordinary meeting, this could be called within 48 h, and considered legitimate if at least a third of the CER members are present, including the Chairperson.



7.3. The Chairperson will sign the notification of meeting that is drawn up by the Secretary and includes the order of the day, which will indicate whether there are projects to evaluate, and will provide CER members with revised documents on the projects in sufficient time.

7.4. For CER meetings to be legitimate, at least half of the members should be present. Decisions, and particularly statements, on the ethical evaluation of a project will preferably be made by consensus. If this is not possible, a vote will be taken and the simple majority will prevail. In this case, the Chairperson has the casting vote.

If it is not feasible for the CER to meet or a quorum cannot be obtained before the date on which the researcher needs the evaluation of the project, the CER will issue a certificate stating that the project has been presented to the Committee and is awaiting evaluation.

When, due to the type of project to assess, the CER considers that an expert on the topic should be present at the meeting, he/she can be invited as an ad hoc member with the right to speak but no decision-making capacity, and with the obligation of maintaining confidentiality.

In projects presented by a researcher that have already been evaluated and approved by another research ethics committee, whether in the medical, clinical or university environment, CER will accept the favourable report that has been issued. Likewise, the CER could initially revise a projects that is then passed on to another committee, and will attempt to include in its report all of the notable arguments or elements that will make it easier to process and validate the project subsequently.

## Article 8. SUBMISSION OF PROJECTS

8.1. Researchers or research groups that have projects to present to the CER for evaluation will send the request through the OTRI at least 15 days before the Committee's meeting date. If the assessment of the project in question is needed before the date of the ordinary meeting, the researchers will ask for an extraordinary meeting to be organised. Exceptionally, an extraordinary meeting will be held according to the provisions in Article 7.2.

8.2. CER has the authority to ask a project's researchers to expand on or complete the documents and information that they have provided if it is not considered to be detailed enough to evaluate the project properly. In addition, if required, the CER may ask the researchers to provide a certificate stating that the centre at which they will carry out the research has the facilities and security measures required to research particularly sensitive materials, such as genetically modified organisms and pathogenic microorganisms.

8.3. If research projects are coordinated with other institutions, the obligatory ethics evaluation report will generally be the responsibility of the institution to which the principal investigator is attached. In any case, the CER must be aware of

any report issued by another Committee and will address the issues that are the direct responsibility of the University, when appropriate.

#### Article 9. CLASSIFICATION OF PROJECTS

9.1. Once all of the documents have been examined and all conflictive points discussed, if there are any, projects or research tasks submitted to the CER will be classified as:

- a) Favourable
- b) Favourable, if formal errors are corrected and any additional documents that are requested are provided.
- c) Unfavourable (a reason must be given)

An appeal against this decision can be lodged with the Rector of the University, who will then respond to the appeal within 30 working days.

The report will be drawn up in the format that the Committee will design and which will be added as Appendix I of these Regulations, as soon as it is defined.

9.2. Reports will be sent out by the Secretary, with acknowledgement of receipt, after they have been written and signed by the Chairperson, according to the criteria established by the CER.

#### Article 10. SPACES, ARCHIVE AND DOCUMENTS

10.1. The CER will hold ordinary meetings in the OTRI headquarters, where it will have a meeting room, and the OTRI will be responsible for the archive and for the safekeeping of documents.

10.2. The CER document archive will be safeguarded by the Secretary. All minutes of meetings and all the documents on each project that is submitted and the final report must be kept, under clear archiving criteria that enable easy identification and location of documents when necessary.

#### Article 11. REFORM OF REGULATIONS

Proposal for any modifications in these regulations must be submitted in writing to the CER for analysis during an ordinary session. No modifications can be made to the Regulations that go against the legislation that is currently applicable in this area.

Proposals for modifications could be made by the members of the Committee

themselves, by the OTRI, or by heads of research groups, faculty deans, the Rector or other vice-rectors.

Approval of all modifications in the Internal Regulations will require the absolute majority of CER members and the approval of the University's Board of Governors.

#### FINAL PROVISION

These Regulations will come into force the day after their approval by consensus of the Board of Governors.