



Universidad de Jaén

Vicerrectorado de Investigación y
Transferencia del Conocimiento

INTERNAL REGULATIONS OF THE ETHICS COMMITTEE OF THE UNIVERSITY OF JAÉN

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Preamble

The regulations contained in the various calls for funding for research activities stipulate that proposals involving studies on human beings, the use of biological samples of human origin, animal experimentation, the handling of biological agents, or the use of genetically modified organisms must not only comply with the requirements established in each case in current legislation, but must also have a report issued by the Ethics Committee of the institution where the research is to be carried out.

Furthermore, the University of Jaén, aware of its duty and responsibility to society and its status as a public teaching and research institution, given the extensive legislation that has appeared in recent years on the subject, established an Ethics Committee that provides a swift and effective response to regulations, as well as to current and future needs, with respect to the bioethical principles and commitments assumed by the scientific community and by the Statutes of the University of Jaén.

The functioning of the Ethics Committee and its respective subcommittees will enable researchers at the University of Jaén to carry out their research work in accordance with the ethical principles agreed upon by the scientific community, within the framework of current legislation. This is in response to the great scientific and technical progress of the last century and its social implications, which are leading to the implementation of various measures to guide the research process and its applications, guaranteeing freedom of thought, creation and scientific production, as well as its balance with other values and rights that may be involved. These measures are mainly aimed at research involving interventions in and with human beings, their samples or data, research using animals, and research using biological agents and genetically modified organisms.

The Ethics Committee has been organised within the University of Jaén with the aim of responding to the ethical, methodological and legal issues that have arisen in relation to the primary function of university research. Ethics and scientific integrity are fundamental and must go hand in hand in the research process. This requires compliance with current regulations, so that interest in the aims and benefits of research is accompanied by respect for the participants, minimisation of the risks to which they are exposed, and observance and promotion of ethical and responsible behaviour in science.

Royal Decree 53/2013, of 1 February, establishing the basic rules applicable to the protection of animals used in experimentation and other scientific purposes, including teaching, provides, among other things, for the legal obligation to create an Animal Experimentation Ethics Committee (art. 37) in every institution that uses animals. In addition to having proceeded to the creation of this Animal Experimentation Ethics Committee (CEEA) at the University of Jaén, this

body has been designated as the 'Body Authorised for the Evaluation of Projects and Other Activities in the Field of Animal Experimentation' by the 'Competent Body in these Matters of the Autonomous Community', as provided for in Royal Decree 53/2013, of 1 February, which establishes the basic rules applicable to the protection of animals used in experimentation and other scientific purposes, including teaching.

Likewise, the Ethics Committee intends to comply with the data protection legislation contained in Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and Organic Law 3/2018 of 5 December on the Protection of Personal Data and Guarantee of Digital Rights, which aims to bring Spanish law into line with Regulation (EU) 2016/679. In particular, it is necessary to comply with letter h) of the seventeenth additional provision of the aforementioned Organic Law, which establishes that Research Ethics Committees, in the field of health, biomedicine or medicine, must include among their members a data protection officer or, failing that, an expert with sufficient knowledge of Regulation (EU) 2016/679 when dealing with research activities involving the processing of personal data or pseudonymised or anonymised data.

Article 1. Purpose and nature

1.1.- The purpose of these Regulations is to regulate the composition, functions and operating procedures of the Ethics Committee of the University of Jaén, as a body subject to current regulations on animal experimentation, biomedical research, data protection and biosafety risk prevention in the evaluation, from an ethical point of view, of research and development or technological innovation activities carried out at the University of Jaén.

1.2.- The Ethics Committee of the University of Jaén is an independent collegiate body with a multidisciplinary composition that promotes the development of ethics in research and facilitates and coordinates the activity of the Committees in the evaluation of scientific and technical research projects.

Article 2. Scope of application

2.1.- The main mission of the Ethics Committee of the University of Jaén (hereinafter the Committee) is to offer public assurance that research projects submitted to the supervision of this body have obtained a favourable opinion on procedural, ethical and legal aspects, and to ensure the protection of the rights, safety and well-being of subjects who participate in a research activity or for which they have provided samples or data.

To achieve this, the various committees that make up the committee will evaluate the ethical aspects of teaching and scientific research carried out at the University of Jaén that involve animal experimentation, biomedical experimentation on humans or with samples of human origin, and experimentation with biological agents or genetically modified organisms, in accordance with current legislation. biomedical experimentation on humans or with samples of human origin, and experimentation with biological agents or genetically modified organisms, in accordance with the provisions of current legislation.

2.2.- The Commission also extends its competence to investigations that use personal data subject to confidential treatment because it affects the rights and freedoms of individuals, interests related to the defence and protection of the environment, or other constitutionally and legally protected assets.

2.3.- The Commission, through its various Committees, shall report on teaching and research protocols carried out at the University of Jaén that have ethical implications. In the event that these protocols involve subjects or biological samples from other institutions, a positive assessment from their respective Bioethics Committees or similar bodies shall be required.

Article 3. Affiliation

The Ethics Committee is a body attached to the Vice-Chancellor's Office with powers in the field of research at the University of Jaén. It is independent in its operation and decision-making.

Article 4. Structure and composition

4.1.- The Ethics Commission is composed of three committees with their respective coordinators, a Board of Directors, and a General Coordination.

4.2.- The Commission's Management Board shall comprise the Vice-Chancellor responsible for Research, who shall act as chair, the Commission's General Coordinator, who shall act as secretary, and the coordinator of each of the Committees, who shall act as members.

The Board of Directors shall be ultimately responsible for the reports issued by the Committees.

4.3.- The main mission of the Committees of the Ethics Commission of the University of Jaén is to issue reports, proposals and recommendations to the University of Jaén on matters related to the ethical implications of research within its sphere of action. In particular, the following committees are established:

- Human Research Ethics Committee (HREC)
- Animal Experimentation Ethics Committee (CEEA)
- Ethics Committee on Research with Genetically Modified Organisms and Biological Agents (CIOMAB)

4.4.- Each Committee shall have a minimum of four members, except as provided for in the relevant regulations. A coordinator shall be appointed from among its members and shall be appointed by the Chair of the Commission's Governing Board on the proposal of the General Coordination.

The Committees may seek advice from research staff at the University of Jaén who are experts in legislation related to ethics.

Efforts shall be made to achieve gender parity in the composition of these committees.

Article 5. Functions of the Ethics Commission

The Ethics Committee of the University of Jaén has the following functions within its sphere of competence:

- Ensuring compliance with good research and experimentation practices, as well as developing and maintaining the University of Jaén's Code of Good Research Practice.

- Approve the proposed reports submitted by the Ethics Committees.
- Certify, on behalf of the chair, the accreditation of the procedures employed, provided that they have been previously evaluated and approved by the Commission, when required in the case of manuscripts intended for publication.
- Prepare reports for the University's governing bodies on ethical issues related to the above sections that may arise in research and teaching.
- Undertake activities aimed at raising awareness and understanding of the ethical implications of research, as well as improving communication on this subject among research staff, research institutions and society in general.
- Promote continuing education activities for its members on the methodological, legal, and ethical aspects of the research activities to be evaluated.
- Ensure the confidentiality of the data of those participating in the research.
- Coordinate its activities with those of similar committees from other institutions that may be related.
- Support the work of the Committees, without prejudice to their independence.
- Approve the working procedures of the Committees.
- Prepare, through the General Coordination, the Annual Report that will collect data on its activity, evaluation and assessment thereof.
- Any other functions assigned to them by current legislation.

Article 6. Functions of Ethics Committees

Each of the Ethics Committees of the University of Jaén has the following functions within its area of competence:

- Evaluate applications arising from research projects or work.
- Issue draft reports at the request of institutions or researchers on projects or research work to be carried out at the University of Jaén within the scope of their respective areas of expertise.
- Any other functions assigned to it by current legislation.

Article 7. Functions of the Ethics Committee's Governing Board

The functions of the Board of Directors are:

- Intervene exclusively in the event of a negative assessment issued by an Ethics Committee, under the terms set out in Article 14.3.
- Propose to the Governing Council of the University of Jaén the creation of other Research Ethics Committees, as well as the modification of the powers of existing ones.

Article 8. Functions of the General Coordination of the Ethics Committee

The person responsible for General Coordination is responsible for:

- Convene meetings, lead and moderate them.
- Draft and keep the corresponding minutes.
- Establish control measures to ensure the submission and receipt of documentation to the Committees.
- Invite experts where appropriate.
- Promote and organise events that support the work of the Committees.
- Ensure compliance with the Regulations.
- Safeguard declarations of conflict of interest that may be made by any member of the Committees when evaluating a project.
- Propose to the Vice-Chancellor responsible for Research the members who may form part of the Committees.

Article 9. Human Research Ethics Committee (HREC)

9.1.- The Human Research Ethics Committee (HREC) is responsible for evaluating projects involving human subjects and those requiring the processing of personal data.

9.2.- It will be composed of a healthcare professional and representatives from those centres at the University of Jaén that offer teaching in the field of biomedical sciences. Its members will include an expert with sufficient knowledge of personal data protection or the Data Protection Officer of the University of Jaén. Likewise, external personnel from the University of Jaén who are experts in legislation related to ethics may also be included.

Article 10. Animal Experimentation Ethics Committee (CEEA)

10.1.- The Animal Experimentation Ethics Committee (CEEA) is the body responsible for animal welfare (OEBA) and for ensuring the proper evaluation of projects that use animals in experimentation and other scientific purposes, including teaching.

10.2.- This committee will include the person responsible for animal health and welfare at the University of Jaén, the person responsible for scientific matters at the University of Jaén's Animal Production and Experimental Centre (CPEA), two members of the research staff with experience

and knowledge of animal welfare and experimentation at the University of Jaén, and one person who has no direct connection with the projects, but who has experience and knowledge of animal welfare and experimentation.

Article 11. Ethics Committee on Research with Genetically Modified Organisms and Biological Agents

11.1.- The Ethics Committee on Research with Genetically Modified Organisms and Biological Agents is responsible for evaluating projects involving the use of genetically modified organisms or biological agents.

11.2.- Its composition includes an Occupational Risk Prevention technician from the University of Jaén and research staff from the University of Jaén with experience in research involving the use of biological agents and genetically modified organisms.

Article 12. Membership requirements

12.1.- The General Coordination of the Ethics Committee shall belong to the group of teaching staff with a PhD and permanent employment status.

12.2.- The person who assumes the functions of General Coordinator of the Ethics Committee shall be appointed by the Governing Council, at the proposal of the Vice-Chancellor for Research, for a term of two years, which may be tacitly renewed for equivalent periods up to a maximum of six years.

12.3.- The members of the various committees shall be appointed by the Vice-Chancellor on the recommendation of the Vice-Chancellor responsible for research, after consultation with the General Coordination Committee, from among the teaching staff of the University of Jaén and external personnel, as indicated in the composition of each committee.

Article 13. Confidentiality and data protection

The members of the Commission and the Committees shall be bound by the principle of confidentiality and shall not disclose to third parties any information they become aware of through their participation in these bodies. They shall comply with the obligations set out in the data protection regulations in force.

Article 14. Basic rules of internal operation

14.1.- The Ethics Committee shall hold an annual meeting with the various committees in order to inform them and ensure their proper functioning.

14.2.- The Ethics Committee shall act in full compliance with current legislation and, specifically, with the Statutes of the University of Jaén and other regulations implementing them, as well as with the recommendations and statements of both national and international scientific and technical research bodies and internationally recognised scientific protocols.

14.3.- The Committees shall report on and grade research projects or work in the following ways:

- a) Positive evaluation: favourable report.
- b) Positive assessment pending the provision of additional documentation proving compliance with the requirements for the issuance of a conditional favourable report.
- c) Pending correction. Relevant data will need to be provided for proper assessment by the Committee within the timeframe determined by the Committee.
- d) Negative assessment: unfavourable report which must be justified and subject to reassessment if the applicant provides sufficient grounds to justify a new study. In this case, the relevant Committee shall issue a new report. If the report remains unfavourable and a new reassessment is requested, the Commission's Management Board shall take a reasoned decision on the appropriate course of action.

An appeal may be lodged with the Rector against the decision made by the Commission's Governing Board, which does not exhaust the administrative process, in accordance with the provisions of current administrative procedure legislation, within one month from the day following the date of notification.

14.4.- The members of the Ethics Committee and its respective subcommittees participate in these bodies under their own responsibility, with complete independence, impartiality and objectivity of judgement.

They shall refrain from participating in the examination, deliberation and decision-making of matters in which they are directly interested or affected, or in which their independence, impartiality or objectivity of judgement could be compromised. They are obliged to declare any conflict of interest they may have in the evaluation of a project, and shall refrain from participating in its evaluation.

Conflict of interest declarations shall be kept by the General Coordination Office, with the corresponding exclusion from the evaluation of research activities of those members who have declared the existence of a conflict.

Final Provision

In accordance with Article 30 of the Regulations governing the organisation and functioning of the Governing Council of the University of Jaén, these regulations shall take full effect from the moment of their approval, without prejudice to their subsequent publication in the Official Gazette of the University of Jaén.