

ANIMAL EXPERIMENTATION ETHICS COMMITTEE (AEEC)

University of Jaén

Internal operating regulations

Article 1.- Justification and scope

The Animal Experimentation Ethics Committee (AEEC) is part of the Ethics Committee within the Vice-Chancellor's Office for Research, Technological Development and Innovation at the University of Jaén (UJA). It is established as the body responsible for complying with Royal Decree 53/2013 of 1 February 2013, which in Chapter VI, Articles 37 to 39, sets out the 'Creation of bodies responsible for animal welfare'. Specifically, Article 37 states:

1. Each breeder, supplier and user shall establish an Animal Welfare Body, hereinafter referred to as 'AWB'. For users, this body shall be called the Animal Experimentation Ethics Committee (AEEC).

2. The AWB shall adopt internal regulations defining and developing its composition and basic functioning according to criteria of confidentiality and representativeness, guaranteeing impartiality in the decisions taken by it. Single-member AWB shall be exempt from this requirement.

Article 2.- Functions

2.1. The following functions correspond to the AEEC of the University of Jaén, within its sphere of competence and in accordance with Royal Decree 53/2103:

- a) Advise animal care staff on matters relating to animal welfare in terms of acquisition, accommodation, care and use.
- b) Advise staff on the application of the requirement for replacement, reduction and refinement, and keep them informed of technical and scientific advances in the application of that requirement.
- c) Establish and review internal operational processes with regard to the control, communication and monitoring of information related to animal welfare.

- d) Advise on rehoming or adoption schemes, including the appropriate socialisation of animals to be rehomed or put up for adoption.
- e) It shall prepare the report(s) referred to in Article 33.1 of Royal Decree 53/2013 and shall monitor the projects, taking into account their effect on the animals used, as well as determining and evaluating the elements that best contribute to replacement, reduction and refinement.

2.2. Furthermore, based on its functions as AWB and, where applicable, as the body authorised by the competent authority, it is also responsible for:

- a) Propose, evaluate and inform researchers about the animal welfare studies necessary to determine the establishment of a line of genetically modified animals, and that, under the conditions maintained, these animals do not experience pain, suffering, distress or lasting harm equivalent to or greater than that caused by the insertion of a needle.
- b) Review projects already evaluated, corresponding to types II and III (retrospective evaluation) and, where necessary, inform the researcher responsible for the project of any deviations observed.
- c) Notify the administrative officer referred to in Royal Decree 53/2013 of any relevant modifications to any project that has already begun and does not have authorisation.
- d) As an authorised body, it must submit a detailed annual report on its activities to the competent body, which shall include at least a list of all the projects it has assessed.

Article 3.- Composition of the AEEC

3.1. As established by Article 39 of Royal Decree 53/2013:

- 1. *The AEEC must be composed of individuals with the necessary experience and knowledge to ensure the welfare and care of the animals. It shall be composed of at least the following members:*
 - a. *The person responsible for the welfare and care of animals*
 - b. *A researcher or other scientific member.*

c. In the event that the animal experimentation ethics committee acts as the body authorised to carry out the assessment or retrospective assessment of projects, its composition shall also include researchers or other scientific members who are not directly involved in the project and a person with experience and knowledge of animal welfare who has no direct relationship with the user or the project.

3.2. In accordance with the above premises, the AEEC of the UJA, as agreed by the Governing Council on 19 July 2013, is composed of the following members:

- The person responsible for managing the Animal Production and Experimentation Centre (APEC), who will act as coordinator of the AEEC and serve as Secretary of the Governing Board of the UJA Ethics Committee.
- The Head of Animal Health and Welfare at the APEC
- The Scientific Director of the APEC, a researcher chosen from among the UJA departments that conduct experiments with animal models or their tissues.
- Two researchers with experience and expertise in animal welfare and experimentation.
- A person outside the UJA who has no direct relationship with the centre or its projects, with experience and knowledge in animal welfare and experimentation, and who holds at least categories C and D1 accreditation.
- Occasional assistance may be requested from a person with experience in statistics and experimental design and, depending on the projects, advice may be sought from experts outside the AEEC for the analysis of aspects of the evaluation subject matter.

Article 4. - General operating rules

4.1. The Committee shall operate in accordance with the provisions of these Regulations and the legislation in force on the legal regime of public administrations.

4.2. The AEEC shall meet once every four months on a regular basis, and on an extraordinary basis whenever research project calls so require, or when requested by at least one third of its members.

4.3. All meetings shall be convened sufficiently in advance, attaching to the notice of meeting the agenda for the meeting and the corresponding documentation.

4.4. For the Committee to be constituted, the minimum number of members established by Royal Decree 53/2013 and mentioned in these regulations in points 3.1, 1a, 1b, and 1c must be present.

4.5. No member may delegate their duties or be replaced at the Committee's face-to-face meetings.

4.6. Committee members who are unable to attend any of the meetings may send the coordinator their comments and opinions on the procedures to be evaluated, which will be taken into account in the evaluation process carried out during the meeting.

4.7. Committee members shall be bound by the principle of confidentiality, both in terms of prior information and in discussions or reports.

4.8. Committee members shall abstain from proceedings affecting projects in which they participate as researchers or in other cases where conflicts of interest may arise.

4.9. When the Committee deems it appropriate, it may seek the opinion of external experts, who shall also be subject to the principle of confidentiality.

4.10. The Committee has the authority to request from the researchers of a project under evaluation any additional information it deems necessary.

Article 5. - *Approval of procedures*

5.1. Resolutions shall be adopted by a simple majority of the members present at the meeting, a simple majority being understood to be when the votes in favour exceed the votes against by one.

5.2. In the event of a tie, the vote shall be repeated, and if there is still a tie, the coordinator shall have the casting vote.

5.3. No proposal that is not included in the agenda may be agreed upon, unless it obtains the favourable vote of the majority.

5.4. For projects or research work submitted to the AEEC for review, and once the documentation submitted has been examined, modifications or the provision of additional information may be required.

5.5. A positive evaluation of the procedure, project or research work shall determine the issuance of the corresponding favourable report.

5.6. When the research project or work is positively evaluated, subject to the correction of any formal defect or the provision of additional documentation proving compliance with the requirements for this purpose, a conditional favourable report will be issued. In this case, the AEEC will request the correction of the defect or the provision of supplementary documentation from the person responsible for the research. Once the formal defect has been corrected or the additional documentation has been provided, the corresponding favourable report will be issued. The decisions thus adopted will be reported to the Committee Plenary at its next meeting.

5.7. The issuance of an unfavourable report must in all cases be justified and subject to reassessment if the applicant can provide sufficient grounds to justify a new study.

5.8. All reports shall be sent by email from the Vice-Chancellor's Office for Research, Technological Development and Innovation to the interested party before being processed and sent to the competent authority.

Article 6. - *File and documentation*

6.1. The Committee's file shall remain in the custody of its Coordinator.

6.2. This file shall contain the originals of the minutes, a copy of all reports, and any other documentation generated during the information and evaluation process. This file may be consulted by any member of the Committee.

6.3. To facilitate filing and documentation, all projects and procedures will be assigned an identification number.

6.4. The researcher responsible for the project shall complete all documents and forms provided by the AEEC via its website, including those required by the Competent Authority of the Regional Government of Andalusia in cases where the AEEC acts as the Authorised Body for project evaluation.

6.5. The safekeeping and custody of information and documentation shall be as established in Article 38, and for the purposes of Articles 40 and 41 of the Royal Decree.