

ETHICS COMMITTEE ON RESEARCH AND ANIMAL WELFARE OF THE UNIVERSITY OF LA LAGUNA REGULATIONS

STATEMENT OF MOTIVES

The University of La Laguna (ULL), as public research and teaching body, is aware of its responsibility to society in terms of monitoring and control of the research carried out in it and its ethical aspects, such as imposed by art. 15 of Act 14/2011, of June 1, on Science, Technology and Innovation. To be able to do it effectively, it constitutes an Ethics Committee on Research and Animal Welfare, under the provisions of article 12 of Act 14/2007, of July 3, on biomedical research, as well as in the Royal Decree 53/2013, of February 1, establishing the applicable basic rules for the protection of animals used for experimentation and other scientific purposes, including teaching.

In this way, it intends to provide an agile and effective response to current needs or those that may arise in the future, regarding scientific research developed in its field, in order to protect people's fundamental rights, animal welfare and the environment and the respect for the bioethical principles and commitments assumed by the scientific community and by the Statutes of the University.

Its functions, composition and basic operating rules are those contained in these Regulations, which replaces the previously in force, in order to adapt them to the new rules that have been passed in this topic.

Furthermore, the regulations contained in different calls for research funding requires those projects involving research in the biomedical area or in humans, the use of personal data or biological samples of human origin, animal experimentation or use of biological agents or genetically modified organisms, and other areas, not only to meet the requirements established in each case by current legislation but also to obtain the explicit authorization issued by the Ethics Committee of the Center where the research is to be carried out, for which the constitution of an ethics committee in each research centre is needed.

Article 1. Committee's functions

The functions of the Ethics Committee on Research and Animal Welfare (Comité Ético de Investigación y Bienestar Animal) (CEIBA) of the University of La Laguna (from now on the Committee), within its scope, are the following:

1.1. To issue the reports requested by the research staff of the ULL, and by the researchers from other research institutions who request it, on projects or research work involving human studies, use of personal data or biological samples of human

origin, use of animals for experimentation and teaching or use of biological agents or genetically modified organisms, or any other project that by its nature involves security risks, without prejudice to the powers that, in the case of use of data or samples of patients correspond to the Ethics Research Committees of health centres.

1.2. To assess any other research project that may affect the fundamental rights of people, the welfare of animals and interests linked to the defence and protection of the environment.

1.3. To ensure compliance with good research practices and experimentation and to prepare the recommendations that it considers pertinent.

1.4. To prepare reports on the ethical problems that may arise from research and teaching.

1.5. To promote debate in the university community on ethical research issues of general interest.

1.6. Any other functions attributed to it by current legislation.

Article 2. Composition and appointments

2.1. The Committee shall be composed of at least:

- A representative person, belonging to the teaching and research staff of the University of La Laguna, from the following branches of knowledge:

- Arts and Humanities
- Sciences
- Health Sciences
- Social and Legal Sciences
- Engineering and Architecture

In any case, there will always be a representative person, belonging to the teaching and research staff at the University of La Laguna, of:

- Ethics or Political Philosophy
- Law

Also, a minimum of three people with the experience and knowledge necessary to ensure the well-being and care of the animals, which will be the following:

- a) The Specialist responsible for animal welfare at the University of La Laguna.
- b) Two researchers with animal research experience and the accreditation for the actions described in article 15 2.d -Design of the projects and procedures- (according to RD 53/2013), not being able to act in the procedures in which they are involved or in which they present a conflict of interests. They may be representatives of the ULL Quality Assurance Unit, or be an external member, without a direct or contractual relationship with the ULL.

2.2. The appointment and removal of those who form the Committee, as well as the appointment of those who must exercise the functions of Presidency, vice-Presidency

and Secretariat corresponds to the Rector, on the proposal of the Plenary of the Committee, who will inform the University's Executive Board (*Consejo de Gobierno*).

2.3. The Committee will be renewed by halves every four years, and its members may opt for reelection.

2.4. No one holding the vocals can delegate their functions or be substituted or replaced at the Committee sessions.

2.5. The Committee will establish subcommittees to study projects related with experimentation on humans, animals, biosecurity or other matters when the number, deadlines or the nature of the reports to be carried out so require.

Article 3. General operating rules

3.1. The operation of the Committee will be subject to the provisions of these Regulations and in the current legislation on the legal regime of public administrations.

3.2. Whoever holds the Presidency will convene the Committee at least once a year, whenever the calls for research projects so require, or when a quarter of its members request it. These meetings may be held by telematically if deemed necessary, following the provisions of Act 40/2015, of October 1, on the Legal Regime of the Public Sector.

3.3. The Committee will work in plenary and in subcommittees. The Subcommittees will carry out how many functions are delegated to them by the Plenary. The Plenary may advocate for itself the knowledge of any matter.

3.4. For the constitution of the Committee's Plenary Session, the presence of at least the half plus one of their members on the first call, while on second the assistance of a third of the people who integrate it would suffice. The Meetings will be called by whoever holds the Secretary of the Committee, with the approval from the President, with a minimum notice of forty-eight hours. A simple majority will take the decisions of the Committee.

3.5. The work of the subcommittees to be determined, especially if they are for the evaluation of a request for a report may be made through the computer application which has been made available for the Committee's activity by the Research Vice-chancellor of the ULL.

3.6. The Committee's members will be bound by the principle of confidentiality of both discussions and reports.

3.7. The Committee's members must abstain from the procedures that affect projects in which they participate as research staff or in other cases in which conflicts of interest may arise.

3.8. When the Committee considers it appropriate, it may seek the opinion of external staff with experience, which will also be subject to the principle of confidentiality. The Secretary, at the request of the Committee's majority, will make the request with the approval of whoever holds the Presidency.

3.9. The Committee is competent to request researchers of a project under evaluation the additional information it considers necessary. The Secretary, at the request of the

Committee's majority, will formulate the petition with the approval of whoever holds the Presidency.

3.10. The reports will be issued within a maximum period of one month from their entry into the Registry of the Committee, dependent on the Research Vice chancellor's Office.

Article 4. Projects' submission

The evaluation request, as well as the research documentation that requires a report from this Committee, must be submitted electronically through the CEIBA computer application, dependent on the Research Vice chancellor's Office.

Article 5. Qualification of research projects or works subject to Committee report

5.1. Research projects or works submitted to the Committee's Plenary report, once the documentation submitted has been examined will be classified in one of the following ways:

- a) With a favourable report.
- b) With a favourable report conditioned on the correction of formal defects or the provision of additional documentation expressly requested.
- c) Resolution pending.
- d) With unfavourable report.

5.2. Positive evaluation of the ethical research aspects involved in the project or research work will determine the issuance of the corresponding favourable report.

5.3. When the research project or work is qualified as described in section 5.1.b) of this article, the Committee will request the correction of the defects or the provision of supplementary documentation to whoever responsible for the investigation. Strict compliance with what is requested, which will be verified by whoever holds the Secretariat of the Committee with the approval of its President, will have the effects provided in the previous section. The decisions thus adopted will be reported to the following Committee's Plenary Session.

5.4. When the Committee' Plenary observes in the submitted documentation the absence of data whose content is relevant to positively or negatively evaluate the project or research work in question, will qualify as pending resolution and will request the responsible researcher for clarifications or pertinent details. Once such clarifications have been received, the final decision shall be adopted by the Committee at its next session.

5.5. The issuance of an unfavourable report must, in any case, be motivated.

Article 6. File and documentation.

The file of the Committee will remain in the custody of its Secretariat.

The originals of the Minutes will be kept in this file, a copy of all the reports as well as any other documentation generated in the process of information and evaluation. This

file may be consulted by anyone that integrates the Committee and will be included in the computer application of the Committee.

REPEALING PROVISION: The University of La Laguna's Research Ethics Committee Regulations, approved by the Executive Board of this University in its session on May 14, 2010, are repealed by these Regulations.

FINAL PROVISION: These Regulations will enter into force the day after their publication in the Official Gazette of the University of La Laguna