Pontificia Universidad Católica del Perú's Research Ethics Committee

Regulations

VICERRECTORADO DE **INVESTIGACIÓN**
COMITÉ DE ÉTICA DE LA **INVESTIGACIÓN**
OFICINA DE ÉTICA DE LA **INVESTIGACIÓN** E **INTEGRIDAD CIENTÍFICA**
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Regulations of the Pontificia Universidad Católica del Perú's Research Ethics Committee

Section I. The committee and its organization

Chapter I. The committee

Article 1:

The Research Ethics Committee (hereinafter, "the Committee") is in charge of ensuring the ethical commitment of all researchers, as well as of certifying and supervising that every research submitted for their consideration, both if carried out or sponsored by the university or by third parties, abide by the research ethics principles.

Article 2:

The Committee shall:

a. Assess, approve, reject, suggest amendments, supervise, or interrupt any research projects that involve humans, animals, and ecosystems within the framework of national and international ethical standards.

b. Promote different training activities in research ethics geared towards the university community.

c. Make varying efforts to disseminate their role and activities that foster ethical reflection about research issues.

Article 3:

The Committee consists of the following members, appointed for a two-year period:

a. The Chair, who presides over the sessions of the Executive Committee and the Full Committee, and represents the Committee before other bodies.

b. The Vice-Chair, who assumes the Chair's responsibilities in the event of his or her absence.

c. A faculty member per each University department, who shall be elected by the Head of the corresponding Academic Department and ratified by the Department's Board. The faculty members may be reelected by their corresponding departments.

d. Three external members appointed and re-elected by the Research Vice-Rectorate.

Chapter II. Work instances

Article 4:

The Committee has two work instances:

a. The Full Committee, comprised of all members. The Full Committee elects the Chairman and vice-Chairman, positions that are assumed by two members of the faculty.

b. The Executive Committee, elected by the Full Committee and consisting of five members, one of whom is the Chairman.

Article 5:

The Executive Committee will hold ordinary sessions every fortnight and may celebrate extraordinary sessions.

The quorum required for the Executive Committee to hold session is half plus one of its members. Decisions are made by simple majority. In the event of a tied vote, the Chairman shall bear the casting vote.

When a member of the Executive Committee is unable to continue fulfilling his or her responsibilities (attending meetings and reviewing research projects, among others) he or she may request the Executive Committee to appoint a replacement.

Article 6:

The Full Committee holds sessions at least once every six months. The Chairman may convene the Full Committee for sessions or require support from some of its members, as needed.

The quorum for the Full Committee to hold session is half plus one of its members. Decisions are made by simple majority. In the event of a tied vote, the Chairman shall bear the casting vote.

When a member of the Full Committee has not fulfilled the minimum required attendances (two consecutive absences or half of the sessions), their department will be asked to choose a replacement to hold the position for the remainder of the initial member's commission.

Chapter III. Duties of the members

Article 7:

The duties of the Committee members are as follows:

a. To guarantee respect for the rights of humans, the well-being of animals and the protection of the ecosystems during research, as well as to guard scientific rigor.

b. To handle the research protocols proposed to the Committee, the internal deliberations on each of them, and the personal information on research participants confidentially.

c. To consult with experts in the field of the approved research when deemed appropriate.

d. To communicate to the Committee any facts that can be characterizes as a conflict of interests. The involved member must abstain from giving an opinion and voting in the corresponding decision.

e. To foster reflection on ethical issues, generate spaces of interest for public dissemination, and participate in education activities on research ethics within the university community.

f. To educate themselves in research ethics during their first year as part of the Committee.

Section II. Research work

Chapter I. Researchers

Article 8:

The duties of the Researchers are as follows:

a. To observe all ethical principles of Research expressed in these regulations, as well as to follow the procedures required by the Committee and its Technical Secretariat.

b. To implement appropriate protection mechanisms to guarantee the rights and the well-being of the humans, animals, and ecosystems involved in the research work.

c. To assume the design, planning, the execution and communication of research results responsibly.

d. To establish transparent processes in their projects that will allow them to identify conflicts of interests involving the institution or the researchers.

Chapter II. Research with humans

Article 9:

For the purposes of research with humans, all live human beings are considered moral subjects, considering that there are differences in the degree of moral agency or ability to make moral decisions among them.

Also, every human matter used in research, such as corpses, human remains, cells, tissue, or biological fluids of the species is considered an object of moral concern.

Article 10:

Research work with humans is governed by the following principles:

10.1. Respect for the people

This principle demands the recognition of the autonomy of people and the protection of those whose autonomy is somehow diminished.

Observing this principle entails providing research subjects with the suitable information and having them participate voluntarily in the research work; additionally, providing them with the possibility to withdraw if they decide to do so. It entails also respect for their fundamental rights, particularly, if they are in a situation of special vulnerability, whether due to age, disease, mental disability, or due to economic, cultural, or other circumstances that affect their autonomy.

10.2. Beneficence and non-maleficence

It is the researcher's duty to ensure the well-being of the people who participate in their research works. The researcher must make sure that his or her behavior does not cause any harm to the subjects being research, to other researchers or third parties. Also, the researcher must try to reduce or compensate the possible adverse effects and to maximize the benefits of the research.

The researchers have an obligation to guard compliance of the precautionary principle, both in research works performed and in the dissemination of results, recognizing the right of the Peruvian society to know the long-term benefits and risks resulting from the acquisition of new scientific knowledge or new research methods.

10.3. Justice

The researcher must exert reasonable judgment and take the necessary precautions to make sure that his or her bias, as well as the limitations to their capabilities and knowledge, do not give rise or tolerate unfair practices. A benefit must not be denied to any person who has a right to it, without a reasonable reason, nor impose such person an undue load. It is recognized that fairness and justice grant all individuals participating in the research a right to access their results. The confidentiality that a researcher is bound to regarding personal information of the subjects participating in their study, the professional secret promised previously to any of the parties or the common good of society are limitations to this right.

Also, the researcher must treat equitably those who participate in the processes, procedures, and services related to the research work.

10.4. Scientific Integrity

This principle demands honest and truthful action in the obtaining, use, and conservation of the data that serves as a basis for a research work, as well as in the analysis and communication of its results. Integrity or righteousness must govern not only the researcher's scientific activity but also include an appreciation about the origin of the funds and the procedures used in obtaining them, in addition to extending to their teaching activities and their professional exercise.

The integrity of the researcher is especially relevant when, based on the code of ethics of their professional activity, potential damages, risks, and benefits that could affect those participating in a research work are assessed and declared. This includes the need to declare any conflicts of interests that may affect the course of a study or the disclosure of its results.

10.5. Responsibility

The researcher must be aware of his or her scientific and professional responsibility before society. Particularly, it is a personal responsibility of the researcher to carefully ponder the consequences of the performance and dissemination of their research work for all participants, and for the overall society. This duty and responsibility cannot be delegated to other people. Neither the act of delegating nor the act of receiving instructions releases any responsibility.

It is the obligation of the individual conducting the research to guarantee that the people in their team are qualified to perform the functions assigned to them and they take responsibility for the fulfillment of the principles contained in these regulations.

Not being familiar with these ethical principles or with the regulations on the matter does not exempt the researcher or his/her team of any responsibility for the consequences of their research works.

Article 11:

In addition to the duties set forth in Article 8, for human research purposes, the researchers' duties are as follows:

a. To provide information to the participants on the objectives, the nature of the research, use of the collected information, possible risks and benefits, and all the doubts that the participant would like to solve with respect to the research work.

b. To guarantee the confidentiality of the information and knowledge provided by participants using suitable procedures for it. Based on the research objectives, the researcher may consider the option of participant anonymity instead of confidentiality. When requested by participants or when the researcher deems it necessary, the participants' authorship of and contribution to the production of knowledge shall be explicated or anonymity shall be ensured.

c. To respect the freedom and autonomy of subjects to participate in the research work or to withdraw from it same if later decided.

d. In the event of research work with non-consenting participants or minors, an informed consent must be obtained from the legally authorized person.

e. When the research works include minors over 12 years of age, an informed assent must be obtained. The informed assent given by minors does not preclude from obtaining an informed consent from the legally responsible individual, except in cases where the study problematic so requires.

f. The researchers must not conduct any research works that involve techniques to deceive participants, except in circumstances where its use is justified and the benefit derived from research widely surpasses any potential damage to these participants.

g. To satisfy any commitments assumed with participants in their research works and with the institutions that have provided any type of collaboration with the study.

h. To return study results whenever possible, or alternatively, provide access to them.

i. To disseminate research findings among the academic community and the society at large in order to contribute to their knowledge and development.

Chapter III. Research with animals

Article 12:

For animal research purposes, the species capable of developing interests based on their capacity to feel and, specifically, experience more sophisticated forms of well-being or neurophysiologic suffering are considered to have moral status, among them, according to scientific evidence, all vertebrate species: mammals, birds, fish, reptiles and amphibians; and some invertebrate species.

Based on their moral status, the interests of these species require respect and protection. It implies developing consultation procedures with institutions that know them and guard their interests.

The interests of the species for which there is no consensus regarding their moral status must be respected and protected to the largest extent possible.

Article 13:

Research with animals is governed by the following principles:

13.1. Principle of Replacement

If the scientific objectives of the research can be attained without the resorting to animals, it will be mandatory to replace their use with alternative means. The use of animals with a greater ability to feel must be replaced with the use of animals with a lower ability to feel, and the use of the latter with the use of non-sentient entities.

13.2. Principle of Reduction

The number of animals used must be reduced to a minimum. Moreover, the use of wild animals as well as of protected or endangered species must be avoided.

13.3. Principle of Refining

Any harm caused by research onto the animals must be reduced to a minimum. Harm is understood as any observable harm caused to animals, including death, pain, suffering, distresses and other lasting or irreversible adverse consequences. The damage must be considered adopting a holistic perspective towards the multiplicity of potential adverse factors. It is fundamental to determine the degree of severity of the damage toward the animal. In general, research should be guided by the assumption that procedures that probably generate pain in humans also cause it in animals, except for any specific evidence for the species that indicates otherwise. The reusability of an animal in research must take its complete recovery, lifespan and level of damage into consideration.

13.4. Principle of Harm/Benefit Ratio

The lower the damage to the animal and the greater the value of the benefit derived from the research, the greater will be the rationale to do it. A research work is acceptable when the damage involved is surpassed by the benefits of the research for humans, other species, or ecosystems.

13.5. Preventive Principle

The researcher must prevent all harm to animals to the largest extent possible. This demands a detailed assessment of the potential risks of the research work.

13.6. Precautionary Principle

When the research work entails danger of serious or irreversible damage or disruption, the lack of absolute certainty about this danger shall not be used as a reason to delay the adoption of effective measures to prevent it. This requires, to the largest extent possible, a complete evaluation, the determination of the degree of uncertainty, and risk evaluation.

13.7. Principle of Responsibility

The researcher and his or her team are responsible for the risks or damages that the research work using animals generates. In that sense, there is an obligation to adopt measures of restoration, rehabilitation, repair, and compensation for the damage caused. The researcher and his or her team must be informed about the behavioral and biological characteristics of the animals under study and must be qualified to take care of, maintain and handle these animals.

Article 14:

In addition to the duties set forth in Article 8 of these regulations, for animal research purposes, the researchers' duties are as follows:

a. To develop procedures that adjust to the Replacement, Reduction, and Refinement principles so as to minimize damage to animals. The researcher must consider these principles sequentially.

b. To justify that the benefits derived from the research work widely surpass any real or potential damages to the animals.

c. To respect the professional standards corresponding to the work with animals, ensuring their health and well-being.

d. To create a protocol that considers the procedures that will be carried out with the participant animals in the study once it is finished, in order to guarantee their health and well-being.

e. To secure the advice of health or animal behavior professional with experience in research work.

Chapter IV. Research in ecosystems

Article 15:

For the purposes of research in ecosystems, these are considered objects of moral concern, due to their intrinsic value and their relationships of interaction with all live beings.

Based on this moral concern, the ecosystems require a certain level of respect and protection, which entails developing consultation procedures with institutions that know and guard their interests.

The research work shall not generate harm or disruption to the ecosystems.

Article 16:

Research in ecosystems is governed by the following principles:

16.1. Principle of Conservation

The researcher must lend particular attention to the protection and well-being of the ecosystems, especially those with protected and endangered species. The research work shall not jeopardize the long-term sustainability of the ecosystems and species that integrate them, which must be safeguarded for the benefit of present and future generations.

16.2. Principle of Replacement

The research work in more sensible ecosystems must be replaced by that in less sensible ecosystems, whenever it is possible and the objectives of the research work are not compromised. Less intrusive research means shall be sought.

16.3. Principle of Reduction

Damage to the ecosystems must be reduced to a minimum. As many possible forms of life as possible shall be protected and, for this, the least possible number of them shall be used. Damage to ecosystems housing protected or endangered species must be avoided.

16.4. Principle of Refining

Harm or disruption caused by research onto the ecosystems must be reduced to a minimum. The procedure that generates the minimum damage or disruption to the individual organisms shall be selected, even if the alternatives involve greater cost and time, especially when it comes to protected or endangered species.

16.5. Principle of Harm/Benefit Ratio

The lesser the harm caused to the ecosystems and the greater the value of the benefit obtained from the research, the greater will be the justification to do it. A research is acceptable when the harm involved is surpassed by the benefits of the research for humans, other species, or the ecosystems.

16.6. Preventive Principle

The researcher must prevent all damage to the ecosystems to the largest extent possible. This demands an exhaustive evaluation of the potential risks of the research work.

16.7. Precautionary Principle

When the research work involves the danger of serious or irreversible damage or disruption, the lack of absolute certainty of this danger shall not be used as a reason to delay the adoption of effective measures to prevent it. This requires, to the largest extent possible, a complete evaluation, determination of the degree of uncertainty, and assessment of risks.

16.8. Principle of Responsibility

The researcher and his or her team are responsible for the risks, damages or disruption caused by the research onto the ecosystems. In that sense, there is an obligation to adopt measures of restoration, rehabilitation, repair, and compensation for the damage or disruption caused. The researcher and his or her team must be informed of the characteristics of the ecosystems under study and must be qualified to deal with them.

Article 17:

In addition to the duties set forth in Article 8 of these regulations, for the purposes of research in ecosystems, the researchers' duties are as follows:

a. To develop procedures that conform to the ethical principles of research in ecosystems.

b. To justify that the benefits derived from research widely surpass the real or potential damages to the ecosystems.

c. To secure the advice of an expert with knowledge of the characteristics pertaining to the ecosystem under study.

Section III. Assessment of research

Article 18:

The Committee evaluates research projects in accordance with its procedure manual.

The Executive Committee may summon the external members for assessment of such projects requiring it.

Article 19:

The Office of Research Ethics and Scientific Integrity (OETIIC, in Spanish) is the administrative team that assists in the evaluation activity of the Committee and offers support to the qualification, diffusion and monitoring efforts relating to research projects. The Technical Secretariat of the Committee is part of the OETIIC and oversees the reception and registry of applications for research work, and of the operational administration of the sessions.

Article 20:

The Committee is responsible for ensuring that all the approved research projects are implemented in light of the provisions set forth in the documentation submitted to the Technical Secretariat. In that sense, it is entrusted with supervising and monitoring research works that obtained positive opinions.

Article 21:

Identifying conflicts of interests is part of the assessment performed by the Committee. There is a conflict of interests every time there is a possibility that somebody who has assumed obligations inherent to the compliance of a role, can be influenced by interests outside of the scope of said role. Any interests outside of the scope of a role are all those private benefits, foreign to the aim and development of their role, that could raise suspicions about their integrity.

The members of the Committee must reveal any conflict of interests in regards to the research to be evaluated and abstain from participating in said assessment. This includes personal involvement in the research, financial interest, or any other type of affiliation that may compromise it.

In the event that the Committee is aware of any conflict of interests that has not been informed by one of its members, it shall assess the situation and weight the continuation of said member in the Committee and notify if to the corresponding instances in the institution.

Temporary and final provisions

FIRST

The Committee recognizes the legitimacy of its assessments performed prior to the effective date of these regulations.

SECOND

The Committee has the authority to regulate its own processes, which emanate from the functions it holds.

THIRD

The Committee has a procedure manual that may be amended based on its own initiative.