



PONTIFICIA
UNIVERSIDAD
CATÓLICA
DE CHILE

GENERAL SECRETARY

RECTORY DECREE No. 370/2019

Promulgates agreement of the Honorable Superior Council that approves new Regulation on Scientific Ethics Committees of the *Pontificia Universidad Católica de Chile*, in the indicated sense.

NOTED:

- 1° That by Rectory Decree No. 231/2014, dated July 17, 2014, the Regulation on Scientific Ethics Committees of the *Pontificia Universidad Católica de Chile* was approved;
- 2° The need to update the regulatory body cited in the preceding paragraph and to meet the new requirements of the University;

The resolution adopted by the Honorable Superior Council of the University in its ordinary session No. 24, held on Friday, November 29, 2019;

What was legally informed by the General Secretary of the University, and

The powers vested on me by article 37 of the General Statutes of the *Pontificia Universidad Católica de Chile*.

I DECREE:

- 1° The agreement of the Honorable Superior Council approving the new Regulation on Scientific Ethics Committees of the *Pontificia Universidad Católica de Chile* is promulgated, the text of which is attached to this Decree and is understood to be an integral part thereof.
- 2° Abrogate the Regulation on Scientific Ethics Committees promulgated by Rectory Decree No. 231/2014, dated July 17, 2014.

Communicate, publish and file it.-
Santiago, December 16, 2019.-

PEDRO BOUCHON AGUIRRE
Vicerrector de Investigación

MUL/cg

IGNACIO SANCHEZ DIAZ
Rector

MARISOL PEÑA TORRES
Secretaría General

Cumplase 19.12.19

Manuel



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REGULATION ON SCIENTIFIC ETHICS COMMITTEES OF PONTIFICIA UNIVERSIDAD CATOLICA DE CHILE

TITLE I DEFINITION

- Art. 1° The purpose of these Regulations is to regulate the composition, attributions and functioning of the Scientific Ethics Committees of the *Pontificia Universidad Católica de Chile*, hereinafter the Committees or CEC. Likewise, its code of conduct, transparency and public account are regulated.
- Art. 2° The Scientific Ethics Committees will be collegiate bodies, of interdisciplinary nature, independent and autonomous in making decisions, as specified in Article 18 of these Regulations. Its main responsibility will be to ensure the rights and well-being of people and communities participating in scientific research, protect the welfare of animals, heritage and the natural environment being researched and promote training in ethics and safety in research.
- Art. 3° The research will require an ethical evaluation by a Committee in the case of a study in which there is intervention of any nature in human beings, which uses samples, data or information that comes from people, animals, heritage, natural, social or cultural environment.
- Art. 4° All research included in the previous article must be supported by an academic from the University, who is ultimately responsible for it, and be approved by the corresponding Committee prior to being initiated, in the following cases:
- a) When the research is conducted by researchers linked to the University and carried out in internal or external premises of the *Pontificia Universidad Católica de Chile*, and
 - b) When the research is conducted by researchers from outside the Institution who carry out the studies in the University premises.



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TITLE II

CREATION

- Art. 5° The University will have Scientific Ethics Committees created by Rectorial Resolution, defined by the area and subject of scientific research. Each Committee will be composed by a President, a Vice President, a Secretary and other members identified in Art. 8 of these Regulations, who are also appointed by Rectorial Resolution and will act in a personal capacity.
- Art. 6° The Committees will be governed by the Apostolic Constitution *Ex Carde Ecclesiae*, the Declaration of Principles, the General Statutes and the general norms of the University, as well as by the provisions contained in these regulations and in their respective internal regulations. They must also ensure compliance with current legal regulations, and the statements to which the University expressly adheres.

TITLE III

FUNCTIONS AND COMPOSITION

- Art. 7° The functions of the Committees will be:
- a) Evaluate the protocols of the research projects and request the modification of the ethical aspects of the researches when necessary;
 - b) Report the resolution, clarification and/or rectification of presented observations, within a maximum period of 20 business days, counted from the entry of the documentation to the ordinary session of the Committee;
 - c) Request, from researchers, authorities or Committees of other institutions, additional information to the research protocol that it deems necessary for the ethical evaluation, being able to also consult the opinion of experts;



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- d) Suspend or terminate a research, if the safety, rights or well-being of people and communities, animals, the environment or heritage is put at risk, after prior warning to the researcher responsible;
- e) Review appeals submitted to the Committee;
- f) Monitor the ethical dimensions of researches, when appropriate;
- g) Assess compliance with the ethical aspects of the final reports of researches when appropriate;
- h) Assess and resolve, when presented to the Committee, background information related to faults and / or infractions in the ethical execution of the research provided by the Academic Units, members of the university community and other people or institutions that have an interest in a research under observation, without prejudice to the provisions of Article 21 of these Regulations, and
- i) Send the corresponding reports to the Dean or the Director of the Villarrica Headquarters and inform of the approval, suspension, reactivation and anticipated termination of researches, including the faults detected, and
- j) Implement, together with the support of the University and according to Title VIII of this Regulation, instances of training, dissemination and discussion of topics associated with research ethics, both for the members of the same Committees and for members of the university community in general.

Each Committee will be composed by a minimum of 8 members, internal or external to the University, among which there must be at least:

- a) A member of the university community with enough experience to review and evaluate researches in their ethical dimension;
- b) A member of the university community with knowledge on research methodology;
- c) An expert in research ethics or security, as appropriate, with training in that discipline;
- d) A lawyer when applicable, and



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- e) A person without ties to the University, with an interest in scientific or ethical research, and who is not linked to entities that carry out this type of researches, in a way that represents the interests of the community, when appropriate.

Art. 9° The members of the Committees will be appointed by the Rector, at the proposal of the respective CEC, after consulting the Dean, or the Director in the case of the Villarrica Headquarters. The appointment will be formalized by Rectorial Resolution and their positions will last two years that may be extended according to the same procedure already indicated.

Art. 10° The Rector, Pro-Rectors, Vice-Rectors, Deans, Directors of Schools or Institutes, Heads or Directors of Department, or other people who have management positions at the University may not be members of the Committees.

Art. 11° The activities described in Art. 12 performed by members of the university community that belong to a Committee, will be recognized and valued as an integral part of their respective working hours.

For these purposes, the Vice-Rector for Research, following a report from the President of the respective Scientific Ethics Committee, will communicate, every six months, to the Dean, or to the Director in the case of the Villanica Headquarters, the number and nature of the activities mentioned in Art. 12 of these Regulations and that have been developed by the members of the corresponding Committee.

Art. 12° The functions and duties of the members of the Committees are:

- a) Evaluate the ethical aspects of the project, including procedures and facilities when appropriate, in accordance with the provisions of Article 3° of these Regulations.;
- b) Declare the existence of conflicts of interest regarding the research to be evaluated and in accordance with the provisions of the Regulations on Conflicts of Interest of the University;
- c) Participate in at least 80 % of the Committee sessions to which they are summoned;
- d) Carry out ethical follow-ups to the development of projects and reviews of adverse events, as designated by the President of the Committee;



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- e) Sign a permanent commitment when joining the Committee, and
- f) Sign a document declaring to know the applicable regulations and standards in research matters.

Art. 13° The Committees will have an Internal Regulation formalized by Rector's Decree, which will contain the necessary provisions for their operation, the ethical foundations for making their decisions, their resolutions, the regular evaluation procedures and the requirements to resolve quickly when appropriate and according to what is established in the current law, having to be adjusted to the present Regulation.

TITLE IV

PRESIDENT, VICE PRESIDENT AND SECRETARY OF THE COMMITTEE

Art. 14° : The President will be a member of the university community appointed by the Rector, from among the members of the corresponding Committee, being formalized by Rector's Resolution, and must have protected time corresponding to 1/3 of their current academic day at the time of their appointment.

Art. 15° The President of the Committee will be responsible for:

- a) Represent the Committee before the authorities, the university community and society;
- b) Propose to the Rector the name of the Vice President from among the members of the respective Committee;
- c) Coordinate, lead and supervise the work of the Committee and its administrative support staff for the fulfillment of the functions defined in this Regulation and the corresponding Internal Regulation;
- d) Prepare, convene and direct the ordinary and extraordinary sessions of the Committee;
- e) Sign the Approval Acts, Observation Letters, Ethical Monitoring Reports and other documents of the Committee;



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- f) Prepare and present the meeting plan and annual report of activities of the Committee;
- g) Lead, together with the support of the University, training activities in research ethics for community members;
- h) Lead, together with the support of the University, the accreditation process of the Committee when appropriate, and
- i) Make decisions on behalf of the Committee in cases of emergency or situations that warrant a rapid resolution, after consultation and support of at least 2 members of the Committee, which in any case must be informed in the immediately following session to the remaining members;

Art. 16° In the absence of the President for a period of up to 90 consecutive days, the Vice President will substitute them. If it is for a longer period of time, a new President will be appointed in accordance with Art. 14 of these Regulations.

Art. 17° The Committee has a Secretary, appointed by the Rector from among the members of the Committee, after consulting the respective President, and formalized by Rectorial Resolution who must:

- a) Collaborate with the President in the preparation of the official documentation of the Committee and in the tasks entrusted to them by the latter.;
- b) Check that there is the necessary documentation to submit a research proposal for the Committee's evaluation;
- c) Follow up on the ethical evaluation process of the researches submitted to the Committee;
- d) Draw up minutes of the Committee meetings in which the quorum and possible conflicts of interest of its members must be recorded, and
- e) Maintain communication with researchers during the evaluation process of their projects by the Committee.



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TITLE V

CODE OF CONDUCT

Autonomy and Independence

- Alt. 18° The Committees must act autonomously and independently in relation to:
- a) The authority or directors of the *Pontificia Universidad Católica de Chile*;
 - b) Researchers;
 - c) Sponsors;
 - d) Public and private organizations and agencies that fund research, and
 - e) Any agent representing or advocating an interest in relation to the evaluation of a study.

Conflicts of interest

- Art 19": The conflicts of interest of the Committee members constitute those situations, actual or potential, that may compromise the impartiality and objectivity of the evaluator, determining that the primary interest defined in Art. 2 of these Regulations may be influenced by secondary interests.

The recognition of conflicts of interest or inability by Committee members seeks to favor transparent and objective behaviors, and their identification and management strategy will be recorded in the minutes of the corresponding session.

This requirement forces Committee members to:

- a) Sign and comply with a commitment to declare conflicts of interest, and
- b) Explain, at the beginning of the session to which they have been summoned, if for any reason - be it direct or indirect - they have a conflict of interest, refraining from participating in discussions that deal with protocols or matters on which they have conflicts of interest.



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Confidentiality

- Art 20° The statement of confidentiality signed by the members of the Committees is permanent and must contain at least the following commitments:
- a) Not to disclose or reproduce, in whole or in part, the confidential information to which they access during the evaluation sessions in their capacity as a member of the Committee;
 - b) Not to publish, totally or partially and by any means, the information and / or documentation related to the research proposals they evaluate as members of the Committee;
 - c) Do not deliver to third parties the information and/or documentation to which they access, either totally or partially;
 - d) Safeguard and not misuse the documents and information to which they access;
 - e) Not to disseminate, distribute or commercialize the personal data contained in the information systems and/or developed in the performance of duties within the Committees, and
 - fi) Respect confidentiality within the limits established by law.

Art 21° Any violation of this Regulation may be sanctioned in accordance with the Regulation of Academic and Disciplinary Responsibility of the members of *Pontificia Universidad Católica de Chile*, having to comply, in addition, to what the current national legislation establishes.

TITLE VI

TRANSPARENCY AND PUBLIC ACCOUNT

Regarding Transparency

Art 22° The general regulation that governs the Scientific Ethics Committees, as well as the particular that governs each one, and the annual calendar of the ordinary sessions of each Committee, will be kept published through the means available to the University.



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Regarding public account

- Art 23° Annually, each Committee will publish a report on its activities for the year. It includes at least: the number of evaluated researches, the response time to requests, the number of approvals, amendments, suspensions, renewals and ethical follow-ups, the participation of members in courses and retrainings and the list of Committee members.

TITLE VII

ADMINISTRATIVE SUPPORT

- Art 24° It will be the function of the Research Ethics and Safety Unit of the University, in accordance with the Internal Regulations of the Vice-Rector for Research, regarding the Committees:
- a) Make the support staff available to the Committees, as well as the infrastructure resources and facilities that allow its proper operation and compliance with the required confidentiality;
 - b) Stay in contact with researchers and provide advice for the compliance with the ethical standards of scientific research;
 - c) Receive and distribute to the corresponding Committee or Committees the documents pertinent to the researches submitted for consideration for ethical review;
 - d) Implement, for members of the university community, together with the Committees, instances of training, dissemination and discussion of topics associated with the ethics of research;
 - e) Propose to the Committee the annual calendar of meetings in which the deadlines for the receipt of documents and dates of regular sessions are indicated;
 - f) Maintain records of the activities carried out by the Committees, and
 - h) Report pertinent matters to the Committees and the corresponding authorities.
- Art. 25° Any request regarding new researches, as stated in Article 3 of these Regulations, must be submitted by the Researcher Responsible to the University's Research Ethics and Safety Unit to be derived, within a period not exceeding 5 business days, to



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the corresponding Committee, where applicable. Likewise, the aforementioned Research Ethics and Safety Unit will notify about the researches that are exempt from ethical review.

TITLE VIII

REGARDING THE RESEARCHER

- Art. 26° The member of the university community responsible for a research, according to Art. 4 of these regulations, must:
- a) Know and respect the institutional ethical framework and conduct researches in accordance with it;
 - b) Prepare and submit within the established deadlines all the documentation and information that corresponds to be reviewed by the Committee;
 - c) Attend the Committee session, if summoned, and respond to the queries that its members ask;
 - d) Respond satisfactorily to all the observations generated by the Committee and reflected in the observation letters;
 - e) Sign the commitments established in the documentation presented;
 - f) Give written notice to the Committee of the beginning and end of the execution of the approved research;
 - g) Conduct the research in accordance with the approved documents, complying with the respective laws and regulations in force, according to the ethical principles that protect the researches;
 - h) Ensure that all the people under their supervision and responsibility and who will participate in the execution of the research will work in accordance with current national and international ethical norms and rules;
 - i) Ensure that all people participating in the investigation have the necessary training and are aware of the precautions and safety regulations involved.;



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- j) Notify the Committee and the corresponding authorities if there are serious and unexpected adverse events that could put the participants, living beings and objects under research at risk during the course of it;
- k) Request and obtain the authorization of the Committee regarding the incorporation of changes to the documents already approved prior to the beginning of the researches, before executing said changes;
- l) Perform the procedures as stated in the approved documents, and
- m) Present to the Committee the ethical approval of other institutions in the corresponding cases.