

**REGULATION OF THE SCIENTIFIC ETHICS
COMMITTEE OF HEALTH SCIENCES
OF PONTIFICIA UNIVERSIDAD CATÓLICA DE CHILE**

TITLE I

Definition

Article 1: The Regulation of the Scientific Ethics Committee of Health Sciences of the *Pontificia Universidad Católica de Chile*, hereinafter CEC-SaludUC or the Committee, is the set of norms that regulate its legal regime, that is, its creation, composition, attributions and operation. The Committee is governed by the Principles, Statutes, Regulations and General Norms of this University, especially by the Regulation on Scientific Ethics Committees of the *Pontificia Universidad Católica de Chile*, Rectory Decree No. 370/2019; the Political Constitution of the Republic of Chile; by Law No. 19,628, on the Protection of Private Life; the provisions of Law No. 20,120 on Scientific Research in the Human Being and its Regulations, contained in the S.D. No. 114 of 2011; the S.D. 30 of 2013, which modifies the previous one; the Exempt Resolution No. 403 of 2013; by Law No. 20,584, on the Rights and Duties that people have in relation to actions related to their health care; by Law 20.850 that Creates a Financial Protection System for High-Cost Diagnoses and Treatments and Pays Posthumous Tribute to Mr. Luis Ricarte Soto Gallegos. The principles proclaimed by the Universal Declaration of Human Rights, adopted by United Nations General Assembly Resolution, 1948, also constitute regulations applied by the CEC-SaludUC; the Declaration of Helsinki of the World Medical Association (1964 and subsequent revisions); the Universal Declaration on Bioethics and Human Rights (UNESCO, 2005); Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research (1979); the International Ethical Guidelines for Biomedical Research involving Humans prepared by the Council for International Organizations of Medical Sciences (CIOMS, 2002); Standards of Good Clinical Practice of the International Conference on Harmonization (ICH, 1996).

Article 2: The CEC-SaludUC is a collegial body, interdisciplinary, independent and autonomous in making its decisions, whose essential responsibility is to protect the rights, safety and well-being of the participants as subjects of scientific research.

TITLE II

Creation and composition of the Committee

Article 3: The CEC-SaludUC was created on January 29, 2014, as stated in the Constitution Act, signed by the Dean of the Faculty of Medicine.

Article 4: The number of members of the CEC-SaludUC is at least eight people and will necessarily include a lawyer, an expert in Bioethics or Research Ethics, an expert in Research Methodology, an expert in Good Clinical Practices and a community representative who has no connection with the *Pontificia Universidad Católica de Chile*, and who represents the interests of the community. Internal members may use as affiliation the one they have in their respective Academic Units, additionally indicating their status as "Member of the CEC-SaludUC".

Article 5: The members of the CEC-SaludUC are appointed by the Rector of the *Pontificia Universidad Católica de Chile*, at the proposal of the Committee, after consulting the Dean or corresponding authority. Their appointments are formalized by Resolution of the Rector and remain in their position for a period of 2 years, and may be renewed.

The members who are proposed to the Rector by the Committee must meet the following conditions: express personal interest in participating in the CEC-SaludUC; have an academic and/or professional degree; have a commitment to confidentiality and adherence to the principles, values and code of conduct that guide the decisions of the CEC-SaludUC.

Article 6: Membership of the CEC-SaludUC may be lost due to:

- a) Voluntary resignation from office;
- b) Decision of the Rector, at the request of the President of the CEC;
- c) Absence or impediment to exercise their functions for more than 90 days;

- d) Breach of the Committee's code of conduct; and
- e) End of their period.

TITLE III

Board of Directors

Article 7: This Committee has a President, who is appointed by Resolution of the Rectorry from among its members, for which the training or academic degree, publications and experience in research ethics are taken into consideration.

The President of the Committee remains in office for a period of 2 years, renewable.

Article 8: Corresponds to the President of the CEC-SaludUC:

- a) Represent the Committee before the authorities, the university community and society;
- b) Prepare, convene and direct the regular and extraordinary sessions of the Committee;
- c) Ensure compliance with all applicable regulations, local regulations, the institution and good clinical practices;
- d) Lead, coordinate and supervise the work and activities of the Committee and its administrative support staff;
- e) Make the official communications of the Committee;
- f) Resolve those matters requiring urgent review;
- g) Sign the official documents such as Acts of Approval, Letters of Observations, Reports and other documents of interest to the Committee;
- h) Prepare and present the Committee's development plan and annual report of activities;
- i) Review and issue their opinion on matters of interest and responsibility of the Committee;
- j) To lead, with support of the University, training activities in research ethics for members of the university community;
- k) To lead, with support of the University, the accreditation and re-accreditation process of the Committee, when appropriate;
- l) Appoint the members in charge of the expedited reviews and pre-review process of scientific research in humans;

- m) Propose to the Rector:
 - 1) The name of the Vice President from among the members of the CEC-SaludUC
 - 2) The name of the Committee's Executive Secretary
 - 3) Candidates for members of the CEC-SaludUC;
- n) Inform the corresponding authority of the performance of the members of the Committee, in accordance with the current regulations at the University; and
- o) Report to the Rector the matters of interest of the Committee.

Article 9: The President of the CEC-SaludUC ceases their functions:

- a) Upon completion of their period;
- b) By voluntary resignation to the position;
- c) By decision of the Rector of the *Pontificia Universidad Católica de Chile*; and
- d) Due to absence or impediment to exercise their functions for more than 90 days.

Article 10: This Committee has a Vice President, appointed by the Rector at the proposal of the President of the CEC-SaludUC, taking into consideration the same criteria for selecting the President. The Vice President remains in office for a period of 2 years, renewable.

Article 11: Corresponds to the Vice President of the CEC-SaludUC:

- a) Assume the powers and responsibilities of the President in the event that they specifically request it, or when the President is prevented from fulfilling their functions.;
- b) Conduct expedited reviews of scientific research in humans, at the request of the President;
- c) To do follow ups on researchers and their research projects, if decided by the CEC-SaludUC and/or requested by the President; and
- d) The Vice President will subrogate the President in the case of absence or impediment to exercise their functions, for a maximum of 90 days.

Article 12: The Vice President of the CEC-SaludUC ceases their functions:

- a) Upon completion of their period;
- b) By voluntary resignation to the position;
- c) By decision of the Rector, at the request of the President of the CEC-SaludUC; and

- d) Due to absence or impediment to exercise their functions for more than 90 days.

Article 13: This Committee has an Executive Secretary appointed by the Rector, at the proposal of the President of the CEC-SaludUC, from among the members of the Committee. The Executive Secretary remains in office for a period of 2 years, renewable.

Article 14: Corresponds to the Secretary of the CEC-SaludUC:

- a) Assume the tasks assigned by the President;
- b) Draw up minutes of the Committee sessions in which it must record the quorum and possible conflicts of interest of its members and keep a written record of the corresponding deliberations and resolutions;
- c) Collaborate with the President in the preparation of the official documentation of the CEC-SaludUC;
- d) Conduct expedited reviews of scientific research involving humans if requested by the President;
- e) Check that the necessary documentation is available to submit a research proposal for evaluation by the Committee;
- f) To do follow ups on research projects and maintain communication with researchers throughout the study process; and
- g) Sign with the President the official documents such as Approval Acts, Observation Letters, Follow-up Reports and other documents of interest to the CEC-SaludUC, when appropriate.

Article 15: The Secretary of the CEC-SaludUC ceases in their functions:

- a) Upon completion of their period;
- b) By voluntary resignation to the position;
- c) By decision of the Rector, at the request of the President of the CEC-SaludUC; and
- d) Due to absence or impediment to exercise their functions for more than 90 days.

TITLE IV

Committee procedures

Regarding Research

Article 16: The CEC-SaludUC evaluates any protocol, study or scientific research project that involves a physical or mental intervention or interaction with human beings, with the aim of improving prevention, diagnosis, treatment, management and rehabilitation of people's health or to increase the biological knowledge of the human being. Likewise, said protocol, study or scientific research project that considers the use of human material or identifiable available information, in the light of what is defined by current legislation.

Regarding the powers of the Committee

Article 17: The Committee's attributions, without prejudice to those indicated in the Regulations on Scientific Ethics Committees of the Pontificia Universidad Católica de Chile already in place, are the following:

- a) Evaluate the protocols, studies or scientific research projects that are submitted for its consideration; and
- b) Report the result of the corresponding evaluation, within 7 business days following its review in the CEC-SaludUC session. Said report will contain the well-founded, favorable or unfavorable rating, unless prior modifications are requested as a condition of its future approval.

In the event that the report is favorable, its merit will be sufficient for the study to be carried out in any establishment, as long as it has the authorization of the Director of the latter, who may deny its performance in the dependencies or request the evaluation of the study by the local Scientific Ethics Committee. In the event that the Committee's resolution is unfavorable to the research, it may not be conducted, unless it is reformulated to satisfy the objections raised.

Regarding the presentation process, review/evaluation and resolution modalities Article

18: The presentation process begins with the entry of the background of the protocol, study or scientific research projects to the Research Ethics and Safety Unit of the *Pontificia Universidad Católica de Chile*. If applicable, this Unit will send it to the CEC-SaludUC for evaluation.

The CEC-SaludUC evaluates a protocol, study or scientific research projects, once the following documentation is available on the platform, as appropriate to each case:

- a) Ethical Review Request Form established by the CEC-SaludUC;
- b) Coverletter from the Researcher Responsible;
- c) Letter of support from direct leadership;
- d) Research protocol;
- e) Researcher's Manual, as appropriate;
- f) Recruitment material;
- g) Information gathering instruments;
- h) Informed Consent Document (s);
- i) Insurance policy required according to applicable regulations; and
- j) Curriculum Vitae of the researchers accompanied by their respective training certificates in research ethics and/or good clinical practices.

Article 19: The CEC-SaludUC has two review/evaluation modalities, depending on the characteristics of each project, which are the following:

- a) **Regular review** of a scientific research project is carried out in a Committee session. On this occasion, its ethical and scientific validity is analyzed and discussed, after presentation and evaluation carried out by three members of the Committee.
- b) **Expedited review** of a scientific research project is the one carried out, prior to the session, by two members of the CEC-SaludUC, depending on its nature, being sanctioned therein.

Article 20: The founded resolution of the CEC-SaludUC, favorable or unfavorable, regarding each scientific research project, is informed in writing to the researcher. Notwithstanding the foregoing, the Committee may previously request modifications as a condition of the future approval of the project. To answer the observations, be they minor or major, the researcher will have a maximum period of two months. In case of not answering within the stipulated period, the corresponding project will be considered as not presented.

In the event that the Committee's resolution is unfavorable to the research, it may not be conducted, unless it is reformulated to satisfy the objections raised.

Consequently, once each of the scientific research projects has been evaluated, the CEC-SaludUC, in session, considers them to be:

- a) Approved
- b) Pending with minor and/or major modifications
- c) Rejected

Regarding the ethical bases of decisions

Article 21: The CEC-SaludUC bases its ethical decisions on respecting and caring for people's dignity. For the understanding of human dignity, its conceptual framework is: natural law and the teachings of the Magisterium of the Catholic Church, in its recognition of the inalienable value of all people from conception to death. Likewise, it subscribes to the basic bioethical principles -generally accepted- of the autonomy of people, justice and beneficence, which govern scientific research in and with people. Human beings participating in scientific research who are in a vulnerable condition are of special concern to the CEC-SaludUC.

These principles will be considered in the review of all the activities of a scientific research, including the design and implementation of the protocol, informed consent document, and the selection of participants.

The CEC-SaludUC is sensitive to the social, cultural and religious environment in which people who participate in scientific research are inserted.

Regarding decision-making on a particular research, the CEC-SaludUC uses as a criterion of ethical validity for its approval, the concept of "ethically acceptable research" based on the following aspects:

- a) Respect for the dignity of people;
- b) Social validity and contribution to human knowledge;
- c) Scientific validity;
- d) Favorable benefit/risk ratio;
- e) Appropriate selection of participants;
- f) Adequate informed consent process;
- g) Collaborative participation and respect for communities; and
- h) Researcher's independent review.

Regarding the sessions and quorum for the decisions of the Committee

Article 22: The CEC-SaludUC meets in ordinary and extraordinary sessions. Ordinary sessions are held twice a month. They are scheduled annually in the month of January of each year, for which their members are summoned via email at least 7 days prior to the date of the session. Extraordinary sessions are called by the President. In any case, to meet the CEC-SaludUC must have the attendance of at least five members including the President or Vice-president, who, as a whole, must comply with the characteristics stated in Article 4 of these Regulations.

In each session a minute will be drawn up that will record, at least, the following:

- a) Number of participants corresponding to the minimum quorum required;
- b) Name and signature of each participant, clarifying if they attended: the President or Vice-president, an expert in research ethics, an expert in research methodology, an expert in Good Clinical Practices, the lawyer and a representative of the community;
- c) Declarations of Conflict of Interest by any of the members and if in this case they or the members abstained from participating;
- d) The resolutions obtained for each protocol evaluated, including the controversial points of the discussion and the result of the votes.; and
- e) Verification of the existence of an insurance policy for the protocols evaluated, when applicable.

Article 23: The CEC-SaludUC makes its decisions by a majority of the members present. In the event of a tie, decides the vote of the presiding officer.

Regarding external consultants

Article 24: When necessary, the CEC-SaludUC may request the advice of an external consultant.

The following conditions apply for its call:

- a) Have no conflict of interest with those responsible for the research (researchers, sponsors and/or Contract Research Organization), or with the matters on which their expert opinion is requested;
- b) Be willing to express their opinion in writing;
- c) Be willing to sign a confidentiality commitment and keep confidentiality on the matters discussed; and

- d) Be willing to have their name recorded in the minutes and eventually made public.

Regarding observation to the course of scientific research projects

Article 25: Regarding each of the approved scientific research projects, the CEC-SaludUC observes the development of the ongoing projects in two modalities, as appropriate:

- a) **Report:** Mechanism through which and through the corresponding guideline, the Researcher Responsible is asked for information on the conduct of the project, at least once during its course.
- b) **On-site visit:** Mechanism through which, given the circumstances, the CEC-SaludUC is present in the place where the investigation is carried out and/or in the establishment where the information corresponding to the research is collected.

Article 26: To comply with what is stated in the previous article, the Committee requests the Researcher Responsible to present all the documentation pertinent to the research project, such as:

- a) Institutional authorizations;
- b) Notification of adverse events;
- c) Protocol deviation notification;
- d) Amendments to the protocol and the Informed Consent document and their respective approval by the Committee;
- e) Security report, if applicable;
- f) Data collection instruments in their final version, when it comes to their construction and validation; and
- g) Annual progress report of the research.

Regarding the training of the members of the Committee

Article 27: The members of the CEC-SaludUC must continually tend to their training in research ethics.

For this, the CEC-SaludUC must:

- a) Have a virtual library of texts related to research ethics;

- b) Invite its members to participate in formal courses on research ethics, general ethics, research methodology and clinical research; and
- c) Organize annual outreach activities on topics of ethical and scientific interest related to research on people, aimed at its members, members of other committees, undergraduate and graduate students, and researchers and the general public.

TITLE V

Code of conduct

Regarding Autonomy and Independence

Article 28: The CEC-SaludUC is an autonomous and independent entity, responsible for protecting the rights, safety and well-being of the participants as subjects of scientific research. Consequently, the resolutions of the Committee are adopted independently of:

- a) The authority or directors of the *Pontificia Universidad Católica de Chile*;
- b) Researchers;
- c) Sponsors;
- d) Contract research organizations; and
- e) Any agent representing or advocating an interest in relation to the evaluation of a study.

Article 29: The CEC-SaludUC, to ensure what is stated in the preceding article, has the following mechanisms:

- a) It does not include among its members people affiliated with companies promoting or developing biomedical research;
- b) None of the authorities of the *Pontificia Universidad Católica de Chile* can integrate it;
- c) Researchers and/or entities participating in a scientific research will not be present at the sessions in which decisions are made regarding a protocol or related matter; and
- d) Does not receive direct or indirect payments from sponsors for the evaluation of research projects.

Regarding the Management of Conflict of Interest

Article 30: Conflict of Interest constitutes a situation that may compromise the impartiality and objectivity of the evaluator, in which the judgment that involves a primary interest, in this case the well-being of the person subject of the research and the integrity of the research, may be influenced by secondary interests, threatening the independence of judgment in the evaluation. The declaration of the Conflict of Interest or inability, if applicable, seeks to promote transparent and objective conduct.

To expose potential conflicts of interest, the members of the CEC-SaludUC must, in each session:

- a) Read, complete the details of the protocol and sign the Conflict of Interest Declaration Form.
- b) Once the foregoing has been fulfilled, expose the Conflict of Interest at the beginning of the session to which they have been summoned, refraining from participating in part of the session that deals with matters related to the conflict. This procedure must be recorded in the minutes of the session.

Regarding Confidentiality

Article 31: The members of the CEC-SaludUC, at the time of forming part of the Committee, must sign and comply with a confidentiality declaration, which contains the following:

- a) Not to disclose or reproduce, in whole or in part, the aforementioned information to which they access, during or outside the session.
- b) Keep a reservation on the deliberations related to the content of the debates and with the information provided to them.
- c) Not to publish, totally or partially and by any means, the information and/or documentation related to the studies they evaluate as part of their work within the CEC-SaludUC.
- d) Do not deliver to third parties the information and/or documentation to which they access, either totally or partially.
- e) Safeguard and not misuse the documents to which they access.
- f) Not to disseminate, distribute or commercialize the personal data contained in the information systems and/or developed in the exercise of the functions within the CEC-SaludUC.

Regarding the Obligations and Responsibilities of the members of the CEC-SaludUC

Article 32: The following are the obligations and responsibilities of the members of the Committee:

- a) Attend and actively participate in the deliberations in the ordinary and extraordinary sessions to which they are summoned;
- b) Comply with an attendance of at least 80% of the sessions convened;
- c) In the case of being assigned as a reviewer of a study in regular modality, present in plenary session the result of the evaluation of the corresponding study; and
- d) Sign the document in which they declare to have taken full knowledge of these Regulations.

TITLE VI

Communication, Transparency, Public Account and Quality

Regarding the communication of the Committee's decisions

Article 33: Given the circumstances, the Committee communicates, as the case may be, the following:

- a) The decisions of the CEC-SaludUC regarding modifications to both the internal regulations and their composition, operation and dependencies, to the Health Authority; and
- b) The resolutions of the CEC-SaludUC that suspend a scientific research, as well as those that report breaches of the responsibilities of the researcher, in relation to what is prescribed in Law No. 20,120 and its Regulations, as appropriate:
 - 1) To the Researcher Responsible, their direct Head and the Dean;
 - 2) To the Director of the Institution in which the research is carried out;
 - 3) To other Scientific Ethics Committees;
 - 4) To the Health Authority;
 - 5) To the Institute of Public Health;
 - 6) To the Sponsor of the research; and
 - 7) To the Public Ministry

Regarding Transparency and Public Account

Article 34: The CEC-SaludUC maintains these Regulations on the CEC-SaludUC website, which, in turn, is hosted on the website of the *Pontificia Universidad Católica de Chile*. A copy of it is kept updated in the files of the CEC-SaludUC Secretary.

Once a year the CEC-SaludUC publishes a report of the activities carried out during the period. This must include at least the number of researches evaluated; a breakdown of the different review situations, and their corresponding results. Likewise, it includes an updated list of members and their training in advanced training courses.

Regarding Quality

Article 35: The CEC-SaludUC updates its procedures according to the modifications experienced by the Legal Order of the Republic of Chile. This considers the modifications that directly affect the Regulation of the Health Sciences Scientific Ethics Committee of the *Pontificia Universidad Católica de Chile*. Notwithstanding the foregoing, it will be modified, if necessary, at least every three years.

The Committee conducts an annual self-evaluation session that must be attended by at least one third of its members, including the President and/or Vice-president.

For this extraordinary day all members are summoned, by email or other means that make it possible.

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