

RECTORY DECREE No. 310/2021

Approves the new Regulation of the Scientific Ethics Committee of Health Sciences of the Pontificia Universidad Católica de Chile.

NOTED:

- 1° The Scientific Ethics Committee of the Faculty of Medicine of the Pontificia Universidad Católica de Chile constituted on January 29, 2014, as stated in its Constitution Act;
- 2° The Regulation on Scientific Ethics Committees of the Pontificia Universidad Católica de Chile, promulgated by Rectory Decree No. 370/2019, dated December 16, 2019;
- The Regulations of the Scientific Ethics Committee of Health Sciences of the Pontificia Universidad Católica de Chile, approved by Rectory Decree No. 143/2020, of June 1, 2020, which updated the name and the regulatory body that regulates said Committee;
- The need to adapt the current regulations to the requirements and needs of the University;
- 5° The favorable opinion of the Vice-Rector for Research;
- 6° Legally informed by the General Secretary of the University, and
- 7° The powers conferred on me by article 37 of the General Statutes of the Pontificia Universidad Católica de Chile.

DECREE:

103/201

SAY MUSE

- The new Regulation of the Scientific Ethics Committee of Health Sciences of the Pontificia Universidad Católica de Chile is approved, the text of which is attached and understood to be an integral part of this Decree, as of the date of this Decree.
- 2° Abrogate the Rectory Decree No. 143/2020, of June 1, 2020.



Communicate, publish and file it.-Santiago, September 20, 2021..-

PEDRO BOUCHON AGUIRRE Vicerrector de Investigación IGNACIO SANCHEZ DIAX Rector

CRISTINA FERNANDEZ ARETXABALA General Secretary

MGDE/cg





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

TITLE I

Definition

Art. 1°

The Regulation of the Scientific Ethics Committee of Health Sciences of the Pontificia Universidad Católica de Chile, hereinafter CEC-SaludUC or the Committee, s 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 Universityespecially 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; ethe 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 21.331, On the Recognition and Protection of the Rights of People in Mental 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; by Law 21,278 which modifies the Health Code to regulate the performance of clinical studies and trials, aimed at obtaining pharmaceutical products and medical devices, for the fight against diseases that cause a health alert.

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); IBelmont 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).



Art. 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

Art. 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.

Art. 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, n expert in Good Clinical Practices and someone 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".

Art. 5° :

The members that make up the CEC-SaludUC are elected by the Committee in ordinary session and ratified by the Rector of the Pontificia Universidad Católica de Chile. Their appointments are formalized by Resolution of the Rectory and they remain in office for a period of 2 years, and may be renewed.

The members that make up 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.

The substitution procedure is considered for critical members, which are the lawyer, the person who represents the interests of the community and the expert in good clinical practices. These are previously elected by the Committee in session and ratified by the Rector of the Pontificia Universidad Católica de Chile. The alternate members must meet the same requirements indicated in the second paragraph of this Art. Their appointments are formalized by Resolution of the Rectory and remain in office for a period of 2 years, and may be renewed.



The President, Vice-President and Executive Secretary of the Committee are elected by vote and by simple majority. Voting is mandatory and secret by all members of the Committee.

- Art. 6° : Membership of the CEC-SaludUC may be lost due to:
 - a) Voluntary resignation from office;
 - b) Resolution 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;
 - e) End of their period.

In the cases of letters a), b), e) and d), the loss of membership of the Committee is formalized by a Resolution of the Rectory.

TITLE III

Board of Directors

Art. 7°: This Committee has a President, who is ratified by Resolution of the Rectory, at the proposal of the Committee, for which the training and/or academic degree, and publications and/or experience in research ethics are taken into consideration.

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

- Art. 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;
- 1) Appoint the members in charge of the expedited reviews and pre-review process of scientific research in humans;
- m) Request the ratification of the appointments by Resolution of the Rectory of:
 - 1) The Vice-President from among the members of the CEC-SaludUC
 - 2) Tthe Committee's Executive Secretary
 - 3) The members of the CEC-SaludUC;
- mi) Inform the corresponding authority of the performance of the members of the Committee, in accordance with the current regulations at the University; and
- mii) Report to the Rector the matters of interest of the Committee.

Art. 9°: The President of the CEC-SaludUC ceases their functions:

- a) Upon completion of their period;
- b) By voluntary resignation to the position;
- c) Due to absence or impediment to exercise their functions for more than 90 days.

In the cases of letters b) and), the cessation of their functions in the Committee is formalized by means of a Rectory Resolution.

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

Art. 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.

Art. 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) Por resolución del Presidente del CEC-SaludUC;
- d) Due to absence or impediment to exercise their functions for more than 90 days.

In the cases of letters b), c) and d), the cessation of their functions in the Committee is formalized by means of a Resolution of the Rectory.

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

Art. 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.



- Art. 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 resolution of the President of the CEC-SaludUC:
 - d) Due to absence or impediment to exercise their functions for more than 90 days.

In the cases of letters b), c) and d), the cessation of their functions in the Committee is formalized by a Resolution of the Rectory.

TITLE IV

Committee procedures

Regarding Research

Art. 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

- Art. 17°: The Committee's attributions, without prejudice to those stated 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 for its future approval.



-7-

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

Art. 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.

The Informed Consent document at least contain and, as the case may be, the following:

- Research title, name of Researcher Responsible, Sponsor, and Contract Research Organization, if applicable;
- A statement that explains that it is a scientific research;
- The purpose of the research;



- The justification, objectives, duration and details of all the interventions and procedures of the research;
- Proposed treatment and justification for the use of placebo, if any, together with its criteria for use;
- Foreseeable and potential benefits for the subject and society;
- Responsibilities and description of foreseeable and potential risks and discomfort for the participant:
- Benefits and risks of alternative methods, if any;
- Guarantee of privacy protection and respect for confidentiality in the processing of personal data, indicating the methodology used for this purpose;
- Guarantee of respect for the total willingness to participate throughout the entire research;
- The explanation of the right to not participate or towithdraw from the study at any time;
- Information on the aspects of medical care to which there is access in connection with the research;
- Guarantee of access to all new relevant information;
- Potential uses of research results, including commercial uses;
- Adverse event resolution protocol:
- Guarantee of coverage of general expenses for participation in the research and the compensation that the subject will receive;
- Insurance guarantee for compensation for eventual injury caused by the research;
- The legal regulations that govern scientific research on human beings; and
- Contact telephone number of the researcher and the President of the Committee for inquiries about rights and potential injuries.

Art. 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, being sanctioned in the



session. Scientific research projects in which at least one of the following conditions is met is considered for expedited review:

- Does not need to contact the participants;
- The risks are minimal;
- The risk-benefit balance is favorable for the study participants;

The amendment to the protocol is considered for expedited review if it does not modify the scientific validity or the risk-benefit balance of the originally approved study.

Art. 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 for 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
- e) Rejected

Regarding the ethical bases of decisions

Art. 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

Art. 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.
- Art. 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

- Art. 24°: When necessary, the CEC-SaludUC may request the advice of an external consultant who will be proposed by one or more of the members of the Committee in session, being accepted by a simple majority vote of the members present. Once chosen, the following conditions apply for their calling and participation:
 - 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

- Art. 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 research is carried out and/or in the establishment where the information corresponding to the research is collected.



GENERAL SECRETARY
-12-

Art. 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:

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

In the case of clinical studies, the progress report must contain, at least, the following:

- Number of enrolled subjects;
- Number of subjects who have withdrawn at the request of the researcher, stating the reason;
- Number of subjects who have dropped out;
- Verification that all participants signed the Informed Consent;
- Number and description of serious adverse events;
- Notification of adverse events and related procedures;
- Security reports: and
- Notification of protocol deviations

Regarding the training of the members of the Committee

Art. 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

Art. 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.
- Art. 29°: The CEC-SaludUC, to ensure what is stated in the previous 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 bea member of it:
 - e) 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

Art. 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.
- 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

Art. 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 o 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.
- e) 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.

GENERAL SECRETARY
-15-

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

- Art. 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

- Art. 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. The foregoing will be communicated by means of a written note to the corresponding parties' office, this, without prejudice to sending the same information via available email.
 - 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.
 - To the Researcher Responsible, by notification to the corresponding email, through the Ethical Evaluation Platform of the Pontificia Universidad Católica de Chile.
 - 2) To the following, by email:
 - The direct Head and the Dean;
 - The Director of the Institution in which the research is carried out;
 - Other Scientific Ethics Committees;



- The Health Authority;
 - The Institute of Public Health;
 - The Sponsor of the research; and
 - The Public Ministry

Regarding Transparency and Public Account

Art. 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

Art. 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.