



**INSTITUTIONAL REVIEW BOARD
(CEPH/FGV)**

INTERNAL RULES

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INTERNAL RULES

CHAPTER I

ON THE INSTITUTIONAL REVIEW BOARD

ARTICLE 1 – The Institutional Review Board (CEPH/FGV) is a collegial body of Fundação Getulio Vargas with advisory, deliberative and educational character, vested with responsibility to defend research participants interests in view of their integrity and dignity, as well as to promote and safeguard the highest standards of ethical and legal compliance in studies involving human subjects conducted by members of the institution.

Sole paragraph. The members of the CEPH/FGV must act voluntarily, autonomously, independently and impartially in the exercise of their function, which is of public interest.

ARTICLE 2 – It is also a function of the CEPH/FGV to offer to the institution's professors and researchers certification of ethical compliance for their research projects that involve human beings, according to current best practices.

ARTICLE 3 – All the research projects that involve human beings, whose methodological procedures: (i) involve obtaining data by means of direct intervention or interaction with an individual; or (ii) involve obtaining identifiable information about an individual; or (iii) can cause risks greater than those existing in everyday life, must be submitted to the consideration of the CEPH/FGV.

Sole paragraph. This article applies to all forms of research involving human beings, irrespective of the level of study or investigation.

ARTICLE 4 – The evaluation of the ethical aspects of the study shall take into consideration the bylaws and rules of Fundação Getulio Vargas and the highest national and international standards of research ethics.

ARTICLE 5 – The CEPH/FGV shall concentrate its activities with priority on the analysis and monitoring of research projects in the areas of the applied human and social sciences.

Sole paragraph. The CEPH/FGV may forward, for analysis of another specialized institutional review board or of CONEP, research projects in areas of knowledge in which the institution does not yet have specialization (such as clinical research).

CHAPTER II

GENERAL ATTRIBUTIONS

ARTICLE 6 – The attributions of the CEPH/FGV are:

- I** – To define specific guidelines and procedures to evaluate research protocols and projects;
- II** – To evaluate research protocols submitted to the CEPH/FGV by professors, researchers, students or other members linked to FGV;
- III** – To issue opinions attesting the ethical compliance of research protocols submitted for its consideration;
- IV** – To request, consider and decide on the ad hoc opinions that evaluate research projects under its consideration;
- V** – To ask the researcher in charge for clarifications or additional information about the project and the execution of the study, if necessary;
- VI** – To maintain, in a confidential file that may be digital, for a period of 5 (five) years from the closing date of each study, the research protocol, project and reports, accompanied by the pertinent documentation;
- VII** – To receive and evaluate, from the research subjects or any other person, any reports of abuses or notices of adverse facts in the conduction of studies;
- VIII** – To request the commencement of internal investigations in case of ethical irregularities in research, and, if there is evidence, to communicate this to higher instances or competent public authority;

IX – To inform FGV professors, researchers and students about the ethical standards to be followed in research;

X – To promote a training plan for its members, so as to comply with its educational character;

XI – To exercise other functions necessary for the good fulfillment of the attributions described above.

CHAPTER III

COMPOSITION AND FUNCTIONING

ARTICLE 7 – The CEPH/FGV is a collegial body composed of at least 7 (seven) permanent members.

ARTICLE 8 – Its meetings shall be held whenever necessary, but shall not occur more frequently than once a month.

§ 1 – The quorum to start a meeting, as well as for deliberation on research projects, is the absolute majority, consisting of the presence of 50% (fifty percent) plus one of the permanent members of the CEPH/FGV.

§ 2 – The objects of deliberation at the ordinary meetings shall be the research projects submitted to the consideration of the CEPH/FGV at least 15 (fifteen) days in advance.

§ 3 – The extraordinary meetings shall be held whenever necessary, called by the Coordinator or by the majority of its members, at least 5 (five) days in advance, at which time there may be no deliberation on matters not on the respective agenda.

§ 4 – The CEPH/FGV shall deliberate on the approval of a protocol by consensus or majority.

§ 5 – In case of a tie, the vote cast by the Coordinator of the CEPH/FGV shall prevail.

ARTICLE 9 – The content dealt with at the meetings of the collegial body, as well as the research protocols processed in the CEPH/FGV, are strictly confidential.

§ 1 – The meetings of the CEPH/FGV shall be closed to the public, so as to guarantee the secrecy and confidentiality of the research projects submitted and the corresponding deliberations.

§ 2 – Minutes shall be prepared of all the meetings, which shall be made available to all the members of the CEPH/FGV within 30 (thirty) days. The minutes shall contain the decisions reached, the date and starting and ending time, and nominal attendance roll.

ARTICLE 10 – The members of the collegial body must be qualified, as a group, to evaluate the compliance of the research protocols with the applicable rules and regulations; the highest international ethical standards; the fields of investigation pertaining to each case; and the institutional commitments of FGV.

§ 1 – The CEPH/FGV shall have multidisciplinary character, so that no more than one-half of its members may belong to the same professional category, and it must be composed of persons of both sexes.

§ 2 – The CEPH/FGV shall count on at least 1 (one) member whose main activity is scientific research, and at least 2 (two) external members, and at least half of its members must have proven experience in scientific research.

§ 3 – Alternate members may be designated, who will be called to substitute the permanent members when it is not possible for them to participate in ordinary and extraordinary meetings of the CEPH/FGV.

§ 4 – The CEPH/FGV may count on ad hoc consultants, persons who do or do not belong to the institution, for the purpose of providing technical-scientific input to the analyses.

§ 5 – The CEPH/FGV shall count on a Coordinator and a Vice Coordinator, who will substitute the Coordinator in her/his absence, both of whom must be permanent members of the CEPH/FGV.

ARTICLE 11 – The members of the CEPH/FGV shall be appointed by the President of FGV for a term of 3 (three) years, with reelection permitted.

CHAPTER IV

FUNCTIONAL RULES

ARTICLE 12 – The duties of the members of the CEPH/FGV are:

- I** – To analyze and issue an impartial and independent judgment about the compliance of the research projects carried out at FGV with ethical and legal standards;
- II** – To act with fortitude, honesty, decorum, veracity, loyalty, dignity and good faith;
- III** – To maintain the secrecy of information and data about the research projects submitted to the consideration of the CEPH/FGV;
- IV** – To abstain from receiving gifts or any type of advantage or benefit from the researcher or sponsor of the study, the subject of the study, or interested third parties;
- V** – To reveal any conflict of interest, as the case may be, and declare their recusal or impediment to deliberate on the research project.

Sole paragraph. Ad hoc consultants are subject to the same duties as the members of the CEPH/FGV.

ARTICLE 13 – No member of the CEPH/FGV may deliberate on a research project submitted to ethical review:

- I** – When she/he is the researcher in charge, participant, promoter or sponsor of the study;
- II** – When she/he has received gifts, advantages or benefits from the researcher, promoter or sponsor of the study, or a third party with a private and direct interest in the project.
- III** – When she/he is a spouse, relative, kin or similar person of the researcher in charge, promoter or sponsor of the study, in direct or collateral line, to the third degree.

§ 1 – The members of the CEPH/FGV may declare their recusal to consider a study for unidentified personal motives.

§ 2 – The ad hoc consultants are subject to the same impediments as the members of the CEPH/FGV and also may declare their recusal to consider a study for unidentified personal motives, under the terms of § 1 of this article.

§ 3 – In case of declaration of impediment or recusal of a member, an alternate member shall assume her/his function, or a new ad hoc consultant shall be designated, as the case may be.

CHAPTER V

COMPETENCE

ARTICLE 14 – The CEPH/FGV has competence to consider all the scientifically valid research projects that involve human beings, about whom the researcher obtains: (i) data by means of intervention or interaction with an individual; or (ii) identifiable private information about an individual; or (iii) that can cause risks greater than exist in everyday life.

ARTICLE 15 – The following do not need to be submitted to the CEPH/FGV:

- I** – Public opinion surveys with unidentified participants;
- II** – Research that uses publicly accessible information, under the terms of Law 12,527 of November 18, 2011;
- III** – Research that uses non-identifiable information in the public domain;
- IV** – Research with databases whose information is aggregated, without the possibility of identifying individuals;
- V** – Research performed exclusively with scientific texts for literature reviews;
- VI** – Research that seeks theoretical deepening of situations that emerge spontaneously and with contingency in professional practice, provided there is no revelation of data that can identify the subject; and
- VII** – Activity carried out with the exclusive intention of education, teaching or training, without the purpose of scientific research, of undergraduate, technical, specialization and professional master's degree students, such as final works of a discipline.

§ 1 – The preceding item does not apply to undergraduate and graduate theses or monographs, as well as professional or academic master's and doctoral dissertations, in which cases the research protocol must be submitted to the CEPH/FGV if it has the characteristics of research defined in Article 14.

§ 2 – If during the planning or execution of an activity for education, teaching or training the intention arises to incorporate the results of these activities in a research project, the research protocol must be submitted to the CEPH/FGV.

§ 3 – In all other cases of studies involving human beings that do not fit under the numerals above, submission to the analysis of the CEPH/FGV is required.

CHAPTER VI

RESEARCH PROTOCOL

ARTICLE 16 – The research protocols subject to analysis of the CEPH/FGV shall be sent to the Committee's Secretariat, via the submission form, available at the official website of the CEPH/FGV.

CHAPTER VII

PROCEDURE FOR EVALUATING PROJECTS

ARTICLE 17 – The procedure for evaluating projects by the CEPH/FGV starts with submission of the research protocol by the researcher in charge, accompanied by the necessary documents to support analysis of ethical compliance of the project.

ARTICLE 18 – After the research project is submitted, the Coordinator shall designate a rapporteur to present an opinion on the research project for deliberation of the CEPH/FGV.

§ 1 – The documental verification of the research protocol must be concluded within 10 (ten) days after submission.

§ 2 – The time limit for issuance of the initial opinion by the CEPH/FGV is 30 (thirty) days as of acceptance in full of the documents of the protocol.

ARTICLE 19 – Members of the CEPH/FGV may ask the researchers for additional information and/or their presence to clarify details of the study.

ARTICLE 20 – The opinion of the rapporteur shall be submitted to the discussion and deliberation of the CEPH/FGV.

ARTICLE 21 – The Coordinator shall conduct the dynamics of the work of the CEPH/FGV, and in case of her/his absence, shall be substituted by the Vice Coordinator or another member who is so designated.

CHAPTER VIII

CATEGORIES OF DECISION

ARTICLE 22 – The analysis of the research protocol will culminate in its classification in one of the following categories, as the case may be:

- I – Approved:** when the protocol is totally adequate for execution;
- II – With pending corrections:** when the decision is for the need for correction, in which case alterations or complementation of the research protocol will be requested. No matter how simple the requirement is, the protocol will continue being “with pending corrections” until the request is completely satisfied;
- III – Not approved:** when the decision considers that the ethical obstacles of the protocol are so severe that they cannot be overcome by the “pending corrections” process;
- IV – Archived:** when the researcher fails to heed the time limit to send responses regarding the pending matters indicated, or to appeal;
- V – Suspended:** when an approved study, already in progress, has to be interrupted by reason of security, especially referring to the participants in the study;
- VI – Withdrawn:** when the CEPH/FGV accepts the justified request of the researcher in charge to withdraw the protocol before its ethical evaluation, in which case the protocol will be considered closed.

§ 1 – The research activities can only be started after grant of the status “approved” by the CEPH/FGV, save determination otherwise by the CEPH/FGV.

§ 2 – If the opinion is for pendency, the researcher shall have 30 (thirty) days, counted from its issuance, to resolve the problem. After this period, the CEPH/FGV will have (thirty) days to issue the final opinion, approving or rejecting the protocol.

§ 3 – Pending matters that only involve documents will be considered previously by the technical-administrative staff and/or the Coordinators of the CEPH/FGV, and communicated directly to the researcher.

§ 4 – The CEPH/FGV will determine the archiving of the research protocol in cases where the researcher in charge fails to satisfy the solicitations presented within the indicated time limit.

CHAPTER IX

RESEARCHER IN CHARGE

ARTICLE 23 – The researcher in charge who submits a research project to the ethical consideration of the CEPH/FGV must:

- I** – Observe the formalities necessary for submission of a research project;
- II** – Send to the CEPH/FGV via the research project submission platform of the CEPH/FGV the submission form, duly supported;
- III** – Wait for the approval decision regarding the ethical implications and precautions before starting the study, save determination otherwise by the CEPH/FGV;
- IV** – Conduct the project in the form delineated and approved by the CEPH/FGV and/or send an amendment to the initial project via the platform of the CEPH/FGV when there is an alteration of the project;
- V** – Send a brief annual monitoring report about the ethical aspects of the research to the CEPH/FGV;
- VI** – Send a brief final report about the ethical aspects of the research to the CEPH/FGV when it is concluded;

- VII** – Justify the interruption of the project or non-publication of the results, as the case may be;
- VIII** – Present data requested by the CEPH/FGV at any moment;
- IX** – Report to the CEPH/FGV any adverse events as well as ethical or legal infractions that occur, and evaluate, with emergency character, the need to adjust or suspend the study;
- X** – Maintain the research data in a file, physical or digital, under her/his safekeeping and responsibility, for a minimum period of 5 (five) years after the end of the study;
- XI** – Observe and abide by the rules and resolutions issued by FGV;
- XII** – Observe the highest national and international ethical standards regarding research in conducting the research project.

CHAPTER X

DEVIATION AND NONCOMPLIANCE WITH THE PROTOCOL

ARTICLE 24 – Any deviation of the protocol approved by the CEPH/FGV and/or its determinations must be communicated immediately.

§ 1 – The deviation and/or noncompliance with the approved protocol can alter the risk-benefit ratio to the participants or compromise their safety, rights and welfare.

§ 2 – Exceptional situations justify the deviation of the approved research plan or continuation of the study before its approval, in order to protect the subjects participating in the study.

CHAPTER XI

SUSPENSION, REVOCATION AND TERMINATION OF THE PROJECT

ARTICLE 25 – The CEPH/FGV has the authority to suspend, revoke or declare termination of studies involving human beings.

ARTICLE 26 – The CEPH/FGV may suspend or revoke studies in cases when:

- I** – They are not being conducted under the terms of its decision;
- II** – They are associated with unforeseen risks or damages to the participant, such as:
 - a.** Severe and unexpected supervening adverse situations;
 - b.** Harmful changes in the risk-benefit relation of the study;
 - c.** Investigation activities without the prior approval of the CEPH/FGV;
 - d.** Failure to obtain appropriate consent of the participants;
 - e.** Failure by the researchers to complete the necessary training for the study;
 - f.** Other situations of noncompliance of the project.

ARTICLE 27 – Suspension causes temporary cessation of all the activities of the project, until pending questions can be resolved satisfactorily.

Sole paragraph. Suspended projects are still considered approved, but with the status of “suspended”, until the pending questions are resolved.

ARTICLE 28 – Revocation causes immediate cessation of all the activities of the project, and any subsequent analyses shall be considered invalid.

Sole paragraph. Revoked studies will not be considered concluded.

ARTICLE 29 – Termination will be declared with the end of the time period set by the CEPH/FGV for realization of the study, without the researcher having presented a request for renewal or the end of the study.

Sole paragraph. The CEPH/FGV will in this case presume that there is no investigation activity involving human subjects in course.

CHAPTER XII

APPEALS

ARTICLE 30 – If the researcher disagrees with a decision reached by the CEPH/FGV, she/he may request, one time only, reconsideration of the decision by the collegial body itself, by presenting the reasons for believing the proposed research procedures obey the requirements of these Rules, within 30 (thirty) days counted from issuance of the opinion by the CEPH/FGV.

CHAPTER XIII

AMENDMENTS AND EXTENSIONS

ARTICLE 31 – An amendment is defined as any proposal for modification of the original project, presented with the proper justification.

Sole paragraph. The amendments must be presented to the CEPH/FGV clearly and succinctly, identifying the part of the protocol to be modified and the respective justifications. The amendment will be analyzed by the instances of its final approval.

ARTICLE 32 – An extension is any prolongation or continuation of the study with the same participants, without essential change in the objectives and methodology of the original project. In the event of important or substantive modifications of objectives and methods, another research protocol must be submitted.

CHAPTER XIV

SECRETARIAT OF THE CEPH/FGV

ARTICLE 33 – The attributions of the Secretariat of the CEPH/FGV are:

I – To provide to the CEPH/FGV the technical and administrative support necessary for it to exercise its functions;

- II** – To maintain on file the minutes of meetings, along with the reports and other documents related to the studies, for a minimum period of 5 (five) years after the conclusion of the study;
- III** – To guarantee the confidentiality of all the documents and data that circulate within the CEPH/FGV;
- IV** – To offer training to its members and promote education about ethics of research involving human beings;
- V** – To comply with the other attributions inherent to the nature of the function.

ARTICLE 34 – The attributions of the Secretary of the Committee are:

- I** – To guarantee the technical and administrative support necessary for the functioning of the CEPH/FGV;
- II** – To analyze the research projects submitted via the digital platform of the CEPH/FGV, according to the applicable rules, indicating any failures or missing documents to be rectified;
- III** – To record, in minutes, the main deliberations of each meeting, along with the date, time and members in attendance;
- IV** – To comply with the other attributions inherent to the nature of the function.

CHAPTER XV

MISCELLANEOUS PROVISIONS

ARTICLE 35 – The CEPH/FGV will resolve any ambiguities or omissions in each case.

ARTICLE 36 – The present Rules may be modified by the Presidency of FGV at any moment, and the updated version will be immediately communicated to the community.

ARTICLE 37 – The present Rules will take effect on the date of their approval by the Presidency of FGV.