Rule of Procedure for the Activities of the Research Ethics Committee of GIPA – Georgian Institute of Public Affairs

Article 1
Scope of Regulation

1.1 This statute is developed in accordance with the applicable legislation of Georgia, including the Law of Georgia on Higher Education, and defines the rules and procedures for the establishment and operation of the Research Ethics Committee of N(N)LE GIPA – Georgian Institute of Public Affairs (hereinafter – the University), as well as other issues related to the functioning of the Ethics Committee.

1.2 This rule applies to the academic and invited staff of the University (including vocational education teachers), students (including vocational students and listeners), and individuals who, in any other capacity, may be involved in research/creative activities organized within the framework of the University.

2. Purpose and Functions of the Research Ethics Committee:

2.1 The Research Ethics Committee is an independent body of the University, established on a multidisciplinary basis, responsible for ensuring that the research/creative activities conducted within the University comply with universally recognized ethical and legal standards. Its purpose is to review research projects/plans in order to ensure the protection and respect of the dignity, fundamental rights, safety, and well-being of research participants.

2.2 The functions of the Research Ethics Committee include, but are not limited to, the following:
2.2.1. Assessing the compatibility of research projects/plans to be implemented within the University and by the University's academic and invited staff (including vocational education teachers), students (including vocational students and listeners), and individuals who, in any other status, may participate in research/creative processes organized within the University, with the standards of research ethics and integrity, and preparing an appropriate conclusion;
2.2.2. Developing and approving the application form for submission of a research project/plan and other related documentation;
2.2.3. Monitoring ongoing research to confirm that it is conducted within the framework of the approved research project/plan and in accordance with international standards, including the European Code of Conduct for Research Integrity, the Declaration of Helsinki, the Singapore Statement on Research Integrity, and nationally recognized ethical standards;
2.2.4. Promoting and raising awareness about the activities of the Research Ethics Committee;
2.2.5. Preparing recommendations to ensure compatibility with research ethics and integrity standards within the University;
2.2.6. Registering data on research evaluated by the Ethics Committee and ensuring alignment with open science standards;

2.2.7. Preparing an annual report on the work performed by the Committee and presenting it to the University's Academic Council (hereinafter – the Academic Council);
2.2.8. Other activities aimed at establishing modern standards of research ethics.

2.3 The Research Ethics Committee is independent in its decision-making; it must not be subject to any pressure, and none of its members shall experience a conflict of interest.

2.4 All members of the Research Ethics Committee and representatives of the administrative support unit shall maintain the confidentiality of any information submitted to the Committee. An expert invited to provide an opinion on a specific research project/plan is also obligated to uphold confidentiality. The content of discussions during the review of a research plan and other details of the evaluation process are also subject to the principle of confidentiality. The application submission procedure itself is confidential, and for that purpose, the application must include a designated contact person who will be responsible for communication with the Research Ethics Committee and for responding to the Committee's questions.

2.5 The Research Ethics Committee, as needed, shall prepare a draft of amendments and additions to the statute and submit it to the Rector of the University for approval.

3. Composition of the Research Ethics Committee

3.1 The composition and chairperson of the University's Research Ethics Committee shall be approved by the Rector of the University, based on the nomination submitted by the Head of the Research Department in agreement with the University's Scientific Council.

3.2 The University's Research Ethics Committee consists of no more than 9 members and is chaired by a Chairperson. The role of Secretary is performed by the Research and Development Manager of the University's Research Department. The Secretary also participates in all administrative activities of the Research Ethics Committee and supports the operational process of the Committee.

3.3 A member of the Research Ethics Committee may be:
3.3.1. Academic staff of the University who demonstrate high scientific productivity and have publications in internationally indexed peer-reviewed journals;
3.3.2. Representatives of the Research Department;
3.3.3. Representative(s) of the University's Legal Office;
3.3.4. Invited experts, member(s) who do not have voting rights in decisions made by the Research Ethics Committee.

3.4 One-third of the composition of the Research Ethics Committee is subject to renewal every three years.

3.5 The composition of the Research Ethics Committee shall be renewed in the following cases:

3.5.1. When a member of the Ethics Committee leaves the Committee;
3.5.2. When the Rector of the University decides to replace a member or members of the Committee based on the principle of rotation.

3.6 Upon recommendation to the Rector, the Research Ethics Committee may establish a temporary commission (e.g., a temporary quality/internal audit commission) responsible for monitoring the quality of activities outlined in the Committee's statute.

3.7 A session of the Research Ethics Committee is considered valid if 2/3 of the total membership is present. Decisions are made by a simple majority vote. In the event of a tie, the Chairperson of the Committee holds the deciding vote. The following decisions are discussed and approved during sessions of the Research Ethics Committee:
3.7.1. Conclusions prepared by the Committee;
3.7.2. Annual reports of the Committee;
3.7.3. Selection and approval of members and chairpersons of temporary commissions from among the Committee's composition;
3.7.4. If necessary, involvement of invited experts to provide expertise on conclusions and recommendations prepared by the Committee;
3.7.5. The Chairperson of the Research Ethics Committee, in coordination with the Committee Secretary:
3.7.5.1. Prepares, convenes, and leads regular and ad hoc meetings;
3.7.5.2. Represents the Research Ethics Committee before relevant governing bodies of the University and the public;
3.7.5.3. Develops plans for the Committee's meetings and other activities;
3.7.5.4. Ensures timely responses to applications;
3.7.5.5. Signs official documents of the Research Ethics Committee, including the Committee's conclusion regarding the ethical review of a research project/plan, as well as other documents;
3.7.5.6. Coordinates, manages, and supervises the operations and various activities of the Research Ethics Committee and the Secretariat's work;
3.7.5.7. Supervises and plans information and awareness-raising activities.

4. Submission of a Research Project/Plan to the Research Ethics Committee

4.1 Any researcher whose scientific study is planned to be conducted on the basis of GIPA – Georgian Institute of Public Affairs, with the participation of GIPA, or in an institution affiliated with GIPA, may apply to the Research Ethics Committee in order to determine the compatibility of their research project with ethical and integrity standards.
4.2 The Research Ethics Committee focuses on assessing the research project/plan prior to the actual start of the study and does not accept applications requesting a review of ongoing or completed research in terms of ethical compatibility. Such applications, if submitted, shall be rejected.
4.3 To submit an application, the author(s) of the scientific-research-creative project must first contact the Research Department of GIPA – Georgian Institute of Public Affairs to evaluate the scientific-research characteristics and value of the project. Only after this step is the project

forwarded to the Research Ethics Committee and the corresponding application filled out (see Annex #1).

4.4 If the research project, ongoing or completed study is already registered and confirmed by the Research Department of GIPA – Georgian Institute of Public Affairs, and the researcher, participant, or sponsor deems it necessary to request a later or repeated ethical review or clarification, it is permissible to apply directly to the Ethics Committee, while simultaneously informing the Research Department about the submission.

4.5 The application for ethical review of the research project/plan and all other necessary documents required for ethical expertise, the list of which is provided in the following points of this article, shall be submitted to the Secretary of the Ethics Committee.

5. The application must contain sufficient information to allow the Research Ethics Committee to conduct an ethical review of the research plan. Members of the Research Ethics Committee must be assured that the risk and burden associated with participation in the research do not exceed acceptable limits for participants, and that participant recruitment/selection follows these three principles: participation is voluntary; recruitment corresponds with the main research question (objective) and methods; and selection is conducted without discrimination.

5.1 The following documents must be submitted to the Research Ethics Committee for ethical review of the research project/plan:

4.6.1. Application for ethical review of the research project/plan, in a form developed and approved by the Research Ethics Committee;

4.6.2. Research plan including the following information:

4.6.2.1. Name of the principal investigator, qualifications and experience of the researchers;

4.6.2.2. Funding details of the research project;

4.6.2.3. Research objective and justification of necessity, based on recent scientific evidence;

4.6.2.4. Research methods and procedures, including statistical and other analytical methods;

4.6.2.5. A comprehensive summary of the research plan presented in simple, layperson-accessible language;

4.6.2.6. Information on whether the research plan has been submitted for review and approval by other ethics committees, the outcome of such reviews, and any changes made to the research project/plan following such decisions;

4.6.2.7. Justification for the participation of representatives of the target group in the research; inclusion and exclusion criteria for research participants; selection method, if necessary; research type: open, single-blind, or double-blind; procedures for selecting and inviting participants; reasons for use or non-use of a control group; interventions used for the control group;

4.6.2.8. Description of the nature and degree of anticipated risks related to research participation; the nature, extent, and duration of planned intervention, as well as any inconvenience or discomfort associated with participation in the study; measures for monitoring, evaluating, and responding to unforeseen events that could have significant implications for the current or future health of research participants and/or others connected with the research;

4.6.2.9. Description of the information provided to research participants, including the timing and method of delivery; documentation and any visual or other materials to be used to obtain consent or authorization (where the person lacks the ability to give consent), including: informed consent form; brochures, information sheets, or other materials intended for the research subject and/or their legal representative, if available;
4.6.2.10. Measures to ensure the protection of participants' privacy and the confidentiality of personal data; how information obtained during the research process will be used, especially if it may affect the current or future health and emotional well-being of participants or their family members;
4.6.2.11. Any additional information regarding the implementation of the research, including: description of required facilities, equipment for conducting the study; any compensation or incentives for participation; all circumstances that could lead to a conflict of interest and interfere with the independent judgment of the researchers, particularly concerning the health and emotional well-being of research subjects; potential future uses of the research results or data, including commercial use; description of any other ethical issues deemed important by the researchers; details of any insurance or compensation intended for damage caused by participation in the research.
5.2 The documentation listed in subparagraph 2 of this article must also be submitted in electronic format.
5.3 The Research Ethics Committee is entitled to request any additional information necessary for the ethical evaluation of the research project.
5.4 Applications are registered in the register of the Research Ethics Committee under an assigned number, and the title of the research, date of submission, personal details (name, surname, position) of the research project leader/principal investigator and the contact person, and the name of the institution, organization, or initiative group conducting the research are recorded. In communication with the Research Ethics Committee, the research project leader/principal investigator may also act as the contact person.

5. Evaluation of the Research Plan by the Research Ethics Committee and Decision-Making

5.1. The Secretary of the Research Ethics Committee conducts a preliminary evaluation of the application for a biomedical research plan and the accompanying documentation to determine whether the documentation has been submitted in full.

5.2. If the documentation is not fully submitted, a conclusion is prepared listing the inadequately completed documents or those that are required but missing. To supplement the documentation specified in the conclusion, the application authors are notified through the contact person. The authors of the research project/plan are granted an additional 5 working days to address the deficiencies and submit the required documentation. If the documentation is not submitted, the application will not proceed to the meeting of the Research Ethics Committee and will be assigned a "pending" status.

5.3. If the documentation is fully submitted, the Secretary of the Committee, in agreement with the Chair of the Research Ethics Committee, forwards it to the relevant members of the Committee for evaluation. A selected Committee member must decline to evaluate the research plan if they have a conflict of interest. In such a case, the Secretary of the Committee forwards the research plan to another Committee member. Additionally, the Secretary sends the electronic versions of the documents listed in Article 4, Paragraph 3 to all Committee members via email.

5.4. The selected member of the Ethics Committee analyzes the research plan based on the submitted documentation and prepares for discussion of the given research plan at the next meeting. Furthermore, based on the content of the research, the selected Committee member determines the necessity of inviting an expert, identifies the expert, and the issues to be clarified with them, and informs the Secretary of the Ethics Committee accordingly.

5.5. The Secretary of the Ethics Committee, together with the Chair of the Ethics Committee, makes the decision regarding the necessity of inviting the expert and their selection. The Secretary forwards the research plan and other necessary documents to the selected expert and invites them to the next session of the Ethics Committee.

5.6. The invited expert reviews the documents provided to them, prepares responses to the questions posed, and presents their conclusions to the Ethics Committee at its next session. The invited expert participates in the session of the Ethics Committee without voting rights.

5.7. The Ethics Committee discusses the research project plan, evaluates its ethical aspects, and determines whether the research may be conducted from an ethical standpoint. The main presenters during the discussion are the selected members of the Ethics Committee who were previously provided with the full package of documents related to the research (see Paragraph 3 of this Article), and the invited expert (if applicable). All Committee members present participate in the discussion.

5.8. Members of the Ethics Committee who are involved in a conflict of interest must not participate in the ethical evaluation of the given research plan.

5.9. In the ethical evaluation of the research plan, the members of the Ethics Committee are guided by Georgian legislation and universally recognized ethical and professional standards. Specifically, the members of the Ethics Committee must evaluate: the necessity of the research and the need for human (living subject) participation; the sufficiency of the qualifications and experience of the researcher and their team to conduct the proposed study; the level of risk and expected benefit of the research, and whether conducting the research is acceptable under the existing risks to achieve the stated goals; whether the participation in the research poses a threat to the subject's health and emotional well-being; whether the informed consent procedure is adequately planned, and whether the research subject is provided with all necessary information in a language they understand; whether any pressure (including

financial) is excluded during the consent process; whether any form of discrimination is excluded during the selection of research participants; whether the guarantees for the confidentiality of information about research subjects provided in the research plan are adequate.

5.10. As a result of the relevant discussion, the Research Ethics Committee makes one of the following decisions regarding the research project/plan:

5.1.1. Approval without changes (consent), which grants the researcher/research group the right to conduct the research within the framework of the research plan, without making any changes to it.

5.1.2. Conditional approval (conditional consent with modifications), which grants the researcher/research group the right to begin the research only after introducing specific changes recommended by the Research Ethics Committee to the plan and/or submitting the requested additional information. In this case, the submitted changes are evaluated either by the Chair of the Committee or by a designated member of the Committee, based on which the Chair of the Committee gives consent or refusal to carry out the research.

5.1.3. Rejection until the next session, meaning that the given research project/plan requires significant revision, after which it may be reviewed at one of the Committee's subsequent sessions.

5.1.4. Final rejection, meaning that the given research must not be conducted.

5.1 The decision of the Research Ethics Committee must be reasoned and based on the relevant factual circumstances and evidence.

5.2 In addition to what is stated in paragraph 5.1, the conclusion may contain a request:

5.3.1. To submit a progress report or reports on the research to the Ethics Committee;

5.3.2. Regarding the need for re-evaluation of the research plan, when due to the long duration of the research (several years) and/or high risk or other circumstances, there is a basis for caution.

5.3 The conclusion of the Research Ethics Committee regarding the ethical evaluation of the research project/plan shall be issued no later than one month from the date the research documentation is submitted to the Committee.

5.4 In exceptional cases, the evaluation period may be shortened or extended, for which a reasoned decision of the Chair of the Research Ethics Committee is required.

5.5 The conclusion of the Ethics Committee is recorded in a protocol and entered into the Ethics Committee register.

5.6 At the request of the research project leader/principal investigator or their representative (as indicated in the contact person's section), an excerpt from the protocol is provided, indicating the result of the research plan review and the conclusion of the Research Ethics Committee.

Article 6. Supervision of Ongoing Research

6.1. The Research Ethics Committee shall:

6.1.1. Review interim and final reports of research projects operating with the support of the Research Ethics Committee;

6.1.2. Re-evaluate the research plan, if a decision to do so has been made in accordance with the circumstances specified in subparagraph 5.1.2 of paragraph 5.1 of Article 5;

6.1.3. Request and review information, as needed, regarding the progress of research conducted with the support of the Research Ethics Committee.

6.2. The head/principal investigator of a research project operating with the support of the Research Ethics Committee is obliged to inform the Ethics Committee:

6.2.1. Of any changes made to the research plan, if these are related to matters of research ethics and integrity;

6.2.2. Of any issues arising during the research process that concern the health, safety, and rights of research subjects and/or may necessitate the re-evaluation of the research from an ethical standpoint.

Article 7. Appeal of the Evaluation Made by the Research Ethics Committee

7.1. A research/creative project plan leader/principal investigator who disagrees with the evaluation of the Research Ethics Committee has the right, within 3 calendar days from the date of receiving the evaluation result, to submit a written, reasoned appeal to the Chair of the Research Ethics Committee.

7.2. Within 30 calendar days of receiving the written appeal, the Research Ethics Committee shall review it and decide whether to uphold or reject the appeal.

7.3. If the appeal is upheld, the Research Ethics Committee shall define the composition of the Appeals Commission and submit it for approval to the Rector of the University.

7.4. The Appeals Commission shall consist of no fewer than three members holding a doctoral or equivalent academic degree. No individual who participated in the original evaluation of the research/creative project/plan may be included in the Appeals Commission.

7.5. The Appeals Commission must, within no more than 60 calendar days from its establishment, examine and re-evaluate the research/creative project/plan.

7.6. The Research Ethics Committee shall ensure that the Appeals Commission members receive the research/creative project/plan in a form that does not disclose the original evaluation.

7.7. Appeals Commission members shall individually assess the research project/plan according to pre-established criteria. The Appeals Commission's evaluation is final and not subject to further appeal.

Article 8. Response to Violations of Scientific Ethics and Research Integrity

8.1. Each participant is individually responsible for adhering to the standards of scientific ethics and research integrity in the course of research and creative activities.

8.2. Any type of misconduct occurring within the framework of research/creative processes organized at the university level is considered a violation and is treated as a breach of research ethics and scientific integrity. Such cases are addressed in accordance with the University's Code of Ethics and Conduct.

Article 9. Raising Awareness about the University's Research Ethics Committee

9.1. As part of informational literacy and awareness-raising campaigns aimed at promoting academic and scientific integrity, the University's Research Department periodically disseminates information through research integrity officers about the Research Ethics Committee, its mission, the procedures guiding its operations, the mechanisms for addressing violations of these rules, and issues of incompatibility with standards of scientific ethics and research integrity in the research process.

Article 10. Temporary Commission of the Research Ethics Committee

10.1. Based on a submission to the Rector of the University, a temporary commission of the Research Ethics Committee, composed of no fewer than three members, shall be appointed at the end of each year in order to monitor the performance quality of the activities outlined in the committee's charter. Its goal is to ensure that the policies and procedures of the Research Ethics Committee align with applicable requirements.

10.2. The commission evaluates: the structure and composition of the Research Ethics Committee in relation to the number and nature of research projects conducted at GIPA – the Georgian Institute of Public Affairs; the adequacy of its management and procedures; whether research protocols are reviewed in a timely manner and in accordance with established procedures; the appropriateness and effectiveness of communication with researchers; and the practices of documentation and record-keeping.

Article 11. Final Provisions

11.1. Amendments and additions to these rules may only be made by order of the Rector of the University.

11.2. These rules shall enter into force upon approval.

Annex #1: *Template of the Application to be Submitted to the Research Ethics Committee for Ethical Evaluation of a Research/Creative Project/Plan*

Research Ethics Committee of a N(N)LE GIPA – Georgian Institute of Public Affairs
Application for the Review of a Research-Creative Project

Please, at the Research Ethics Committee, discuss the aspects of research ethics and integrity of the submitted research/creative project ----------
---
---------- and issue an appropriate conclusion.

Project Author(s): ----------

Principal Investigator(s): ----------

Institution(s) Planning the Research:----------

Implementers: ----------

Project Sponsors: ----------

Contact Person:----------

Application Submitted by: ---------- Date: ----------