## Guideline

## Conditions under which research activity needs to be reviewed by the Research Ethics Committee

Ethical norms adherence needs to be established by the Research Ethics Committee if the research involves the use of experimental animals and human subjects.

The Research Ethics Committee of the Faculty of Natural Sciences and Medicine of LEPL Ilia State University must assess the adherence of the activities planned within the framework of the research project with the international ethical standards and regulations and those of Ilia State University.

The information below will help you determine whether your research activity requires review by the Research Ethics Committee.

### Is the activity research?

Research activity must meet both of the following criteria:

- ✓ The activity is a systematic investigation and involves the conduct, analysis, and evaluation of research.
- ✓ The activity aims to develop or contribute to the generalization and accumulation of knowledge.

### Identification of ethical issues – to be completed by the researcher

| 1. Human research | Yes | No |
|---|---|---|
| **Please note:** Any research involving human subjects may not commence until an application submitted by the researcher(s), detailing the rationale for the study and the details of the study procedures, has been approved by the Research Ethics Committee. | | |
| Does the submitted research involve healthy adult volunteers (including conducting surveys)? | ☐ | ☐ |
| Does the submitted research involve children (under 18 years of age)? | ☐ | ☐ |
| Does the proposed research involve patients? | ☐ | ☐ |
| Does the research involve vulnerable individuals? | ☐ | ☐ |
| Does the proposed research involve individuals who are unable to give consent? | ☐ | ☐ |

| 2. Privacy/Personal Data | Yes | No |
|---|---|---|
| Does the proposed research involve the collection and storage of personal data? | ☐ | ☐ |
| Does the submitted research involve the processing of genetic information or personal data (e.g., health, sexual lifestyle, ethnicity, political opinions, religious or philosophical | | |

| | | |
|---|---|---|
| beliefs)? | ☐ | ☐ |
| Does the proposed research involve location tracking or observation of people (audio/visual recording)? | ☐ | ☐ |
| Does the research involve the prospective publication of personal data? | ☐ | ☐ |
| Please note that the following information must be submitted with the application:<br>Detailed procedures regarding data collection and storage, confidentiality, anonymity. As well as the right to request deletion of the requested data. | | |

| 3. Research on human genetic material | Yes | No |
|---|---|---|
| Does the submitted research involve the collection/research of human genetic material? | ☐ | ☐ |
| Does the submitted research involve the collection/research of human biological samples? | ☐ | ☐ |

| 4. Human or animal research | Yes | No |
|---|---|---|
| Does the submitted research involve the use of a new medical product or medical device or application, or the use of an existing product outside the terms of the license for that product? | ☐ | ☐ |
| Does the proposed research involve the use of ionizing or non-ionizing radiation, radioactive substances, or X-rays? Should a competent radiation protection advisor be involved in its implementation? | ☐ | ☐ |

| 5. Research on human embryos/fetuses | Yes | No |
|---|---|---|
| Does the submitted research include human embryos? | ☐ | ☐ |
| Does the submitted research include human fetal tissues/cells? | ☐ | ☐ |
| Does the submitted research include human embryonic stem cells (hESCs)? | ☐ | ☐ |
| Does the submitted research include human embryonic stem cells in culture? | ☐ | ☐ |
| Does the submitted research include the extraction of cells from human embryos? | ☐ | ☐ |

| 6. Animal research | Yes | No |
|---|---|---|
| Does the proposed research involve animal research? | ☐ | ☐ |
| Are these animals transgenic small laboratory animals? | ☐ | ☐ |
| Are these animals transgenic farm animals? | ☐ | ☐ |
| Are these animals primates from another group? | ☐ | ☐ |
| Are these animals cloned farm animals? | ☐ | ☐ |
| Are these animals wild animals? | ☐ | ☐ |
| Does the research involve surgical experimentation on live animals? | ☐ | ☐ |
| Does the submitted research involve animal tissues/cells? | ☐ | ☐ |

| 7. The removal of living organisms (animals or plants) from their natural environment | Yes | No |
|---|---|---|
| Does the research involve the removal of organisms from the natural environment? | ☐ | ☐ |
| Does the research involve the removal of legally protected species from the wild? | ☐ | ☐ |
| Does the research involve the collection of tissue samples from living animals in the wild? | ☐ | ☐ |
| Does the research involve the killing of vertebrates during the collection process? | ☐ | ☐ |

| 8. Other ethical issues | Yes | No |
|---|---|---|
| Are there other activities that could raise ethical issues? | ☐ | ☐ |
| If yes, please specify: | | |
| | | |

**Note:**

If the activity is assigned the research category and you answer "Yes" to any of the questions in the guideline, you must submit an application to the Dean of the Faculty of Natural Sciences and Medicine of Ilia State University or to the Rector of Ilia State University in order to determine the ethics of the research.

Please attach the application form and other required documents to the application and send it to the email address of the University Chancellery: info@iliauni.edu.ge.

Detailed procedures are described in the document "Regulations of the Research Ethics Committee of the Faculty of Natural Sciences and Medicine".

Application Form

(Information must be provided in full in accordance with the requested sections)

| Contact information of the researcher | |
|---|---|
| **Researcher (first name, last name)** | |
| **Academic degree/status** | |
| **Name of the organization/university Institute/school** | |
| **Name of the training program (if you are a student)** | |
| **First name, last name of the supervisor (if you are a student)** | |
| **Contact information of the supervisor (if you are a student)** | Phone number: |
| | E-mail: |
| **Do you have a certificate from a bioethics course?** | Yes ☐<br>No ☐ |
| **Address** | |
| **Phone** | |
| **E-mail** | |

| Information about the project | | |
|---|---|---|
| **Title of the research** | | |
| **Does the research have a donor/sponsor?** | Yes ☐ | No ☐ |
| | (If yes, please provide as an attachment) | |
| **Start date of the research** | Click here to enter a date. | |
| **End date of the research** | Click here to enter a date. | |

| **Overview and relevance of existing scientific research on the research topic** (why is the research topic important; what potential benefits will the research and general population receive; what will the research add to the relevant field) |
|---|
| |

| |
|---|
| |

| Research goals and objectives |
|---|
| |

| **Research design and procedures (full research protocol must be attached with the application form)**<br>(research object, research method, participant selection, data collection, inclusion and exclusion criteria, research instrument) |
| --- |
| |

| Are vulnerable groups included in the research? |
|---|
| ☐ Vulnerable groups<br>☐ Minors<br>☐ Prisoners<br>☐ Pregnant women<br>☐ People with special needs (people with disabilities)<br>☐ People with mental health problems<br>☐ People who are socially vulnerable or uneducated<br>☐ Groups that are marginalized in society (e.g., LGBT, illegally employed immigrants, drug users, sex workers)<br>☐ People employed in sectors with a hierarchical structure (e.g., those employed in the armed forces)<br>☐ People with terminal illnesses or patients in the final stages of their illness<br>☐ Elderly people<br>☐ People from social shelters/institutionalized people<br>☐ Unemployed and people living below the poverty line<br>☐ Ethnic minorities<br>☐ Homeless, internally displaced persons, refugees, nomadic migrants<br>☐ Embryo Use |

| Consideration of animal welfare and environmental impact |
|---|
| ☐ Not considered in the research |

| **Removal of living organisms (animals or plants) from their natural environment**<br>1) If the collection involves protected species, the relevant permit must be presented if necessary; 2) If live samples of vertebrates are taken or they are killed for storage in a collection, this must be explained in the section - "Research design and procedures". |
|---|
| ☐ Not considered in the research |

| **Use of cell cultures**<br>(When using cells from different sources — **human cells**: were the cells obtained ethically, for example, with informed consent from donors? If **embryonic or stem cells** are used, were they obtained in accordance with ethical guidelines? **Animal cells**: were the cells obtained in accordance with animal welfare standards? |
|---|
| ☐ Not considered in the research |

| **Potential risk**<br>(Health, medical, psychological, social, etc.) **Physical risks**: harm from procedures, tests, or interventions. **Psychological risks**: stress, anxiety, or trauma. **Social risks**: Violation of confidentiality or social stigmatization. **Legal risks**: legal consequences of sharing or disclosing information about participation, disclosure of personal data. **Economic risks**: loss of income, benefits, or employment. |
| --- |
| |

| **Research data protection procedure** |
| --- |
| ☐ Not considered in the research |

| Protection of anonymity and confidentiality |
| --- |
| ☐ Not considered in the research |

| Procedure of getting informed consent<br>(Whether the research participant's consent document is in their native language. Describe the setting and vulnerable population) |
| --- |
| ☐ Not considered in the research |

| **Compensation for participation in research**<br>(e.g., monetary/incentive gifts, credit hours for students participating in the research, etc.) |
| --- |
| ☐ Not considered in the research |

| **Statistical analysis** |
| --- |
| |

**The following documents must be attached to the application form as an appendix**:

1. Informed consent form, accompanied by a research information sheet (if applicable);
2. Complete research protocol;
3. All other resources provided to participants (e.g., screener, questionnaire, etc.).
4. Relevant permits for conducting the research

**Appendix #1**

## Conflict of Interest Form for Ethics Committee Members

### Information about the research

| | |
|---|---|
| Title of the research | |
| First name, last name of the main researcher | |
| First name, last name of the Research Ethics Committee member | |
| Application number | |
| Email address of the Research Ethics Committee member | |

"I, [Name of the Research Ethics Committee member], the scientific supervisor of [First name, last name of the student/researcher] confirm that they have submitted the application entitled [application number]. Due to the aforementioned professional relationship with the student/researcher, I inform you and acknowledge that this constitutes a conflict of interest. Therefore, in order to ensure an impartial review process, I recuse myself from all discussions, evaluations and decision-making related to this application."

Signature: _____

Date: _____

Appendix #2

## Application Evaluation Criteria

In order for the Research Ethics Committee to grant permission for conducting the research, it must be satisfied that the research meets the following requirements (taking into account the research objects):

**Criterion 1.** The risk to the subjects of the research is minimized.

**Criterion 2.** The risk is reasonable in relation to the expected benefit;

- With regard to the significance of the knowledge obtained as a result of the research, the Research Ethics Committee should consider only those risks and benefits that can be obtained as a result of the research.
- The Research Ethics Committee should not take into account the long-term effects of the knowledge obtained as a result of the research if the risks outweigh the benefits or may involve certain risks for the subjects involved in the research.

**Criterion 3. The selection of subjects is fair.**

- The Research Ethics Committee should take into account the purpose of the research, the setting in which the research is conducted, and the vulnerable populations (children, prisoners, pregnant women, people with mental health problems, etc.) that are participating.

**Criterion 4.** Informed consent is obtained from each subject or an authorized representative.

- The Research Ethics Committee may also authorize an informed consent procedure that modifies some or all elements of informed consent.

**Criterion 5.** The informed consent form is properly reasoned.

Where appropriate:

**Criterion 6.** Data collection is monitored to ensure the safety of research subjects.

**Criterion 7.** The anonymity and confidentiality of participants and their data are protected.

**Criterion 8.** Additional safeguards are provided for vulnerable populations to protect their rights and well-being.

**Appendix #3**

## Amendment Report

Instructions for submitting an application

Please complete this form in full and submit it to the Research Ethics Committee for review at the following email address: info@iliauni.edu.ge

Information about the researcher

First Name _____ Last Name_____ ID _____

Address _____ City _____

Country _____ Postal index _____

Phone number _____ E-mail _____

Title of the Project _____ Supervisor _____

Application number _____

Please attach a document describing any changes you intend to make to your project (e.g., change in main researcher(s) or donor; change in procedure; which impacts risk/benefit ratio; significant change in research population or recruitment method, etc.).

Please attach, as appropriate, documentation describing changes to informed consent, confidentiality, or other procedures that are associated with increased risks.

Researcher's signature _____ Date _____

Supervisor's signature _____ Date _____

For office use only

Application number _____ Session number _____

Conclusion: ☐ Permit granted ☐ Permit granted with conditions ☐ Denied

Signature of the Chairman of the Research Ethics Committee _____

Date _____

**Appendix #4**

## Consent Form for Participation in the Research

**Note to the researcher:** If a minor respondent is included in the research, it is necessary to document their positive response to participation in the research. A consent form is a written document used to inform the minor in a language they understand so that they can determine whether to participate in the research. The consent form is presented to children aged 6 and above. If the child is unable to read and write, then procedures should be used to present it verbally and obtain verbal consent from the minor.

**Note:** Parents (legal guardians or other authorized persons) must sign an informed consent form that gives the researcher permission to include the minor in the research. All research involving minors is required to have a signed consent form from the parent (legal guardian or other authorized person) before the consent form is presented to the minor.

*See below for a sample consent form. Use language appropriate to the minor's age.*

### Title of the Research

1. Introduce yourself and the people with whom the child will interact [first name, last name].
2. Describe the purpose of the research: We are asking you to participate in the research that will examine [research topic].
3. Describe the questions you will ask the child: If you agree to participate in the research, you will be asked questions such as… [describe the process in language the child can understand. If the research involves several tasks, use a bulleted format to list these tasks. Indicate the time it will take for the child to participate in the research].
4. Describe the procedures that will be followed in the case of taking biological material and laboratory testing.
5. Describe the risks (if any) and how these risks will be managed: [e.g., the needle may hurt, but this pain will go away very quickly].
6. Describe the benefits (if any) that the child will experience from participating in the research: [e.g., the research will not help me feel better, but the findings the doctor/researcher discovers as a result of the research will later help children in my situation].
7. Make sure the child has talked to their parents about their participation in the research: [e.g., please talk to your parents about your participation in the research before you decide to participate. We will ask your parents if they want you to participate. If your parents decide that you can participate in the research, you can still refuse to participate in the research].
8. Explain that they can ask you questions: you can ask me any questions about the research and I will try to answer them. If you have any questions later, you can contact me (provide a phone number).
9. Talk about the voluntary nature of participation: [e.g., your participation in the research is voluntary. It is up to you. No one will be angry with you if you refuse to participate. If you want to participate in the research, give your consent. If you change your mind after you consent, you can withdraw from the research at any time.

Please select one of the following options:

☐ No, I do not want to participate in the research

☐ Yes, I want to participate in the research

First and last name initials:

Date:

Parent/Legal Guardian Informed Consent Form

## Parent/Legal Guardian Informed Consent Form (Project Name)

Dear Parent or Guardian,

Your child is invited to participate in a research project being conducted by (insert first name and last name), who is a (student/researcher) at (organization/university).

The purpose of the proposed project is (describe the project in a language that is easy for the parent or guardian to understand).

What participation in the research involves — survey / procedures / etc. The potential risks associated with this research are as follows (list any foreseeable risks or discomforts that the research participant may face). We expect that your child will receive the following benefits from this project (list any foreseeable benefits). (If there are no direct benefits to the participants, describe other benefits expected from the research project).

The privacy of your child will be protected in all publications and presentations resulting from this research. (Describe the methods you will use to protect the confidentiality and anonymity of the research participants or explain that participant names may be used in the final research document. If you are conducting an experiment in which participants are audio- or videotaped, you should explain what will happen to the recordings at the end of the research.)

If you agree to allow your child to participate in this project, please understand that their participation in the research is voluntary and that you and your child have the right to withdraw consent or withdraw from the research at any time without penalty. Your child also has the right to refuse to answer any question for any reason without penalty. (Describe the process by which withdrawal from the research may be made.)

If you have any questions about the project, you can contact the researcher (enter email address and/or phone number) or the research supervisor (enter supervisor's name, email address and/or phone number).

If you have any questions about your or your child's rights as a research participant, or any questions about the project, you can write – confidentially – to the committee chairman (davit.otiashvili@iliauni.edu.ge).

You will be provided with a copy of the consent form.

I understand the information provided above and voluntarily consent to my child's participation in the research. I further confirm that I am at least (indicate the age of majority in your country) years old.

Parent/Legal Guardian signature:_____ Date:_____

Child's first and last name: _____

Research Ethics Committee approval number:_____

Research Ethics Committee expiration date_____

Appendix #6

# Organizational Permission Form

Researcher's name _____

Title of the project _____

Name of the organization or institution _____

Type of the organization or institution _____

Address of the organization _____

Please indicate all requested permissions:

☐ Permission to obtain information about participants through the organization (e.g., member lists and contact information, subscribers, registry, etc.)

☐ Permission to collect data through the organization — in person, by phone, or electronically.

☐ Permission to use the organization's name.

☐ Permission to access organization data and/or documents that are not publicly available.

Name of authorized person _____

Position title _____

Signature _____ Date _____

Printed signature