APPROVED BY RESOLUTION N7

OF THE ACADEMIC COUNCIL

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SCIENTIFIC RESEARCH ETHICS STATUTE

CHAPTER I – GENERAL PROVISIONS

SCOPE

This document sets out standard operating procedures Research Ethics Committee of BAU International University, Batumi, and sets up a framework for evaluation the ethical part in the organized/co-organized and/or funded/co-founded by the university carried out by its affiliated staff.

Research, carried out by the university/staff in partnership with other institutions/staff is also subject to procedures, described in the document.

REFERENCES

This document is based on the current Helsinki Declaration, the Regulation on Clinical Trials.
to provide complementary guidance and support to the principles of Good Clinical Practice

MISSION

The mission of this document is to protect the rights, safety, dignity and well-being of research participants and to facilitate and promote ethical research that is of potential benefit to participants, University, science and society.

OBJECTIVE

The objective of the document is providing and supporting robust, proportionate and responsive ethical review of research, carried out in the University through Research Ethics Committee

GENERAL PRINCIPLES

All research involving human beings should be conducted according to ethical principles, which are universally recognized, in particular:

Autonomy,

The principle of autonomy is exercised in particular through the process of free and informed consent (appendix 1), which may be withdrawn without detriment at any time. Potential research participant must therefore be provided with appropriate, accurate and understandable information about the research project before being asked to choose whether or not to participate

Beneficence and non-maleficence,

The principles of beneficence and non-maleficence encapsulate the moral obligation to maximize potential benefit and minimize potential harm. Design of the research project shall be sound and meet accepted criteria of scientific quality and the researchers shall demonstrate competence to carry out the research in accordance with relevant professional obligations and standards and to ensure appropriate protection of the research participants.

Justice.

Selection criteria should be related to the purpose of the research and not merely based, for example, on the ease with which consent is likely to be obtained.

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CHAPTER II - ETHICS COMMITTEE

RESEARCH ETHICS COMMITTEE

Research Ethics Committee is multidisciplinary, independent groups of individuals appointed to review research projects and protocols to help ensure in particular that the dignity, fundamental rights, safety, and well-being of research participants and or animals, participating in the research are duly respected and protected.

Considering the purpose of the Ethics Committee, the scientific method and the concerns of the society, to protect the rights, safety and well-being of volunteers involved in clinical trials. The Ethics Committee, acting in accordance with the current World Medical Association Helsinki Declaration, UNESCO Universal Declaration on Bioethics and Human Rights, Oviedo Convention on Human Rights and Biomedicine as well as local regulatory acts and by following the national and international standards regarding its applications, provides timely, comprehensive and independent reviews of its ethical characteristics

Aim of the committee is:

Ensure that biomedical research is conducted ethically
Support improving the overall culture of research,
Enhance communication between researchers and society,
Raise awareness of ethical issues in biomedical research.

Role of the committee in research process:

Providing information to researchers, as needed during research preparation phase
Ethics review of the submitted research proposal
Follow up of the research project, in particular ethical aspects during conduction of the research
Review reports by the end of the research

The Ethics Committee advises the relevant regulatory institutions, the requirements of the relevant laws, the applicants and bears the responsibility to act in accordance with the society.

FUNCTIONS OF THE EHICS COMMITTEE

The functions of research ethics committees include:

- **A)** identifying and weighing up the risks and potential benefits of research;
- **B)** assess the scientific validity of the study design to ensure that it is capable of producing reliable information
- **C)** evaluating the process and materials (printed documents and other tools) that will be used for seeking participants' informed consent;
- **D)** assessing the recruitment process and any incentives that will be given to participants;
- **E)** evaluating risks to participants' confidentiality (and the related risk of discrimination) and the adequacy of confidentiality protections;
- **F)** examining any other issues that may affect the ethical acceptability of the research.

In international research, the committee represents the interests of the local population. Thus, it should ensure that the participants and their communities will receive fair benefits from the arrangement.

APPOINTMENT OF THE ETHICS COMMITTEE

Ethical Committee is established with the decision of the Academic Council of the in University.

STRUCTURE OF THE ETHICS COMMITTEE

Ethics Committee, consists of at least seven and at most fifteen members, provided that at least one is a non-healthcare professional and one is a lawyer, and the majority of its members are professionals of healthcare, natural and/or biomedical sciences, trained at the level of doctorate of medical specialty.

a. At least one is a clinic regulated according to Good Clinical Practice guidelines.
b. physicians who participated in research as researchers,
c. Medical doctor with a doctorate or specialty in pharmacology or pharmacist,
d. Biostatistician or PhD in public health;
e. Doctorate, specialty or higher in medical ethics (deontology), if applicable
f. Lawyer,
g. Person who is not a healthcare professional
h. if research covers natural sciences apart from medicine, a person from biomedicine and/or natural sciences shall be included in the ethics committee

Ethics committee shall consist both from university employed members and external members

EXTERNAL CONSULTANTS OF THE ETHICS COMMITTEE

1. In case of need, Ethics Committees may consult experts from the relevant branch or minor and invite them to the meeting as consultants.

For a decision to be ethically legitimate, it must be made in an open and inclusive process that takes into account the views of all stakeholders.

Research ethics committee should be encouraged to include individuals from diverse professional and social backgrounds and, where appropriate, to solicit input proactively from the community

2. The Ethics Committee can not approved the study without the positive opinion of a child psychiatrist or a specialist in pediatric health and diseases in clinical trials to be carried out on children, and a dentist who has received a doctorate or specialty in pediatric dentistry for clinical trials on children.

3. The Ethics Committee cannot approved the study in terms of fetus / baby health, without a perinatologist or a gynecologist give content in researches to be carried out on pregnant women and breastfeeding women, and a neonatal physician or a pediatrician specialist in pediatric health and diseases.

ETHICS COMMITTEE SECRETARIAT

1.Receiving applications to the Ethics Committee, informing the sponsor and / or contracted research institution and / or responsible researcher, archiving documents, making necessary correspondence, organizing meetings and similar tasks are carried out by the ethics committee secretariat.

2. The staff working in the secretariat of the Ethics Committee are obliged to comply with the confidentiality principle for any information they receive; They start their duties by signing the confidentiality document.

TRAINING

Members of the ethical committee should receive training in the international and local ethical and legal standards governing research, as well as in the process the committee uses to review and approve protocols.

Nonscientific members should be given an understanding of medical terminology and research methodology sufficient to enable them to participate intelligently in the committee's discussions.

Teaching university assures all committee members to participate in trainings and supports the organization of the training process.

CHAPTER III - WORKING PROCEDURE OF ETHICS COMMITTEE

APPLICATION

An application for ethical review of a research study should be made by the Chief Investigator for that study.
Application shall be submitted by the template presented in Annex 2

REVIEW METHOD

All applications that have been properly processed must be reviewed in a timely manner and in accordance with the specified review method.
The members of the Ethics Committee must meet in accordance with the regularly scheduled meeting dates announced by the Ethics Committee secretariat.
The Ethics Committee convenes at least twice a month, unless it convenes with a special agenda.
The meetings follow the agenda, which was previously programmed by the ethics committee secretariat and prepared by considering the application date order, provided that changes are made when necessary.
When necessary, the applicant and / or researcher are invited to the Ethics Committee meeting to get information about the application.
When necessary, representatives of special patient groups or groups related to specific topics are invited to assist studies and reviews at the meeting.
In its review, the Ethics Committee should consider the following points in addition to the issues stated in the relevant legislation:
A) The adequacy of the information provided and the responsiveness to ethical questions that arise,
B) Research in relation to the objectives of the research / study
Compliance of protocol / plan and data collection forms,
C). Statistical analysis and scientific effectiveness, i.e. the potential for solid conclusions with the smallest possible volunteer exposure and the determination that the predictable risks and constraints are acceptable in the face of the expected benefits for the volunteer and / or others
D). The researcher's suitability for the research / study submitted regarding his qualifications and experience,
E). Competence of the center, including supporting staff, available facilities and emergency methods,
F). The adequacy of the medical monitoring and administrative control of the trial,
G). Volunteers, if necessary, their legal representatives
adequacy, completeness and understandability of written and spoken information,
H). How volunteer enrollment is carried out, how complete information is provided
and how to obtain the informed consent form,
I). The content and expression of the informed consent form and, if appropriate, will not be able to give personal informed consent.
The consent form for the volunteer who is in a state,
J). All volunteers related to them during the research / study.

guarantees that they will be informed about the information,
K). Provided to and respondents who accept and respond to surveys and research / study
The commitments given regarding the complaints of the volunteers, 8.10.12. Provided for compensation / treatment in case of injury / disability / death attributable to volunteers' participation in the trial / study
undertakings,
L). Taking responsibility of the researcher by the sponsor
providing insurance and compensation agreements,
M). To ensure the confidentiality and protection of volunteers' personal information
measures for
N). Payments for volunteers, if any

EVALUATION OF RISKS AND BENEFITS

Evaluation of risks for research subjects shall consider:

A) Risks to physical integrity, including those associated with experimental drugs and treatments and with other interventions that will be used in the study
B) Psychological risks: for example, a questionnaire may represent a risk if it concerns traumatic events or events that are especially stressful.
C) Social, legal and economic risks: for example, if confidential information collected during a study is inadvertently released, participants may face a risk of discrimination and stigmatization.

Evaluation of the research risks for the community shall consider:

A) Certain ethnic or population groups may suffer from discrimination or stigmatization as a result of research, particularly if members of those groups are identified as having a greater-than-usual risk of having a particular disease.
B) The research may have an impact on the existing health system: for example, human and financial resources devoted to research may divert attention from other pressing health care needs in the community.

PHASES OF RISK/BENEFIT ASSESSMENT

Ethical review of research must contribute to a practical solution in order to minimize risks and maximize benefits, while ensuring respect for persons and providing the best possible response avoiding unjustified harm while not holding back potentially beneficial research.
The phases of risk/benefits assessment are:

Identification of expected risks

Committee must specify the nature, characteristics and scale of the risks in the research protocol submitted to the research ethics committee. The committee should carefully consider the description of risks contained in the protocol, but it should not assume that this description is necessarily accurate or complete.

Identification of the expected benefits

Research interventions, that are expected to produce scientific information that may benefit society in the future shall be reasonable in relation to the importance of the knowledge to be gained, compared to respective risks.

Evaluation of the risk/benefit ratio

Committee must carry out scrupulous evaluation of the relationship between the risks and the potential benefits for the participants and/or their communities. Evaluating the risks/benefit ratio, committee shall avoid underestimating the risks and/or overestimating the potential benefits, either of which can result in exposing participants to unjustified harm as well as overestimating the risks and/or underestimating the potential benefits, thereby holding back potentially beneficial research.

The level and type of risks to which participants may be exposed must be described in detail in the protocol.

Committee members should not, base their assessment solely on the information in the protocol, but are eligible to seek out additional information, consulting experts and exchanging information with other committees when appropriate.

CONFLICT OF INTEREST

A conflict of interest (COI) in research exists when researchers or institutions in which the research takes place have specific interests which might affect the primary obligations associated with research.

The membership should be designed to minimize the potential impact of conflicts of interest on the decision-making process.

Members who have a conflict of interest with respect to a particular study should not participate in the review of that study

Researchers should disclose any financial interest in the subject of their research to the research ethics committee.

The committee should have access to the research budget and receive information about all other relevant financial interests of investigators and of the institution.

Research agreements should not allow researchers to enter into contracts that give a sponsor a right of veto over publication.

CONFIDENTIALITY

Research ethics committees must ensure that basic standards of information protection are guaranteed.

Research proposal shall consider to safeguard all personal information from unauthorized disclosure. Personal information includes all information “relating to an identified or identifiable natural person (‘data subject’); an identifiable person is one who can be identified, directly or indirectly, in particular by reference to an identification number or to one or more factors specific to his physical, physiological, mental, economic, cultural or social identity.

All personal information must be safeguarded, whether or not the researcher and participant are in a formal physician/ patient relationship. This applies even to personal information that the researchers would not consider particularly “sensitive”.

Ethics review committees must look closely at how information obtained during the trial will be protected from disclosure and ensure that the risk that patients will suffer negative consequences due to information disclosure is reduced to a minimum. This includes:

Information related to an individual’s participation in a certain trial,

Information uncovered during the research
Information uncovered after the research.

Research proposal shall be evaluated considering the following principles of personal data protection:

Collection of data that can lead to the identification of research participants only if this information is necessary for the successful completion of the research project.

When identifiable information must be collected, replacing individuals' names with code numbers and storing the key to the code in a secure location accessible only to a limited number of persons. Destroy the key code when it is no longer necessary to link data with identities for the purpose of research.

If linkable information (that is, potentially identifiable data) is held, the purpose of this storage, its duration and the persons who will be granted access to it must be made explicit.

Information is secured by limiting access, using safe storage and using protected means of communication.

Information is destroyed as soon as it is no longer needed.

Participants should be informed about any personal information that will be collected, who will have access to that information, the confidentiality protections that will be implemented and the risks that could arise if the information is improperly disclosed

REPORTING

Mandatory registration of all clinical research and mandatory reporting of all research results are important to ensure the integrity of medical research.

All clinical trials must be registered in a publicly accessible database before recruitment of the first subject

Authors have a duty to make the results of research publicly available and to report accurately

Research ethics committee imposes trial registration as a condition for final approval of the research protocol. They also should ensure that there are no contractual clauses preventing appropriate results reporting and that all research results will be reported at the end of the research.

DECISION MAKING PROCEDURE

1. Ethics Committee members convene with two-thirds of the total number of members and make decisions with the absolute majority of the total number of members.

2. The members convene within fifteen days at the latest after being established with the approval of the and elect a president, vice president and reporter among them by secret ballot.

3. The head of the Ethics Committee represents the Ethics Committee. In the absence of the president, the vice president represents him.

DECISION-MAKING METHOD

The decision of the Ethics Committee can only be taken after the evaluation of the applications examined, after the third parties have left the meeting, and sufficient time is allocated for examination and discussion.

The Ethics Committee should ensure that the information and documents required in the application form are complete and that they are addressed before a decision is made.

The Ethics Committee can add a non-compelling recommendation to the decision.

In cases where the decision is taken with the absolute majority of the total number of members, members who do not agree with the decision will make the decision of the Ethics Committee by stating the issues they oppose.

they sign.

A negative opinion about an application is for clearly stated reasons.

must be supported.

Members of the Ethics Committee, name and surname, research / study writes, signs and dates the full name, subject and decision clearly and understandably.

DOCUMENTATION AND ARCHIVING METHOD

All documents and correspondence of the Ethics Committee must be dated, filed and archived.

Access to and utilization of various documents, files and archives should only be by administrative staff.