

NaUKMA Committee on Research Ethics

In its activity the NaUKMA Committee on Research Ethics is guided by the international standards and norms of human subject research, including: Declaration of Helsinki (1964), Belmont Report (1979), Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 (with amendments) on the "Approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use", ICH General Considerations for Clinical Trials (1997), parts 50 and 56 of title 21, and part 46 of title 45 of the US Code of Federal Regulations; Law of Ukraine «On medicines», Regulation on “Ethics commissions at the disease treatment and preventive care establishments conducting clinical trials” adopted by the Decree of the Ministry of Health of Ukraine of July 12, 2012, No. 523, as well as Ethical Code of Ukrainian Doctor of September 27, 2009.

Attachment
to the NaUKMA Decree
of April 12, 2016 No. 148

PROVISION

for the Committee on Research Ethics of the National University of Kyiv-Mohyla Academy

General provisions

The Committee on Research Ethics of the National University of Kyiv-Mohyla Academy (hereafter – Committee) – is a standing body established by the NaUKMA Academic Council with the aim of developing procedures and reviewing issues, which pertain the observance and enforcement of the ethical norms in the course of research conduct and the use of its results.

The Committee’s goal is to ensure the compliance of all the research undertaken at NaUKMA with the ethical standards and to control the observance of policies on the prevention of plagiarism, falsification of the research results or any other unsanctioned use of someone else’s intellectual property.

In its activity, Committee is governed by the legislation of Ukraine, NaUKMA Statute, internal provisions and regulations of NaUKMA, Provision on the Committees of the NaUKMA Academic Council, as well as the present Provision.

In its activity, Committee is subordinate to the NaUKMA Academic Council.

Key Directions of Activities, Principles, Tasks

The primary goal of the Committee's activity is the control over the NaUKMA research staff and students research work compliance with the ethical standards, as well as the analysis of the ethical norms' observance in the course of research.

Key directions of Committee's activities are:

- Enforcement of the bioethics principles in all the research involving human subjects, biological material and/ or laboratory animals;
- Control over the observance of policies on the prevention of plagiarism and unsanctioned use of someone else's intellectual property.

Key principles of Committee's activity are:

- Fostering of confidentiality principles and respect to each individual;
- Compliance with ethical and deontological principles of research;
- Independence and impartiality in controlling the conducted research;
- Public accessibility to the research sources;
- Transparency;
- Responsibility.

Committee is empowered to:

- Develop NaUKMA documents and procedures defining criteria and NaUKMA policies in the field of human subject research;
- Define the order of reviewing the issues dealing with approval of research projects to be undertaken with involvement of human subjects in regards to compliance with ethical requirements to research and types of documents for its review by the Committee;
- Review and approve the order of the research results' disclosure for the compliance with the ethical requirements and official legislation on personal data protection;
- Provide control over the observance of the policy on prevention of plagiarism in the academic environment;

- Review and evaluate the human subject research undertaken by the university staff/ students for compliance with the ethical requirements and the absence of the conflict of interest;
- Review appeals by researchers on the issue of their research compliance with the official legislation, NaUKMA internal documents and the norms of ethics;
- Review proposals on any changes in the topic of the initial research approved and/or agreed earlier, research reports conducted with involvement of human subjects;
- Determine the responsibility of participants of the research process, including cases of violation of the ethical norms;
- Create informational resources, including electronic ones, as well as presentation materials for undertaken research;
- Foster publication of research papers, collections, manuals, translations of the works of foreign authors, organization of conferences, workshops, roundtables etc., on the issues of academic integrity, plagiarism prevention, norms of research ethics etc..

The review of any issues/ cases by the Committee is conducted on the basis of a personal appeal made by the NaUKMA employee or student, as well as by the assignment of the NaUKMA Academic Council.

Provisions, rules, instructions and other regulations developed by the Committee, which have general nature should be approved by the NaUKMA Academic Council and become effective after the NaUKMA President's order.

Committee decisions in the form of excerpts from the protocols of the meetings are submitted:

- on issues, which require review and approval by the NaUKMA Academic Council – to the Academic Secretary;
- on issues, which do not require review and approval by the NaUKMA Academic Council (in accordance with its decision) – to the President and Vice-President pertaining their mandates and competences.

In execution of its tasks Committee interacts with the structural units of NaUKMA, other educational and research institutions, public authorities, municipalities, enterprises, institutions, organizations on the issues in the area of its mandate.

Types of Committee Activities

- Development and introduction of internal documents, which define criteria and NaUKMA policy in the area of the human subject research;
- Development of internal documents, which define the norms of ethical behavior of researchers, including the prevention of plagiarism in the academic environment, and enforcement of compliance with these regulations and procedures;
- Creation of electronic informational resources, databases, popular science multimedia and presentational materials on the issues of research ethics;
- Setting relations with Ukrainian and international institutions with the goal of deepening the cooperation, exchange and experience sharing in the area of research ethical standards' compliance;
- Organization and implementation of various scientific conferences, workshops, roundtables and other events on the issues pertaining Committee's competences with the involvement of students and faculty;
- Review of the written appeals from researchers on the issue of compliance of the planned research and research that is already in progress with the official legislation, internal documents of NaUKMA and the Committee, as well as the ethical standards;
- Review of human subject research reports on compliance with the ethical standards.

Organization of Activity

NaUKMA Academic Council approves quantitative (not less than 5 persons) and elects personalized membership of the Committee for three years, as well as approves the Committee Chair.

Committee meetings are convened ad-hoc, but not less than once per three months for the discussion of the issues in accordance with the approved workplan. The Committee Chair is responsible for the elaboration of the Committee's Regulation and its workplan, which are further approved by the NaUKMA Academic Council.

The Committee Chair:

- Leads the general management of the Committee's activity and ensures the implementation of its tasks in accordance with the agreed timeline;

- Organizes the Committee's work, carries responsibility for the implementation of the tasks undertaken by the Committee, determines the employees' level of responsibility, sets duties for Committee members, provides control over their activity;
- Represents interests of the Committee before the NaUKMA administration and its Academic Council, other organizations and institutions of Ukraine, as well as international organizations and institutions;
- Has a right to sign documents pertaining the Committee activities;
- Executes other duties foreseen by the official legislation and the internal Committee's documents.

Members of the Committee are elected by the NaUKMA Academic Council with a simple majority of votes. Members of the Committee:

- Ensure the implementation of the Committee's goals and tasks;
- Execute directions of the Committee's Chair in the scope of issues pertaining Committee's functions and competences;
- Can include for Committee's reviewing proposals on resolving the current issues of its activities, organization of events in the directions of Committee's activities.

The Committee's meeting is considered valid, when no less than $2/3$ of its members are present at the meeting and under the condition of mandatory presence of the Committee's Chair.

Before the meeting starts, the Secretary of the meeting is selected by the open voting to write the protocol of the meeting. Protocol should contain the following data:

- Date and place of the meeting;
- List of persons taking part in the meeting;
- List of issues discussed;
- Short overview of the issues' discussion results;
- Decisions, which have been made upon the results of the discussion with mandatory indication of the results of voting.

Decisions at the meeting of the Committee are made via open voting by the simple majority of votes. In cases, when the votes split equal, the Committee's Chair has a crucial vote.

The Order of Introducing Changes or Amendments to the Provision

The decision about the creation of the Committee and the approval of the Provision is taken by the NaUKMA Academic Council via open voting by the simple majority of votes and comes into action upon NaUKMA President's order.

Changes and amendments to the present Provision are approved by the NaUKMA Academic Council upon the recommendations made by the Committee's Chair and approved by the order in accordance with proceedings set at the NaUKMA.