

Appendix № 1
Minutes № 105
dated 08.08.2017

**AUTONOMOUS ORGANIZATION OF EDUCATION
“NAZARBAYEV UNIVERSITY”**

**Bylaws of Institutional Research Ethics Committee
of the autonomous organization of education “Nazarbayev University”**

Approved by the decision of Research Council
of the autonomous organization of education “Nazarbayev University”

Minutes № 105 dated 08.08.2017



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1. General Provisions

1. The Bylaws of Institutional Research Ethics Committee of the autonomous organization of education “Nazarbayev University” (hereinafter – the Bylaws) was developed in accordance with the autonomous organization of education “Nazarbayev University” (hereinafter - the University), Bylaws of Research Council of the autonomous organization of education “Nazarbayev University” (hereinafter – Research Council) and internal documents of the University.

2. The Institutional Research Ethics Committee of the autonomous organization of education “Nazarbayev University” (hereinafter – the “Committee”) is a constant body overseen by Research Council and has the status of “subcommittee” that is responsible for oversight of ethical standards while conducting human subject research at the University.

3. The Committee’s activities shall be conducted in compliance with the Charter of the University, Bylaws of the Research Council, these bylaws and internal documents of the University.

2. Definitions

4. Terms and abbreviations used in the Bylaws:

1) Initiator - a representative of the faculty members, an employee or student of the University or a person who has a joint research project with the University, who submits the application for consideration of the Committee.

2) Application - a package of necessary documents, including the Protocol Form of the research project established by the Committee and submitted by the Initiator, in electronic and hard copy for consideration by the Committee.

3) Approval of the Committee - approval of the Application by the Committee, which is the official confirmation that the proposed research project will be carried out in accordance with ethical standards while conducting human subject research.

4) The rejection of the Committee - rejection of the Application by the Committee, which is the official confirmation that the proposed research project will not be carried out in accordance with ethical standards while conducting human subject research.

5) Exemption from review - the Application is considered to be exempted from consideration if the Committee concludes that the research project described in the Application is not human subject research.

6) PI - the principle investigator, who is responsible for the content of the Application and package of the necessary documents. PI can be the Initiator.

7) Minimal risk research project refers to research project, in which the probability and magnitude of possible harms implied by participation in the research project is no

greater than those encountered by the participant in those aspects of his or her everyday life.

8) Maximum risk research project refers to research project, in which the probability and magnitude of possible harms implied by participation in the research project is greater than those encountered by the participant in those aspects of his or her everyday life.

9) Expedited review - consideration of the Application for the minimal risk research project.

10) Full review - consideration of the Application for the maximum risk research project.

11) Participant of the research project - a person who participates in the research project that signs a written consent form to participate.

3. Mission

5. The mission of the Committee is to monitor the research projects of the faculty members, employees and students of the University involved in conducting human subject research, in order to verify compliance with ethical standards and their compliance with:

- 1) international standards of research ethics while conducting human subject research;
- 2) University rules and procedures for conducting human subject research.

4. Authorities

6. The Committee has the right to:

- 1) review all research projects of the faculty members, employees and students of the University, who conducts human subject research;
- 2) determine the type of review (expedited review, full review, exemption from review), which is required within the framework of the submitted Application;
- 3) approve, reject, amend an Application or exempt it from review in order to protect participants of the research project;
- 4) suspend the research project in cases of non-implementation of the Committee's recommendations or reject the Application for this research project;
- 5) require reports from the PI on the progress of the research project within the framework of the approved Application for it;
- 6) carry out the necessary monitoring of approved protocols.
- 7) establish subdivisions at the University Schools to perform its functions and approve Bylaws for them.

5. Functions

7. The main functions of the Committee are:

- 1) review of the Initiator's Application to ensure the protection of the Participants of the research project through the compliance of research ethics principles;
- 2) review of all amendments and additions introduced by the Initiator in the Application upon its consideration by the Committee;
- 3) conduct selective monitoring of approved by the Committee Applications in accordance with the degree of risk through regular reports submitted by PI. The reports should include information on the process of obtaining informed written consent, checking the security of confidential materials and confirming that the research project is being conducted in accordance with the Application approved by the Committee;
- 4) provide written notification to the Initiator in electronic form in case of non-compliance with the Protocol Form of the approved application. In order to send such a notice (with indication to whom) the Committee may need to clarify the situation and conduct an additional investigation. If such notification is received, the Initiator has to suspend the research project until the relevant investigation is completed;
- 5) submission of an annual report on its activities and / or report at the request of the Research Council.

6. The subdivisions of the Committee

8. Relevant subdivisions in the University Schools can be created by the decision of the Committee.

9. The purpose of creation, the procedure for the formation, composition and competence of members of such subdivisions are determined by the Bylaws of these subdivisions, approved by the decision of the Committee.

10. Members of the Committee's subdivisions at the school level who are responsible for reviewing, approving and rejecting the Initiator's Application must be successfully trained every 3 (three) years on the Joint Training Program "Members of the Institutional Review Board - Basic Course / Advanced Training Course" (CITI "IRB Members - Basic / Refresher").

7. Governance Principles

11. The composition of the Committee is approved by the Research Council.

12. The Secretary of the Committee shall be appointed by Provost from full-time employees of Office of the Provost. The Secretary is not a member of the Committee.

13. The Committee may entrust the consideration of the Application to its subdivision at the school level if it is a research project with a minimum risk or research project based on course work.

14. The Chair and all the other members of the Committee, with the exception of the independent expert, responsible for reviewing, approving and rejecting the Initiator's Application, have to be successfully trained every 3 (three) years in the Joint Training Program "Members of the Institutional Review Board - Basic / Advanced Course" (CITI "IRB Members - Basic / Refresher").

15. Members have the right to submit questions for consideration by the Committee and have access to all materials of the Committee.

8. Membership

16. The Committee is composed of the following members:

- 1) The Chair nominated by the Provost;
- 2) 1 (one) representative from each school of the University, nominated by the Dean of the corresponding School;
- 3) 1 (one) representative of the Private Institution "National Laboratory Astana", nominated by the General Director;
- 4) One (1) representative of the Faculty Senate appointed in accordance with the internal procedures of the Senate;
- 5) 8 (eight) members nominated by Provost according to their competencies;
- 6) An independent expert who is not an employee or relative of an employee of the University, nor does he or she has a professional relationship with the University;

17. The Committee reserves the right to propose additional members to the Committee on the recommendation of the Chair with in order to share the workload associated with membership.

18. The Deputy Chair is elected by the Committee from among its members. The Deputy Chair shall act as Chair if the Chair is absent or declares a conflict of interest with the PI and / or the Initiator;

19. Members of the Committee are appointed for a three-year term, after which they can be reassigned for a similar period.

20. In the absence of a member of the Committee at three meetings of the Committee in a row during the academic year, the Committee, with the consent of the majority of the remaining members of the Committee, has the right to exclude him or her from the Committee with subsequent notification to the supervisor of the member of the Committee.

21. The Chair and members of the Committee have the right to voluntarily step down from membership in the Committee with a notification to the Chair and the Secretary of the Committee one month before the planned withdrawal.

9. Organization of the Committee's activities

22. The Committee meets on a monthly basis during the academic year. At the same time, the Chair has the right to convene an extra meeting by sending a notice in electronic form to the members of the Committee 5 working days prior to the scheduled meeting.

23. At its discretion, the Chair of the Committee has the right to convene an absentee meeting. At the same time, ballots with the full name of the member and his/her vote, signed by the member of the Committee, shall be attached to the decision of the Committee adopted by means of an absentee vote (online voting).

24. The Committee holds open and closed meetings. The decision to hold an open or closed meeting is taken by the Chair. When holding open meetings, all members of the University community may be present, except for the Initiator, the PI and the persons designated in the Application as participants of the research project, if this Application is considered at the meeting of the Committee. When holding closed meetings, only the members of the Committee can participate in them.

25. Meetings of the Committee are considered legitimate if more than half of the members of the Committee are present according to its composition.

26. Decisions of the Committee are taken by a simple majority of votes from the number of the present Committee members at the meeting. Each member has one vote. The right to vote cannot be transferred to other persons. If the votes are equal, the Chair's vote is decisive. The votes of abstaining members are not taken into account when calculating the number of votes required for adopting the decision of the Committee.

27. The decision taken at the in-person meeting of the Committee is formalized by the minutes of the Committee meeting, which is signed by the Chair and Secretary of the Committee. The decision taken at the meeting of the Committee in absentia is formalized by the decision of the Committee, which is signed by the Chair and Secretary of the Committee.

28. Examination of Applications with expedited review does not require the holding of meetings of the Committee. The review is conducted online without a meeting agenda. The approved Applications with expedited review are formalized by the Minutes of the expedited review meeting, which is signed by the Chair and Secretary of the Committee.

29. The Secretary of the Committee shall be responsible for the preparation, recording and storage of the minutes of the meetings of the Committee, as well as

documents to them. At the same time, the storage of minutes of the meeting is carried out both in print and in electronic form in the Research Services Office, in accordance with the procedures and terms established by the University. The Secretary shall transmit the Committee's documents to the University archives in accordance with the established rules and stipulated deadline.

30. At the request of the Research Council, the minutes of the meeting of the Committee may be presented at a meeting of the Research Council.

31. The Secretary of the Committee issues an extract from the minutes of the Committee on the request of the Initiator, the PI of the Application or interested persons of the University.

32. The official language of the Committee is English.

33. Issues that are not regulated by these Bylaws shall be considered by the Committee independently, in accordance with the University's Charter and internal documents of the University.