Statute of the Research Ethics Committee of the University of Tartu

Following section 92 of the Medicinal Products Act, section 29 of the Human Genes Research Act, clauses 34 2) and 18) of the Statutes of the University of Tartu and clause 19 of the Statutes of the Estonian Genome Center of the University of Tartu, I hereby establish the following Statute of the Research Ethics Committee of the University of Tartu:

I. Objectives

1. The Research Ethics Committee of the University of Tartu (hereinafter referred to as the Committee) shall assess the ethical aspects of human research in the field of medicine and natural science (incl. human gene research and clinical trials of medicinal products) and other human research, if danger to the physical or mental health of human(s) may occur with conducting the aforementioned research.

2. The official name of the Committee in English is the Research Ethics Committee of the University of Tartu (abbr. UT REC)

3. The Committee shall follow in its activities the Constitution of the Republic of Estonia, the European Council’s Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, Additional Protocol to the Convention Concerning Biomedical Research, the Declaration of Helsinki of the World Medical Association, other generally recognized ethical rules and international conventions, the Medicinal Products Act, the Human Genes Research Act, the Personal Data Protection Act, and other relevant legislation as well as the good practice of conducting clinical trials.

4. The objective of the Committee is to ensure the compliance with internationally recognized ethical principles, incl. the protection of health, human dignity, identity, security and other fundamental rights and freedoms of persons participating in the research as human subjects of investigation, and the safety and welfare of the human subjects of investigation.

5. In its activities, the Committee is an independent body, which operates under the University of Tartu and provides its assessment to all projects submitted to the Committee for an opinion.

II. Structure and leadership of the Committee. Rights and obligations of the Members of the Committee

6. The Committee shall contain at least 13 members.
7. The membership of the Committee shall be approved by the Rector according to the proposal of the Vice Rector for Research for three years. During the term of authority of the Committee, a member of the Committee may only be excluded from the Committee on the basis of the written application of the member himself or herself or upon the death of the member.

8. Upon presenting a person to the Committee and approving him or her as a member of the Committee, it shall be taken into account that the Committee shall consist of persons representing various different fields of life with the preparation in the specialties of biomedicine as well as in other specialties. Each member of the Committee shall be a recognized specialist in his or her field with the necessary expertise to perform the duties of a member of the Committee and shall have an impeccable reputation.

9. If a member of the Committee has reported his or her absence, a substitute member may be appointed for the duration of the absence. The member must inform the chairman of the Committee about his or her absence at least three weeks before the next Committee meeting if the member is not able to participate in at least the next six Committee meetings. The authorities of the member substituted are suspended for the period that the authorities of substituting member are valid. The substitute membership of the Committee shall be approved by the Rector according to the proposal of the Vice Rector for Research.

10. A member of the Committee has the right to raise questions about the procedures and documents of the Committee and has the right to examine all documents that the Committee has received. If a Committee member is not able to participate in the Committee meeting the member has the right to submit a written opinion on the documents proceeded.

11. In case of the violation of research ethical principles, a Committee member has the right to make a proposition to delay processing the application or its approval until the circumstances are clarified.

12. A Member of the Committee has the right and the obligation to withdraw from processing and decisional procedures, if he/she is not independent on his or her activity.

13. A member of the Committee is obligated to examine all research application documents submitted to the Committee, not to be absent from Committee meetings without a justified reason, inform the chairman of the conflict of interests in processing procedures, and follow the principles of confidentiality. The University signs a confidentiality agreement with each Committee member.

14. The meeting is the main working procedure of the Committee. Committee meetings must be recorded.

15. The Committee shall convene when necessary, but not less frequently than six times a year. The Committee shall give notice of the times of the meetings by six months on the webpage of the Committee.

16. At least three members of the Committee have the right to assemble an extraordinary Committee meeting.
17. In the first meeting of the renewed Committee the members of the Committee shall elect the chair and the deputy chair of the Committee with a simple majority of votes.

18. The task of the chair of the Committee is to organize the work of the Committee, to call the meetings and to act as a representative of the Committee. If necessary, the deputy chair shall substitute the chair of the Committee.

19. The Committee shall adopt its rules of internal procedure in a Committee meeting.

20. The work of the Committee may be performed in a digital environment if so described in the internal procedure. The Committee shall follow all principles of data protection during working in a digital environment.

21. The chair of the Committee shall report the Committee’s activities to the Rector of the University of Tartu.

III. Application Proceeding

22. The principal investigator shall submit the application and represent the project in relations with the Committee. The principal investigator may be a worker of an institution or enterprise of medicine, nature and social sciences who has an appropriate qualifications to conduct the research.

23. The Committee shall make a resolution on matters presented to the Committee for discussion within 60 days after the submission of all documents specified in clause 25. Upon application for the clinical trial of a medicinal product, gene therapy, cell therapy or an immunological medicinal product as well as using a genetically modified organism, the Committee shall make a resolution within 90 days.

24. The principle investigator shall submit to the Committee the application form on paper or electronically with signatures. The signatures can be in written or digital form. When submitting the application on paper, an electronic copy also has to be submitted.

25. The application shall contain at least the following information and documents:
   25.1 title of project;
   25.2 the first name and surname, academic degree, position, workplace, address of workplace, telephone number, email address, other contact information and signature of the principle investigator;
   25.3 the first names and surnames, academic degrees, workplaces, positions, email addresses and signatures of the persons conducting the research to certify that they agree to participate in the research;
   25.4 the names, addresses and signatures of the authorized representatives of the institution of the principle investigator and of authorized representatives related to the research;
   25.5 the source of financing of the research, the general cost of the research, incl. distribution of remuneration (to whom, to what extent), payment of compensation to the persons under research and the terms and conditions of insuring the persons under research;
   25.6 a brief overview of research conducted on the same topic to this day (up to 2
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25.7 explanation for the research planned (1 to 2 pages in generally understandable wording);
25.8 the time of conducting the research (with month and year precision) when the study began and ended;
25.9 an exact description of persons under research and the way of their recruitment (how many persons are researched, how and from whom the persons under research are selected, what is investigated and how often, an explanation for the use or non-use of control groups and placebo);
25.10 the description of research methodology (incl. the templates of forms, questionnaires, tests);
25.11 an analysis of the ethical aspects of the research;
25.12 information about earlier or simultaneous assessments or approvals of the same project elsewhere;
25.13 the CVs of the persons conducting the research, which contain information about research projects conducted by the researchers during the applying process and the number of persons under research during these projects as well as information about training courses on ethics passed;
25.14 informing and consent forms of the persons under research.

26. Persons who pursuant to clause 41 undertake to pay a fee for the assessment of the application shall also submit, in addition to the documents specified in clause 25, a copy of the payment order concerning the payment of the named fee.

27. If after the approval of the Committee, the principal researcher wishes to amend or modify the initial application for the research during the research, the Committee has to be previously informed thereof and an approval from the Committee obtained. The application with appendixes shall be submitted to the Committee via email to get the approval. When submitting amended versions of the original documents, the changes introduced into the documents have to be marked. The application has to contain at least the following information:
27.1 Title of project
27.2 the first name and surname, academic degree, position, workplace, address of workplace, telephone number, email address and other contact information of the principle researcher; Numbers of approvals given by the Committee (number of the initial approval and number of the last approval).
27.3 List of documents being submitted
27.4 contact details of the applicant: first name and surname, address of workplace, email address, telephone number, and signature.

28. The principal researcher has to submit to the Committee information about each event upon conducting the research, which jeopardizes the life, health, rights and freedoms of the human subjects participating in the research.

29. The principal researcher submits the summary of the results of the approved study to the Committee in reasonable time but not later than six months after the end of research.

30. The Committee’s documentation is registered in documents management system of University of Tartu. The head of the Department of Research and Development is responsible for managing, storing and archiving the documents.
IV. Adoption of Resolutions

31. The Committee is authorized to adopt resolutions, if over one-half of the members of the Committee, incl. the chair or deputy chair of the Committee, participate in the meeting.

32. The resolutions of the Committee shall be adopted on the basis of consensus between the participating Committee members. If consensus is not reached, the chair shall put the matter to a vote. A resolution shall be adopted, if over one-half of the members of the Committee who participated in the vote are in favour of the adoption of the resolution. In case of electronic voting, the resolution shall be adopted if over one-half of the members of the Committee who participate in the vote are in favour of the adoption of the resolution. The disagreement of the members of the Committee shall be stated in the minutes of the meeting.

33. The Committee is entitled to invite the principal researcher and other persons involved in the project to the discussion of the application. If necessary, the Committee may demand the principal researcher to submit a written explanation of the project.

34. If necessary, the Committee may invite other experts outside the Committee to the discussion of the applications submitted. These experts do not participate in the adoption of the resolutions of the Committee.

35. The Committee shall adopt one of the following resolutions:
   35.1 approval of the project;
   35.2 provision of a deadline for the elimination of short comes of the project or for the submission of additional information or materials;
   35.3 refusal to approve;
   35.4 declaration of an earlier approval as invalid or suspension of the approval.

36. The reasons behind the resolutions of the Committee named in articles 35.2; 35.3; 35.4 have to be stated in the minutes and presented to the applicant.

37. If the Committee refuses to approve a project, the principal investigator is entitled to submit additional documents to the Committee and amend the proposed research, and submit a new application for approval of the project.

38. In case of the suspension of an earlier approval, the Committee has the right to demand additional documents and additional explanation about the research project from the principal investigator. After the submission of additional documents by the principle researcher, the Committee makes a decision to declare the given and suspended approval as invalid or to approve to continue the project after the elimination of short comes.

39. If ethical problems or significant inclinations appear in the ongoing and approved research project, the Committee has the right to make comments or prescriptions to the principle researcher for further progress of the research project.
V. Financing of the Committee

40. The Committee shall be technically serviced by the Department of Research and Development.

41. In case of submission of applications by legal persons, except for projects of research and development institutions in public law, and for applications of research on medicinal products, the Committee shall be paid a fee in the amount of (6,000 EEK) 383 EUR (includes VAT) for the assessment of each project application.

42. Decreasing the amount of the fee and releasing from the fee (excluding research in medicinal products) shall be decided by the Committee depending on the amount of work. If the research project is cancelled, the fee shall not be returned.

43. The fee for the assessment of the research shall be used for supporting the work and objectives of the Committee. The chair of the Committee shall decide on the use of the funds.

VI. Amendment and Implementation of the Statute

44. The Statute of the Committee and amendments thereto shall be approved by the Rector.

45. The fee mentioned in article 41 will be 383 Euros after the Euro is legalized as the official currency in Estonia.

46. The Statutes of the Ethics Review Committee on Human Research of the University of Tartu approved by the directive no. 12 from 20.07.2007 shall be declared invalid.

Birute Klaas
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