FENERBAHÇE UNIVERSITY
NON-INTERVENTIONAL CLINICAL RESEARCH ETHICS COMMITTEE DIRECTIVE

PART ONE
Purpose, Scope, Basis, and Definitions

Purpose

ARTICLE 1- (1) The purpose of this directive is to regulate the formation, authority, working procedures, and principles of the Non-Interventional Clinical Research Ethics Committee established at Fenerbahçe University.

Scope

ARTICLE 2- (1) This directive covers the formation, authority, working procedures, and principles of the Fenerbahçe University Non-Interventional Clinical Research Ethics Committee.

Basis

ARTICLE 3- (1) This directive is based on the following documents and legislation:

a) Higher Education Law No. 2547,
b) Law No. 1262 on Pharmaceutical and Medical Preparations,
c) Medical Deontology Regulation No. 10436,
d) Patient Rights Regulation, published in the Official Gazette No. 23420 on 01.08.1998,
e) Health Services Law No. 3359,
f) Turkish Medical Association Professional Ethics Rules, published on 01.02.1999,
g) Regulation on Clinical Trials of Medicinal Products for Human Use, published in the Official Gazette No. 32203 on 27.05.2023,
h) Good Clinical Practice Guide and Good Laboratory Practice Guide, published on 19.12.2020,
i) Declaration of Helsinki by the World Medical Association,
j) The Personal Data Protection Law published in the Official Gazette dated April 7, 2016, and numbered 29677,
k) World Health Organization 2011: Standards and operational guidance for ethics review of health-related research with human participants.

Definitions

ARTICLE 4- (1) Definitions of the terms in this Directive are as follows;

a) Ministry: Ministry of Health,
b) Advisor: A faculty member who shares the scientific responsibility for a research project and contributes to its conduct,
c) Rector: Fenerbahçe University Rector,
d) Senate: Fenerbahçe University Senate,

e) Ethics Committee: Fenerbahçe University Non-Interventional Clinical Research Ethics Committee,
f) President: President of the Fenerbahçe University Non-Interventional Clinical Research Ethics Committee,
g) Rapporteur: Rapporteur of the Fenerbahçe University Non-Interventional Clinical Research Ethics Committee,
h) Member: Fenerbahçe University Non-Interventional Clinical Research Ethics Committee member,
i) Secretary: Fenerbahçe University Non-Interventional Clinical Research Ethics Committee secretary,
j) Principal Investigator: The faculty member who bears full ethical, scientific, technical, administrative, financial, and legal responsibility for the research for which the application is made,
k) Assistant Researcher: The individual who holds scientific responsibility for the research and participates in its conduct,
l) Non-interventional clinical research: Studies that do not involve any applications likely to pose a risk to a person's physical and mental health, including physical interventions or similar procedures, within the context of preventive health, diagnosis, treatment, and rehabilitation,
m) Volunteer: An individual, either sick or healthy, who participates in a study, provided that informed consent is obtained from them or their legal representative,
n) Informed Consent Form: A document that shows the volunteer's consent, obtained in the presence of an independent witness, whose signature is also required. It provides all written and verbal information about the research to the volunteer or their legal representative, ensuring that the decision to participate is made voluntarily and independently, or, if the volunteer cannot read or write, with appropriate accommodations.

PART TWO

Formation, Authority, Working Procedures, and Principles of the Ethics Committee, and Monitoring of Research

Formation of the Ethics Committee

ARTICLE 5- (1) The ethics committee consists of at least seven members, one of whom must be a law school graduate, recommended by the senate and appointed by the rector.
(2) According to Article 62/f of the Regulation on Clinical Trials of Medicinal Products for Human Use, the ethics committee's term of office is two years, and members whose term has expired may be reappointed if necessary.

(3) A member who fails to attend three consecutive meetings without permission within a calendar year loses their membership, and a new member is appointed in their place in the same manner.
(4) The members elect one of themselves as the president. The president appoints one of the members as the rapporteur. In the absence of the president, the most senior faculty member serves as the deputy president.

(5) At least one secretary is appointed to handle the correspondence and archival work of the ethics committee. The rectorate provides the office and stationery materials needed by the ethics committee.

(6) The rapporteur is responsible for ensuring the seamless implementation of procedures related to the examination of office services and research proposals.

Powers of the ethics committee

ARTICLE 6- (1) The ethics committee evaluates research applications involving at least one internal researcher on the following issues:

a) All observational studies, except for drug studies,
b) Survey studies conducted on clinical samples (the ethics committee evaluates only non-interventional research in the field of health sciences; purely social surveys, interviews, or observational studies fall outside the scope of the committee's duties).
c) Retrospective archival reviews, such as file and image records,
d) Cell or tissue culture studies using biochemistry, microbiology, pathology, and radiology collection materials, such as blood, urine, tissue, radiological images, or materials obtained during routine examinations, analyses, and treatment procedures,
e) Research involving genetic material for identification purposes and studies other than gene therapy clinical research,
f) All studies conducted without direct physician intervention, such as those based on anthropometric measurements or the evaluation of life habits,
g) Scientific research using data collected through testing, interviews, and audio/video recordings in a computer environment,
h) Dietary studies involving food additives,
i) Research on body physiology, such as exercise studies that specify accepted risk factors related to exercise (e.g., American College of Sports Medicine Risk Factors Table),
j) Non-pharmaceutical experimental studies,
k) Studies conducted within the scope of nursing activities,

The operating procedures and principles of the ethics committee

ARTICLE 7 – (1) The ethics committee convenes at least once a month upon the committee president's invitation, with at least two-thirds of the total members participating. Decisions are made by a majority vote of those present, and in the event of a tie, the president's vote counts as two.
(2) All decisions made during the committee meeting, along with their justifications, are recorded in the minutes.

ARTICLE 8 - (1) Research proposals submitted for examination by the ethics committee are forwarded to the ethics committee secretariat by the responsible researcher both electronically and as a printed copy with a wet signature. The secretariat conducts a preliminary review of the applications based on criteria and accepts the ones that meet the requirements for the evaluation process.
(2) Ethics committee applications are sent electronically to all members at least one week before the date of meeting. Applications submitted after this date will be evaluated at the next meeting.
(3) When deemed necessary, the ethics committee may seek an opinion by inviting the researchers or experts behind the research proposal under review to its meetings. If necessary, the committee may send research proposals to these experts in advance for scientific evaluation. Experts or consultants do not have voting rights in the ethics committee.

ARTICLE 9 - (1) The committee evaluates research projects based on ethical considerations, including the purpose, methodology, benefits, potential risks, and budget. As a result of the evaluation, it decides whether the research is "approved", "rejected", or "revision required". The responsible researcher whose application is deemed "revision required" may resubmit it to the board after making the necessary corrections or addressing deficiencies.
(2) If the committee requests changes to the research project, it will notify the responsible researcher of the requested changes electronically.
(3) The research cannot begin until the committee's approval is communicated to the applicant.
(4) If the committee decides "approved," the scanned copy of the wet-signed ethical approval certificate is sent to the applicant via the university's electronic document system.
(5) If the necessary corrections are not made within two months for research projects deemed "revision required" by the committee, those applications are considered "rejected". In this case, a new application must be submitted for the research to obtain committee approval.
(6) If changes are needed to the measurement tools (e.g., survey, test, scale, interview, observation, picture, drawing, video, audio recording, method, research title, etc.) of studies approved by the committee, approval must be obtained from the committee for these changes. All legal responsibility for changes made without the committee's approval rests with the researchers.
(7) The research team is responsible for the scientific validity, reliability, confidentiality, and security of all data collected during the research approved by the committee.
(8) Objections to committee decisions must be submitted by the applicant to the committee's secretariat either with a wet-signed petition or via email from a personal or institutional email address. The committee makes a final decision on the objections.

ARTICLE 10- (1) Applications to the committee are discussed and decided within a maximum of three months.

ARTICLE 11- (1) In making its decision, the Ethics Committee considers all relevant legal regulations, professional ethical codes, national and international declarations and announcements, as well as ethical values and principles.

ARTICLE 12- (1) The documents related to the applications submitted to the committee are archived for three years. At the end of three years, these documents are destroyed, and a report is prepared to document the process.

ARTICLE 13- (1) The decisions of the committee are confidential, and no information about the suggestions is shared with anyone other than those who made the suggestions.

Monitoring of Studies

ARTICLE 14- (1) When deemed necessary, the Ethics Committee may monitor research projects and request a progress report on studies it has approved. The principal investigator submits these reports to the Ethics Committee. The reports are placed on the committee meeting agenda and discussed.

(2) If it is determined that a research project approved by the Ethics Committee is not being conducted in accordance with ethical principles, the relevant manager of the institution to which the researcher belongs is notified. If the study is still ongoing, steps are taken to halt it. The committee discusses the study in question at its next meeting and reaches a decision.

(3) The Ethics Committee requests the Rectorate to halt any research found to violate ethical rules and to inform the relevant units.

PART THREE
Final Provisions

Effective Date

ARTICLE 15- (1) This directive takes effect on the date of its approval by the Senate.

Implementation

ARTICLE 16- (1) The provisions of this directive are implemented by the Rector.