

ISTANBUL AYDIN UNIVERSITY
**DIRECTIVE ON THE NON-INTERVENTIONAL CLINICAL
RESEARCH ETHICS COMMITTEE**

CHAPTER ONE
Purpose, Scope, Legal Basis and Definitions

ARTICLE 1 – Purpose

(1) The purpose of this Directive is to determine the establishment and operating principles of the “Non-Interventional Clinical Research Ethics Committee” formed within Istanbul Aydın University in order to examine, express an opinion on, monitor, terminate, decide on—and, when necessary, establish new principles and rules for—research carried out without requiring a physician’s direct intervention on the human body, in accordance with ethical principles and rules.

This includes all observational and survey studies to be conducted at Istanbul Aydın University; retrospective file and radiological image records; studies conducted with biochemical, microbiological and pathology test results obtained from blood, urine and tissue samples; research conducted using findings obtained during routine examination, investigation, analysis and treatment procedures; cell or tissue culture studies; studies conducted with genetic material that are outside gene-therapy clinical research and are descriptive in nature; research conducted within the boundaries of nursing activities; dietary studies using food additives; research related to body physiology such as exercise; studies based on anthropometric measurements; and research evaluating lifestyle habits.

ARTICLE 2 – Scope

(1) This Directive covers the establishment and working procedures and principles of the Istanbul Aydın University Non-Interventional Clinical Research Ethics Committee.

This Directive covers the legislation, rules to be followed and fundamental principles related to protecting the rights of patients and volunteer individuals in the research specified in Article 1; the methods and principles related to examining, evaluating, deciding on and monitoring ethical permission and approval applications for such research; the establishment and working principles of the Ethics Committee; and the related institutional and individual responsibilities and obligations.

ARTICLE 3 – Legal basis

(1) This Directive has been prepared on the basis of the following international and national legislation:

- a) Medical Deontology Regulation published in the Official Gazette dated 19 February 1960 and numbered 10436,
- b) Patient Rights Regulation published in the Official Gazette dated 01 August 1998 and numbered 23420,
- c) Turkish Medical Association (TTB) Rules of Professional Ethics of Medicine published on 01.02.1999,
- d) Turkish Penal Code published in the Official Gazette dated 12.10.2004 and numbered 25611,
- e) International Agreement published in the Official Gazette dated 11.06.2011 and numbered 27961: Convention on Human Rights and Biomedicine regarding Biomedical Research,
- f) Regulation on Clinical Trials of Human Medicinal Products published in the Official Gazette dated 27.05.2023 and numbered 32203,
- g) The current Good Clinical Practices Guideline and Good Laboratory Practices Guideline available on the website of the Ministry of Health, General Directorate of Pharmaceuticals and Pharmacy,
- h) World Health Organization report “Standards and operational guidance for ethics review of health-related research with human participants” (WHO, 2011),
- i) Fundamental Law on Health Services No. 3359 published in the Official Gazette dated 26/4/2011 and numbered 6225,
- j) Declaration of Helsinki.

ARTICLE 4 – Definitions

(1) In this Directive:

- a) Chair: the Chair of the Istanbul Aydın University Non-Interventional Clinical Research Ethics Committee,
 - b) Ethics Committee: the Istanbul Aydın University Non-Interventional Clinical Research Ethics Committee,
 - c) Rapporteur: the Rapporteur of the Istanbul Aydın University Non-Interventional Clinical Research Ethics Committee,
 - d) Principal investigator: the person responsible for conducting the research and applying to the Ethics Committee to obtain ethical approval,
 - e) Rector: the Rector of Istanbul Aydın University,
- shall be understood.

CHAPTER TWO

Establishment of the Ethics Committee and Working Procedures and Principles

ARTICLE 5 – Establishment of the Ethics Committee

(1) The Ethics Committee consists of at least seven and at most eleven members appointed by the Rector, who have completed a doctorate or specialization. Two of the members may be appointed from outside the field of health.

The term of office of Ethics Committee members is four years. Members whose term expires may be reappointed.

When the Rector's term of office ends, the duties of the Ethics Committee members also end.

A member who fails to attend three consecutive meetings within a calendar year without permission loses membership and a new member is appointed by the same procedure.

The members of the Ethics Committee convene within the first 15 days following their appointment and elect a chair from among themselves by secret ballot and by majority vote. The Chair appoints a deputy chair and a rapporteur from among the members.

In cases where the Chair is absent, the most senior faculty member acts as Chair. If the Chair leaves the position for any reason, the Ethics Committee members elect a new Chair from among themselves at their first meeting.

ARTICLE 6 – Working procedures and principles of the Ethics Committee

(1) The Ethics Committee meets at least once a month upon the invitation of the Chair and with the participation of at least two-thirds of the full number of members; decisions are taken by the votes of the majority of the members present.

Voting is carried out openly and abstentions are not permitted.

In the event of a tie, the decision is made in the direction of the vote of the Chair or the person presiding over the meeting.

ARTICLE 7 – Review of research applications

(1) Research proposals requested to be examined by the Ethics Committee are forwarded to the Ethics Committee by the administration of the unit to which the principal investigator belongs. Research proposals received by the Ethics Committee are taken under evaluation at the first meeting.

Where it deems necessary, the Ethics Committee may invite the researchers who made the proposal under review, or experts on the subject, to its meetings to receive opinions. If necessary, it may send research proposals to these experts in advance for scientific evaluation.

(2) In the evaluation process, the Ethics Committee primarily takes into account the following:

- a) Analysis of the expected benefits and risks of the research,
- b) Rationale and purpose of the research,
- c) Appropriateness of the principal investigator and assistants with respect to the research subject,
- d) Scientific productivity/utility of the research,
- e) Whether the research project has been prepared in accordance with procedure,
- f) Method, content and appropriateness of informed consent,
- g) Whether ethical rules are complied with in studies that have a financial sponsor.

(3) After evaluation, the Ethics Committee issues one of the following opinions: “Ethically appropriate”, “Requires revision”, “Not ethically appropriate”; and, if the application contains research that is not within the authority and duty of the Ethics Committee, “Lack of jurisdiction”. The opinion of the Ethics Committee is communicated in writing to the applicant within one week after the meeting. In applications found not ethically appropriate, stating the justification is mandatory.

(4) The Ethics Committee may identify deficiencies and/or request revisions for an application only once. The response letter sent by the applicant regarding the revision and/or deficiency is discussed at the first meeting of the Ethics Committee. If no response is provided to the Ethics Committee within sixty calendar days for revision and/or deficiency, the application is deemed to have been withdrawn.

(5) The Ethics Committee does not place on its agenda research that started or was completed before the application date. If this is noticed after the Ethics Committee has issued an opinion, the decision of the Ethics Committee is annulled and both the applicant and the applicant’s institutional supervisor are informed in writing.

(6) Where research applications belonging to an Ethics Committee member/members are discussed, the relevant member(s) may not participate in these discussions and may not vote; however, where necessary, the Ethics Committee may consult the information of such member(s).

(7) Research files submitted to the Ethics Committee and Ethics Committee decisions are confidential; no information is given to anyone other than the competent authorities and the applicants.

(9) If it is determined that a research for which the Ethics Committee has issued a positive opinion is not being conducted in accordance with ethical principles, the Ethics Committee and the institutional supervisor of the researchers are informed; if the research is still ongoing, it is stopped. The Ethics Committee places the matter on its agenda at its first meeting and may annul its decision.

(10) Interim and final reports regarding research found appropriate by the Ethics Committee are submitted to the Ethics Committee. The principal investigator is responsible for preparing and submitting these reports to the Ethics Committee.

(11) When making decisions, the Ethics Committee considers all legal regulations on the subject, professional ethics, national and international declarations and notices, and ethical values and principles.

ARTICLE 8 – Secretariat and resources

(1) The Rectorate provides at least one secretary, a meeting room and an archive area to conduct the correspondence and archiving of the Ethics Committee, as well as the office and stationery materials required by the Ethics Committee and correspondence expenses.

(2) The rapporteur is responsible for ensuring that office services and procedures related to the review of research proposals are carried out without disruption.

(3) The Ethics Committee conducts all correspondence outside the institution through its secretariat.

ARTICLE 9 – Other provisions regarding the protection of volunteers

(1) The principles in the section “Protection of Volunteers and Obtaining Informed Consent” of the Regulation on Clinical Trials of Human Medicinal Products published in the Official Gazette dated 27.05.2023 and numbered 32203 are valid for all studies conducted on humans, including research conducted with tissue and archive materials.

CHAPTER THREE

Repeal, Entry into Force and Execution

ARTICLE 10 – Repeal

(1) The “Directive on the Non-Interventional Clinical Research Ethics Committee”, which entered into force with the decision of the Istanbul Aydın University Senate dated 12.09.2018 and numbered 2018/12-12, has been repealed.

ARTICLE 11 – Entry into force

(1) This Directive enters into force on the date it is adopted by the University Senate.

ARTICLE 12 – Execution

(1) The provisions of this Directive are executed by the Rector.