# T.C.

ISTANBUL MEDIPOL UNIVERSITY

INSTRUCTION ON THE ETHICS COMMITTEE FOR NON-INTERVENTIONAL CLINICAL RESEARCHES\*

FIRST SECTION

Aim, Scope, Basis, and Definitions

Aim

**ARTICLE 1 -** (1) The aim of this instruction; is to determine the working procedures and principles of the Non-Interventional Clinical Research Ethics Committee to be established within Istanbul Medipol University in order to evaluate non-interventional clinical research scientifically and ethically.

# Scope

**ARTICLE 2 -** (1) This instruction covers the establishment and working principles and procedures of the Istanbul Medipol University Non-Interventional Clinical Research Ethics Committee.

# Base

**ARTICLE 3** - (1) This instruction has been prepared based on the Clinical Trials of Drugs and Biological Products Regulations.

# Definitions

**ARTICLE 4** (1) The definitions in this instruction refer to;

Ethics Committee: Istanbul Medipol University Non-Interventional Clinical Research

Ethics Committee,

1. Non-interventional clinical research: Except for drug observational studies, all observational studies, survey studies, retrospective archive scans such as file and image records, biochemistry, microbiology, pathology and radiology collection materials such as blood, urine, tissue, radiological image or a routine examination, examination, analysis and cell or tissue culture studies with materials obtained during treatment procedures; A physician's approach to human beings, such as research to be done with genetic material for identification, researches to be done within the boundaries of nursing activities, diet studies to be done with food additives, researches related to body physiology such as exercise, studies based on anthropometric measurements and evaluation of life habits, which are outside of gene therapy clinical studies all research that will be done without requiring direct intervention,
2. Rector: Rector of Istanbul Medipol University,

ç) Responsible Researcher: It refers to the person responsible for the conduct of the research and who has completed his speciality or doctoral education.

# SECOND SECTION

Establishment of the Ethics Committee, Working Procedures and Principles

Establishment of the Ethics Committee

**ARTICLE 5 -** (1) The Ethics Committee consists of at least five and seven members who have completed their doctorate or specialization, recommended by the University Senate and appointed by the Rector.

# Establishment of the Ethics Committee, Working Procedures and Principles

**ARTICLE 6** - (1) The term of office of the members of the Ethics Committee is four years. Members whose office expires may be reassigned. When the term of office of the Rector expires, the duties of the members of the Ethics Committee also come to an end.

1. The members elect a Chairman and a Vice-chairman from among themselves at the first meeting of the Ethics Committee. The President appoints one of the members as a reporter. In the absence of the President, the vice-president acts as the President. If the chairman leaves the presidency for any reason, the members of the Ethics Committee elect a chairman from among themselves at the first meeting they will hold.
2. The membership of a member who does not attend three consecutive meetings without an excuse within a calendar year is automatically terminated, and a new member is appointed for four years following the first paragraph of this article.
3. The Ethics Committee convenes with at least four members as needed upon the invitation of the chairman. Decisions are taken by the majority of the participating members. In the case of equality, the Chairman's vote counts as two votes.

**ARTICLE 7 -** (1) Applications to be made from within the institution are made directly to the Ethics Committee by the responsible researcher. For applications to be made from outside the institution, the Rectorate is first applied; With the knowledge and approval of the Rectorate, these applications are forwarded to the Ethics Committee.

1. Applications to the Ethics Committee are included in the agenda at the first meeting.
2. The Ethics Committee may refer to the written or verbal information of the applicant/owners or experts/experts on the subject when it deems necessary; invite them to the meeting.
3. When the Ethics Committee evaluates the application, it gives an opinion as "ethically appropriate" or "ethically inappropriate". The opinion of the Ethics Committee is communicated to the applicant in writing within one week after the meeting. It is obligatory to state a reason for applications that are not ethically appropriate.
4. The Ethics Committee does not include studies that started or were completed before the application date. Suppose this situation is noticed after the Ethics Committee has expressed its opinion. In that case, the decision of the Ethics Committee is revoked, and both the applicant and the applicant's institutional supervisor are informed in writing.
5. In case the research applications of the member(s) of the Ethics Committee are discussed, the relevant member(s) cannot participate in these meetings and cannot vote; however, the Ethics Committee may refer to the information of this member(s) when necessary.
6. The Ethics Committee may, for once, indicate a deficiency and/or request a correction for the applications it evaluates. The reply letter sent by the applicant for correction and/or deficiency is discussed at the first meeting to be held by the Ethics Committee. If no response is made to the Ethics Committee for correction and/or deficiency within ninety calendar days, the application is deemed to be withdrawn.
7. The Ethics Committee considers all relevant legal regulations and ethical principles when making a decision.
8. Research files submitted to the Ethics Committee and the decisions of the Ethics Committee are confidential, and no information is given to anyone other than the competent authorities and applicants.
9. If it is determined that a study that the Ethics Committee has given a positive opinion on is not conducted in accordance with ethical principles, the Ethics Committee and the supervisor of the institution to which the researchers are affiliated are informed about the situation, and if the research is still ongoing, it is stopped. The Ethics Committee puts the situation on its agenda at its first meeting and may cancel the decision.

**ARTICLE 8 -** (1) A secretary, meeting room and archive place to carry out the correspondence and archive works of the Ethics Committee, office and stationery materials and correspondence expenses required by the Ethics Committee are provided by the Rectorate.

1. The reporter is responsible for the smooth execution of the office services and the procedures related to putting the applications on the agenda. The Ethics Committee conducts all correspondence through the reporter. Correspondence outside the institution requires the knowledge and approval of the Rectorate.
2. In applications outside the institution, a fee is paid for stationery and postal expenses to an account indicated by the institution. The amount of the fee is determined annually by the Senate; Unless a determination is made, the amount in force until that day is valid.

**ARTICLE 9 -** (1) Documents belonging to the applications made to the ethics committee are kept in the archive for three years. At the end of three years, these documents are destroyed with a report.

**THIRD SECTION**

**Miscellaneous and Final Provision**

**Enforcement**

**ARTICLE 10 -** (1) This instruction enters into force on the date accepted by the University Senate.

**Execution**

# ARTICLE 11 - (1) \*The provisions of this instruction are executed by the Rector.

\* Accepted by the University Senate's decision dated 18/12/2019 and numbered 2019/13-02.