## T.C

ISTANBUL MEDIPOL UNIVERSITY INSTRUCTION ON CLINICAL RESEARCH ETHICS COMMITTEE \*

Aim

**ARTICLE 1 -** (1) This instruction aims to determine the establishment, duties and working principles of the Istanbul Medipol University Clinical Research Ethics Committee, which was established to provide ethical standards in medical research to be carried out within the framework of European Union standards and Good Clinical Practices and to resolve ethical problems that may be encountered in these researches.

## Scope

**ARTICLE 2 -** (1) This instruction covers all kinds of medical research except studies using experimental animals.

(2) The main medical studies to be conducted on healthy or sick volunteers within the scope of this instruction are as follows:

1. Herbal medicinal products
2. Observational Drug studies
3. Non-drug Clinical Trials
4. Clinical Drug Studies
5. Stem Cell Research

# Research on Organ or Tissue Transplantations

1. Interventional investigations on examinations other than routine follow-up and treatment
2. Medicinal Products

ı) Research on Medical Devices

j) Researching a new surgical method

## Base

**ARTICLE 3.** (1) This instruction has been prepared based on the Health Services Basic Law No. 3359 and the Higher Education Law No. 2547.

## Definitions

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

**Ministry:** Ministry of Health,

**Ethics Committee**: Istanbul Medipol University Clinical Research Ethics Committee**,**

**Rector**: Istanbul Medipol University Rector.

## Establishment and Structure of the Ethics Committee

**ARTICLE 5.** (1) The Ethics Committee, provided that at least one of them is not a member of health professions and one of them is a lawyer, the majority of its members are health professions educated at doctorate or medical specialization level

is formed by the application of at least seven and at most fifteen real persons to the Rectorate.

(2) The Ethics Committee has at least the following members;

Persons who have completed their doctorate or medical specialization training as a researcher, preferably in clinical trials organized in accordance with the "Rules of Good Clinical Practice",

1. Medical doctor or pharmacist with a doctorate or specialization in pharmacology,
2. Medical doctor or biostatistician with a doctorate or specialization in public health,

ç) An engineer or specialist working in the field of biomedicine; in the absence of a biophysicist or physiologist, preferably a graduate of the School of Medicine,

1. Law,
2. Person who is not a member of health professions,
3. A person who has completed a doctorate, specialization or master's degree in medical ethics (deontology).

## Establishment of the Ethics Committee, Working Procedures and Principles

**ARTICLE 6 -** (1) The working principles and procedures of the Ethics Committee are as follows:

1. Members of the Ethics Committee begin their duties by signing a confidentiality document and undertaking.
2. Ethics Committee member(s) who have a role in the research under review or have a relationship with the sponsor in studies that are sponsors cannot participate in the discussions and voting of this research in the Ethics Committee, and cannot sign the decision of the Ethics Committee.
3. The members of the Ethics Committee meet with a two-thirds majority of the total number of members and decide with the absolute majority of the total number of members.

ç) The term of office of members of the Ethics Committee is two years. Members who fail to attend three consecutive meetings or five periodic meetings without an excuse during their membership will automatically lose their membership. Members whose terms of office expire can be re-elected. If the member/members whose term of office has expired or whose membership has expired is one of the non-healthcare professional or a lawyer member, a member with the same qualifications is elected instead; If any of the other members lose their membership, a healthcare professional member who is trained at the level of doctorate or medical specialization is elected instead.

1. In case of need, the Ethics Committee may seek the opinion of experts from the relevant branch or sub-branch and invite these people to the meeting as consultants.
2. The Board convenes within 15 days after it is formed and elects the President, vice-president and reporter by secret ballot. The President represents the Ethics Committee. The vice-president means him when he is absent.

(2) Membership of the Ethics Committee terminates only in the following cases:

1. Completion of the term,
2. Written statement of resignation,
3. Understanding that they cannot attend the Ethics Committee meetings for more than six months without interruption due to reasons such as working abroad or health problems,

ç) Failure to attend three consecutive meetings or five intermittent meetings without an excuse in a calendar year,

1. It is proven that the ethical rules are violated.

## Duties and Authorities of the Ethics Committee

**ARTICLE 7 -** (1) Duties and authorities of the Ethics Committee are as follows:

1. To express an ethical opinion about the medical research applied to the Ethics Committee,
2. To monitor approved medical research with or without prior notice,
3. Requesting the termination of researches that are found to be inconsistent,

ç) Submit the reports required by the legislation on medical research to the competent authorities

## Ethics Committee Secretariat

**ARTICLE 8.**

1. Receiving the applications made to the Ethics Committee, informing the researchers, archiving the documents, making the necessary correspondence, organizing the application forms, organizing the meetings, and similar tasks are carried out by the ethics committee secretariat.
2. Ethics committee secretariat employees sign a confidentiality document and undertaking.

## Research Application and Permit

**ARTICLE 9.** (1) It is also possible to apply for research conducted outside Istanbul Medipol University. However, the applications in question may be evaluated by the committee, provided that they are limited in number within the scope of the working principles to be regulated by the Ethics Committee.

* 1. The research application file is prepared by filling out the application form on the website of the Ethics Committee within the framework of the Good Clinical Practices Guide.
  2. The research application is made to the Ethics Committee by the responsible researcher, sponsor or legal representative
  3. It is sufficient to report the application made to the Ethics Committee, where the coordinating centre is located in multicenter studies.
  4. All documents must be completed in full for the application to be registered. The application process is not started until the documents incomplete by the Ethics Committee secretariat are completed. If the researcher does not make the necessary corrections within three months after notification of the corrections/arrangements requested by the Ethics Committee, the application will be deemed invalid.
  5. If additional information and explanations are needed during the review process of the Ethics Committee, all the necessary requests are forwarded to the applicant at once; The review process is suspended until the requested information and documents are submitted to the Ethics Committee.
  6. After receiving the approval of the Ethics Committee, the researcher applies to the Ministry of Health.
  7. Application forms to be used for application to the Ethics Committee are published on the website of the Ethics Committee, and all clinical research applications are made according to these forms. Applicants cannot edit and use application forms other than these forms.
  8. The Ethics Committee receives an application fee from drug researchers that are sponsors. An application fee is charged for all kinds of research, except for dissertations from research conducted outside the institution and the supporter of state funds (TÜBİTAK, DPT, university research funds, etc.). No application fee is charged for in-house applications without a supporter. The determination and collection of the application fees to be collected are carried out by the Rectorate, not to exceed the amount determined by the Ministry.

## General Principles Regarding the Protection of Volunteers

**ARTICLE 10.** (1) To research volunteers, the following are required:

1. Analysis of the benefits and risks expected from the research,
2. Whether the research is based on a new hypothesis,
3. The necessity of conducting the research primarily in a non-human experimental environment or on a sufficient number of animals,

ç) The fact that scientific data obtained as a result of experiments performed in non-human experimental environments or on animals necessitate making them on humans to achieve the desired goal,

1. Whether the research brochure has been prepared duly or not,
2. Written information about the research, the method followed to obtain their voluntary consent, the adequacy of the justification for the research to be carried out on children, pregnant women, postpartum and breastfeeding women,
3. In cases of injury or death, including possible permanent health problems that may occur in studies, the responsibility of the investigator or sponsor and the coverage of the insurance certificate or policy for the volunteers (Phase IV drug studies and Observational drug studies are not covered by the insurance),
4. If there is an agreement between the sponsor and the place where the research will be carried out regarding the compensation arrangements that are suitable for the researcher and the volunteer, whether the agreement is ethical,

ğ) Whether the research sites comply with the standards.

(2) Observational Drug Studies are evaluated following their respective Guidelines.

## Cases without Provisions

**ARTICLE 11 -** (1) In cases where there is no provision in this instruction, Convention on the Protection of Human Rights and Human Dignity concerning the Application of Biology and Medicine No. 5013 published in the Official Gazette dated 9/12/2003 and numbered 25311: The Law on Approval of the Convention on Human Rights and Biomedicine, Regarding the Medical Deontology Regulation, which was put into effect with the Decision of the Council of Ministers dated 13/1/1960 and numbered 4/12578, and the provisions of other relevant legislation and the rights of the volunteers participating in the research, the Patient Rights Regulation published in the Official Gazette dated 1/8/1998 and numbered 23420, and the specified provisions of the European Union İnstructions apply.

## Enforcement

**ARTICLE 12–** (1) This instruction enters into force on the date it is accepted by the Istanbul Medipol University Senate.

## Execution

**ARTICLE 13– (1)** The provisions of this instruction are executed by the Rector of Istanbul Medipol University.

\*Accepted by the University Senate's decision dated 14.01.2014 and numbered 2014-1/3.