# T.C.

ISTANBUL MEDIPOL UNIVERSITY

CLINICAL RESEARCH ETHICS COMMITTEE INSTRUCTION OF TRADITIONAL AND COMPLEMENTARY MEDICINE PRACTICE\*

Aim

**ARTICLE 1 -** (1) The aim of this instruction is the establishment of the Istanbul Medipol University Traditional and Complementary Medicine Practices 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, with applications to be made inside or outside the institution and to resolve the ethical problems that may be encountered in these researches to determine the duties and working principles.

# Scope

**ARTICLE 2 -** (1) This instruction covers all kinds of Traditional and

Complementary Medicine (GETAT) researches.

# Base

**ARTICLE 3 -** (1) This instruction has been prepared based on the additional Article.10 of the Health Services Basic Law dated 7/5/1987 and numbered 3359, and the first paragraph of the Presidential Decree No. 1 on the Presidential Organization published in the Official Gazette dated 10/7/2018 and numbered 30474 (ğ) and Article 508, Higher Education Law No. 2547 and Instruction on Clinical Researches of Traditional and Complementary Medicine Practices .

# Definitions

**ARTICLE 4** : The definitions in this instruction refer to;

1. Ministry: Ministry of Health,
2. Ethics Committee: Istanbul Medipol University Traditional and Complementary Medicine Practices Clinical Research Ethics Committee,
3. Rector: Refers to the Rector of Istanbul Medipol University.

# Establishment and Structure of the Ethics Committee

**ARTICLE 5 -** (1) The Ethics Committee consists of at least seven and fifteen real persons, of whom at least one is not a healthcare professional, and one is a lawyer. The majority of its members are healthcare professionals with a PhD or specialization in medicine. It is established with the approval of the General Director of Health Services upon the proposal of the Rector. The ethics committee, issues related to research within the scope of Regulation on Clinical Researches of Traditional and Complementary Medicine applications dated March 9, 2019, and numbered 30709

And is evaluated scientifically and ethically about the methods and documents to inform the volunteers and the consent to be obtained from these people.

(2)The Ethics Committee has the following members;

1. A person with a doctorate or specialization training in medical ethics or medical deontology, if any.
2. A person who has a doctorate or specialization in medicine, if any, in pharmacology or pharmacognosy.
3. Specialist physicians, preferably selected from different specialities, have participated as researchers in international clinical studies organized according to the rules of good clinical practice.

ç) Persons who are competent in one or more of the fields of traditional and complementary medicine practices.

1. PhD in biostatistics or public health, if applicable, or

a person who has received their expertise, preferably a healthcare professional.

1. A law graduate, preferably with experience in health law, patient rights or clinical research.
2. A person who is not a healthcare professional.

# 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. The ethics committee is independent in the scientific and ethical evaluation and decision-making of clinical research applications.
2. Ethics committee members must comply with the principle of confidentiality for any information they receive.
3. Ethics committee members begin their duties by signing the confidentiality document and undertaking prepared by the Ministry of Health, General Directorate of Health Services.

ç) The member of the ethics committee, who has a relationship with or has a duty in the research examined, cannot participate in the discussions and voting of this research in the ethics committee and cannot sign the ethics committee decision.

1. Ethics committee members meet with a two-thirds majority of the total number of members and decide with the absolute majority of the members attending the meeting.
2. The term of office of the members of the ethics committee is two years, and the members whose term of office expires are reinstated

can be selected.

1. Instead of a member whose term of office expires or whose membership has expired, a member with the same qualifications is elected within the framework of the fifth paragraph of Article 25 of the Regulation on Clinical Research of Traditional and Complementary Medicine practice.
2. If necessary, the ethics committee may take the written opinion of the person or persons who are competent in the field under investigation or invite such persons to the meeting as consultants.

ğ) The Board convenes within 15 days at the latest after it is formed and elects the president, vice-president and reporter by secret ballot. The President represents the Ethics Committee. The vice-president represents 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. An uninterrupted stay of more than six months due to reasons such as overseas duty or health problems

understanding that he cannot attend the Ethics Committee meetings for some time,

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 give an ethical opinion on the GETAT clinical trials 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) The research application file is prepared by filling in the application form on the website of the Ethics Committee within the framework of the Good Clinical Practices of Traditional and Complementary Medicine Practices Guide published by the Ministry of Health.

1. The research application is made to the Ethics Committee by the responsible researcher, sponsor or legal representative

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1. In multicenter studies, it is sufficient to report the application made to the Ethics Committee, where the coordinating centre is located.
2. All documents must be completed in full in order for the application to be registered. The application process is not started until the documents found to be 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.
3. 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; desired

The review process is suspended until the information and documents are submitted to the Ethics Committee.

1. After receiving the approval of the Ethics Committee, the researcher applies to the Ministry of Health General Directorate of Health Services for permission.
2. 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.
3. 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.

# Cases without Provisions

**ARTICLE 10 -** (1) In cases where there is no provision in this instruction, Convention on the Protection of Human Rights and Human Dignity with respect to 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 European The provisions specified in the Union Directives apply.

# Enforcement

**ARTICLE 11 –** (1) This instruction enters into force on the date it is accepted by the Istanbul Medipol University Senate.

# Execution

**Article 12– (1)** The provisions of this instruction are executed by the Rector of Istanbul Medipol University.

\*Accepted by the University Senate's decision dated 20/11/2019 and numbered 2019/12-03.