

SELÇUK UNIVERSITY
FACULTY OF DENTISTRY

**Principles of Operation for the Non-Interventional Clinical Research
Evaluation Committee**

PURPOSE

Article 1: These regulations establish the procedures and principles regarding the design, conduct, record-keeping, decision-making, protection of voluntary rights, and monitoring of approved studies related to non-interventional clinical research planned to be conducted by academic staff (whether as responsible or other researchers) of Selçuk University Faculty of Dentistry, in order to ensure compliance with international and national ethical and scientific standards.

BASIS

Article 2: These regulations are based on the latest version of the Helsinki Declaration, Good Clinical Practice (GCP) and Good Laboratory Practice (GLP) guidelines, and the Regulation on Clinical Trials (published in the Official Gazette dated December 23, 2008, and numbered 27089), regarding the establishment and operation principles of the Commission.

SCOPE

Article 3: The scope of non-interventional clinical research to be evaluated by the Commission encompasses all non-invasive clinical research defined in the Regulation on Clinical Trials, which does not require direct intervention by a physician. These studies include:

- a) Survey studies,
- b) Retrospective archive searches conducted using file and image records and similar observational studies,
- c) Studies conducted on biochemical, microbiological, pathological, and radiological collection materials such as blood, urine, tissue images, or materials such as extracted teeth and tissue waste obtained during routine examination and treatment procedures, as well as models obtained from patients,
- d) Cell or tissue culture studies,
- e) Studies based on anthropometric measurements,
- f) Research evaluating lifestyle habits and all other research that can be conducted without the direct intervention of a physician.

ESTABLISHMENT AND WORKING PRINCIPLES

Article 4: The Commission consists of 13 (thirteen) members, and the members of the Commission, excluding the Dean, are selected from the following departments in the specified numbers:

- Eight faculty members from the Departments of Clinical Sciences of the Faculty of Dentistry, one from each of the Sub-Disciplines,
- Four faculty members from the Departments of Basic Medical Sciences including Histology-Embryology, Medical Biochemistry, Medical Microbiology, Medical History, and Ethics.

Commission members from the Departments of Dentistry are proposed by the Academic Board decisions of the Departments, while members from the Basic Medical Sciences are recommended by the Dean and appointed by the Faculty Board for a period of three years. Members whose term of office expires may be re-elected. Membership of a member who fails to attend three consecutive meetings ceases. In the event of a member leaving office, a new member is selected using the same method to complete the remaining term.

The Dean or the Deputy Dean appointed by the Dean chairs the Commission. The Commission convenes with a simple majority, and decisions are made by a majority vote of the members present at the meeting. In the event of a tie, the chairman's vote is decisive. Commission members cannot participate in voting during the evaluation of their own work. Abstention is not allowed.

Article 5: Within 15 days following the appointment of Commission members, the Commission holds its first meeting and announces to the relevant parties the method and documents to be used in preparing the application file, as well as the appropriate format for reporting the results. The Commission meets at least once a month. There is no obligation to convene during the months of July and August. Meeting dates are announced to the Commission members in advance by the secretariat.

Article 6: The secretariat of the Commission and the reporting of Commission meetings are carried out by at least one appointed official designated by the Dean. Tasks such as receiving applications, informing researchers, archiving documents, conducting correspondence, preparing application forms, organizing meetings, and similar duties are carried out by the secretariat.

Article 7: The Dean's Office provides suitable physical space, archival unit, photocopy machine, telephone, fax, and internet-accessible computer systems for the Commission to carry out its services.

APPLICATION AND EVALUATION

Article 8: The application file must be submitted to the secretariat at least 3 business days before the meeting date in order to be included in the meeting agenda. Urgent research files may be presented to the Commission under the authority of the chairperson.

Article 9: When reviewing applications, the Commission considers the suitability of the responsible researcher and assistants, the suitability of the unit where the research will be conducted, whether the research topic is supported by sufficient literature, the rationale and objectives of the study, the protection of the rights, safety, dignity, and health of volunteers, the adequacy and suitability of the Informed Consent Form for the proposed research, and evaluates whether health insurance providers and revolving funds are used as financial sources.

Article 10: The Commission must evaluate applications that do not require corrections and notify the outcome in writing at the latest within the following calendar month's meeting. The Commission informs the researcher of any deficiencies and/or errors found regarding the research. Decisions are communicated to the researcher within the following calendar month after the submission of the requested corrections or information. The outcome of rejected research is justified.

Article 11: The Commission may conduct on-site inspections for ongoing studies if deemed necessary, request oral or written information about the research, request the cessation of implementation or research with reasons stated, or withdraw approval. The Commission may invite researchers to its meetings to listen to them and obtain information if deemed necessary, or seek the opinion of experts outside the members regarding the research.

Article 12: Despite the positive opinion of the Commission, legal responsibility rests with the individuals conducting the research. The Commission does not incur criminal, legal, or medical liability for its decisions. Discussions, debates, and objections made during Commission meetings are considered confidential.

Article 13: These regulations come into effect on the date they are approved by the Faculty Board.