

**SELCUK UNIVERSITY FACULTY OF PHARMACY**  
**SCIENTIFIC RESEARCH ETHICS COMMITTEE DIRECTIVE**

**CHAPTER ONE**

**Purpose, Scope, Basis, Definitions**

**Purpose**

**Article 1-** The purpose of this directive is to *determine the Procedures and principles regarding the design, execution, record keeping and decision-making of thesis, research and graduation projects outside the scope of clinical studies in which faculty members working in the Departments of the Faculty of Pharmacy of Selcuk University take part as administrators or researchers, ensuring ethical and scientific standards, and monitoring the studies whose applications are approved.*

**Scope**

**Article 2-** This Directive covers;

- a) Ethics issues related to graduate and postgraduate thesis and research projects outside the scope of clinical studies conducted/carried out by the members of the Faculty of Pharmacy,
- b) The structure, formation, duties and responsibilities of the Ethics Committee,
- c) Working procedures and principles of the Ethics Committee,
- d) It covers the issues related to the evaluation and decision processes of the applications made to the Ethics Committee.

## **Base**

**Article 3-** This Directive; It has been prepared on the basis of Articles 42 and 65 of the Higher Education Law No. 2547 and the "Higher Education Council Scientific Research and Publication Ethics Directive", which entered into force with the decision numbered 2016.23.497 taken at the meeting of the General Assembly of the Council of Higher Education dated 10.11.2016.

## **Definitions**

**Article 4-** (1) Mentioned in this Directive;

- a) Vice President: The Vice Chairman of the Scientific Research Ethics Committee,
- b) President: The Chairman of the Scientific Research Ethics Committee,
- c) Unit: Faculties, institutes, colleges, vocational schools and research centers affiliated to the university and all units affiliated to public institutions,
- d) Dean's Office: Dean of the Faculty of Pharmacy,
- e) Faculty: Selcuk University Faculty of Pharmacy,
- f) Faculty Administrative Board: Selcuk University Faculty of Pharmacy Administrative Board,
- g) Related: Anyone who has a direct or indirect relationship with the subject,
- h) Ethics Committee: The Scientific Research Ethics Committee of the Faculty of Pharmacy,
- i) Rapporteur: The person assigned to record the decisions of the Ethics Committee and submit them in the form of a report,
- j) Rector's Office: The Rector of Selçuk University,
- k) Secretariat: Secretariat of the Scientific Research Ethics Committee,
- l) Senate: The Senate of Selcuk University,

- m) Expert: A person who has advanced techniques or skills in a particular subject,
- n) University: Refers to Selcuk University.

## **CHAPTER TWO**

### **Structure, Duties and Responsibilities of the Ethics Committee**

**Article 5-** (1) The Ethics Committee consists of three full and three substitute members, including faculty members from different departments within the Faculty and/or faculty members who have completed their doctoral education.

(2) The faculty members/staff members who make up the Ethics Committee are elected by the Faculty Administrative Board to serve for a period of two years.

(3) There should be no final judicial or administrative decision or determination that the elected Board members have committed an ethical violation.

(4) Members who are in charge of the University's Science/Health/Social and Human Sciences Scientific Research and Publication Ethics Committees cannot take part in the Faculty Ethics Evaluation Boards.

**Article 6-** (1) The membership of a member who does not attend three consecutive meetings without permission and excuse or who is on leave for at least six months terminates automatically.

(2) The member(s) whose term of office has expired may take part in the Ethics Committee again or a new member may be elected in their place.

(3) The withdrawal and/or dismissal of a person's membership due to reasons such as resignation, retirement, appointment, etc. takes place with the decision of the Faculty Administrative Board. A new member is elected to complete the remaining term in place of the member who leaves his office.

**Article 7-** (1) One of the members of the Ethics Committee is appointed as the chairman by the decision of the Faculty Administrative Board.

- (2) The Ethics Committee holds its first meeting within 15 days following the election of the members in order to establish the structure of the Board by distributing duties among the members and to determine the methods and documents to be followed in the applications. At this meeting, the vice-chairman and rapporteur are elected.
- (3) After the members are elected to the Ethics Committee, they sign a confidentiality agreement.
- (4) The Secretariat of the Ethics Committee is carried out by an administrative staff in charge of the editorial office determined by the Faculty Dean's Office.

**Article 8-** The Ethics Committee is responsible for evaluating the applications in a fast, impartial and fair manner and informing the applicant of the decisions to be made by the Board.

## **CHAPTER THREE**

### **Evaluation and Decision**

**Article 9-** Meeting dates and the deadline for submission of the application file are announced on the website of the faculty at the beginning of each academic year. When applying to the Ethics Committee, the application file must be prepared completely and submitted to the document registration unit of the Faculty Dean's Office by the coordinator at least seven (7) working days before the meeting date in order to be included in the agenda of the meeting. In case of an application outside the meeting dates, the application may be evaluated by the Board with the proposal of the chairman of the Board and the approval of the Dean of the Faculty, if deemed necessary.

**Article 10-** The Secretariat shall carry out the duties of receiving the application files, informing the applicants, conducting correspondence, archiving the documents and similar duties. The Chairman of the Ethics Committee coordinates the work of the Secretariat.

**Article 11-** The Board conducts its first examination of the applications in terms of procedure. If a deficiency is detected in the application file, the applicant is asked to complete the deficiencies of

the file within a period of time to be determined by the Board. The Board may decide to remove the files that are not completed on time and the files that are understood not to be within the scope of its duties (Lack of Duty).

**Article 12-** Studies that have been put into practice before the application to the Ethics Committee are not evaluated and the Ethics Committee permission is not given retrospectively.

**Article 13-** In the event that the opinion of a different discipline is needed in the evaluation of the applications, the Ethics Committee may obtain the opinions of an expert on the subject by inviting a person to the Board meeting and/or sending the application file to these person(s) before the meeting.

**Article 14-** The members of the Ethics Committee convene with a two-thirds majority of the total number of members and take decisions with the absolute majority of the total number of members attending the meeting. In case of equality of votes, the vote of the chairman of the Board is decisive. Board members may not abstain from voting.

**Article 15-** A member of the Ethics Committee cannot participate in the discussions and votes in the Ethics Committee and cannot sign the decision documents in the studies in which he takes part as an executive/researcher and/or in cases where there is any interest relationship with the researchers who will carry out the study.

**Article 16-** The Ethics Committee pays attention to the fact that the permission documents are attached to the application file for studies that require permission from any institution or organization and that the processes followed regarding the permission are clearly stated in the method section of the project.

**Article 17-** The Ethics Committee evaluates the scientific research applications by taking into account the adequacy and appropriateness of the unit to be researched, the purpose of the study, the method to be applied, the literature information presented and the budget. The Ethics Committee evaluates the application files within ten days and decides as "Suitable", "Needs to be Corrected",

"Non-Compliance" or "Not Suitable" as a result of the evaluation. The decisions taken by the Ethics Committee are notified to the applicant and the Faculty Dean's Office electronically.

**Article 18-** If the decision of the ethics committee is "Appropriate", wet-signed Ethics Committee Approval Certificate can be obtained from the Office of the Dean of the Faculty. Researchers cannot start the data collection phase of the research until they are informed that the result of the evaluation of their applications is "Appropriate". Researchers are responsible for the accuracy, confidentiality and data security of the collected data.

**Article 19-** For the application files that have been decided by the Ethics Committee as "Needs to be Corrected", the coordinator may apply to the Ethics Committee again by making the necessary corrections or completing the deficiencies.

**Article 20-** If the decision of the Ethics Committee is "Not Appropriate", the coordinator may appeal to the University's Health Sciences Scientific Research and Publication Ethics Committee within five days. The decision made by the Board is final.

**Article 21-** The Ethics Committee monitors the researches it approves when necessary and may request a progress report. The coordinator of the scientific study is responsible for the delivery of these reports to the Board. The Board examines the progress reports and examines whether the research in question was carried out in accordance with the original application.

**Article 22-** The examination and evaluation processes of the Ethics Committee are confidential except for the general regulations. No information is given about the decisions taken by the Ethics Committee to anyone other than the persons and organizations specified in this Directive and the applicant.

**Article 23-** The text containing the decisions of the Ethics Committee must contain the wet signatures of the members.

## CHAPTER FOUR

### Binding and Obligations

**Article 24-** The decisions of the Ethics Committee are advisory only. In response to the positive or negative decision of the Ethics Committee, the financial and legal responsibility belongs to the researchers who conducted the study. The Ethics Committee and its members cannot be held liable for any criminal or legal responsibility for the decisions they have made.

**Article 25-** The exchange of views, discussions and objections made during the meetings of the Ethics Committee are confidential and the members of the Committee must comply with the principle of confidentiality for all kinds of information they have.

**Article 26-** Any changes to be made during the continuation of scientific studies that have received the permission/approval of the Ethics Committee (changes in the number of samples, sample analysis, etc., changes in the methods and research techniques to be applied, changes in institutional permission, waiver or addition of the researcher, etc.) It should be submitted to the information and approval of the Ethics Committee with a petition. The Ethics Committee decides whether the change in question is appropriate or not.

**Article 27-** The ethical, legal and administrative responsibility of scientific research that is not approved by the Ethics Committee or carried out without any application for the approval of the Ethics Committee belongs entirely to the researchers.

**Article 28-** This directive enters into force after it is approved by the Senate of Selcuk University.

**Article 29-** The provisions of the directive are executed by the Dean of the Faculty of Pharmacy of Selcuk University.