

**SELÇUK UNIVERSITY**  
**FACULTY OF HEALTH SCIENCES**  
**NON-INTERVENTIONAL CLINICAL RESEARCH ETHICS COMMITTEE**  
**DIRECTIVE**

**PURPOSE:**

➤ **Item 1. The purpose of this directive;**

“**Provided that they are Non-Interventional Clinical Research**”, is to determine the procedures and principles regarding the design, execution, record keeping, decision-making, ensuring national and international ethical and scientific standards in order to protect the rights of volunteers, and monitoring the approved studies and **the thesis and research projects in which conducted by academic staff who have completed their doctorate degree in the departments affiliated to the Selçuk University Faculty of Health Sciences, thesis projects of students who are doing postgraduate education in the departments affiliated to Selçuk University Faculty of Health Sciences, and thesis projects of academic staff working in the staff of Selçuk University Faculty of Health Sciences and doing postgraduate education in other universities or departments.**

**DAYANAK:**

- **Item 2.** Within the framework of European Union Standards and Good Clinical Practices; **The Regulation On Clinical Research Published** in the Official Gazette dated “19/08/2011” and numbered “28030” and **The Regulation Amending The Regulation On Clinical Research Published** (The name of the regulation has been

changed to “**Regulation on Clinical Research of Pharmaceuticals and Biological Products**”) in the Official Gazette dated “13/04/2013” and numbered “28617” constitute the basis for the working principles of the ethics committee.

**KAPSAM:**

- **Item 3.** This directive covers the research projects defined as “**Non-Interventional Clinical Research**” in the Regulation on Clinical Research in line with the above-mentioned purposes, which will be carried out without the direct intervention of a physician and will be carried out by the researchers specified in **Article 1**.

**TANIMLAR:**

- **Item 4.** This directive states;

**Faculty Deanery:** Deanery of Selçuk University Faculty of Health Sciences,

**Clinical Research:** Any non-interventional scientific research conducted on human volunteers or materials obtained from them,

**Non-Interventional Clinical Research:** All observational studies, survey studies, retrospective archive scans such as file and image records, non-interventional research to be conducted with biochemistry, microbiology, pathology and radiology collection materials such as blood, urine, tissue, radiological images or materials obtained during routine examination, examination, analysis and treatment procedures, cell or tissue culture studies; research to be conducted with genetic material for identification purposes, other than gene therapy clinical research, Diet studies with food additives, Researches related to body physiology such as exercise, studies based on anthropometric measurements, researches measuring the results of health education, researches on nutrition, researches on the evaluation of living habits, qualitative studies, all researches that do not require the direct intervention of a physician,

**Informed Consent Form:** A written document, signed and dated by the parties, showing that the volunteer has decided to participate in the research with his/her free will, after the volunteer who will participate in the research or, where necessary, his/her legal representative has been informed about all kinds of information about the research, the application and the importance of the risk for human health, or if the volunteer or his/her legal representative is illiterate or if the volunteer is visually impaired, a written document showing the consent of the volunteer in the presence of at least one witness independent of the research and by obtaining the signature of the witness,

**Ethics Committee:** It refers to the committee to be established and approved by the Faculty Board of Directors in order to give scientific and ethical opinions on the research protocol, the suitability of the researchers, the adequacy of the places where the research will be conducted, the methods and documents to be used in informing the volunteers, the methods and documents to be used in informing the volunteers, the consent to be taken from these people and other issues related to the research in order to ensure that the research is carried out and monitored in accordance with the directive.

## **PRINCIPLES OF ESTABLISHMENT OF THE ETHICS COMMITTEE AND**

### **MEMBERS:**

- **Item 5.** Ethics Committee; It is formed with the participation of at least two academic staff from each of the Midwifery, Nutrition and Dietetics, Health Management, Physiotherapy and Rehabilitation, Social Work, Child Development departments of Selçuk University Faculty of Health Sciences or academic staff who have completed their doctoral education. The academic staff who constitute the ethics committee are elected by the Faculty Deanery Board of Directors to serve for a period of two years.

A member who fails to attend three consecutive meetings in a calendar year without permission or excuse shall lose his/her membership and a new member shall be elected in the same way. The departments opened later within the faculty in the ethics committee, It is ensured that there are as many academic staff or academic staff who have completed their doctorate as other departments. Ethics committee member cannot take part as a member of the committee in the meeting where his/her own work is evaluated. Withdrawal from the board membership and loss of membership become effective with the approval of the Faculty Deanery. A new member is elected by the same method to complete the remaining term instead of the member who has left his/her duty. An ethics committee member whose term of office has expired can be reappointed. However, a member cannot serve on the board for more than two consecutive terms. A member with the same qualifications is elected to replace the member(s) whose term of office has expired or whose membership has fallen. At the first meeting, a chairman and a rapporteur are elected among the members.

- **Item 6.** Members shall sign a confidentiality agreement after their appointment. The Board shall hold the first meeting within 15 days following the appointment of the members and shall make the necessary announcements by determining the methods and documents to be used in the preparation of the application file and the appropriate format for the notification of the result. Meeting dates are announced to the board members and researchers in advance by the secretariat.
- **Item 7.** While ethics committee members can only serve in one of the ethics committees; people who have completed their doctorate, specialization or master's degree in medical ethics (deontology) can serve on more than one of these boards.
- **Item 8.** Studies implemented before the application to the Ethics Committee are not evaluated and no Ethics Committee permission is given retroactively.

- **Item 9.** If the opinion of a different branch of science is needed in the evaluation of the research project, the Ethics Committee may invite one of the faculty **members of** the relevant unit to the ethics committee as an expert. If necessary, it can send research proposals to these experts in advance for scientific evaluation. In particular, it may be recommended by the ethics committee to invite an expert in the relevant field as a consultant for “studies on pregnant women and newborn studies in terms of fetus/infant health”.

### **EVALUATION AND DECISION:**

- **Item 10.** In order for the application file to be included in the meeting agenda, it must be submitted to the Faculty Deanery document record at least seven (7) business days before the meeting date. Urgent research files can be submitted to the board with the proposal of the board president and the approval of the Dean. Meeting days and the deadline for submission of the application file are announced on the faculty website at the beginning of each academic year.
- **Item 11.** Ethics committee members meet with a two-thirds majority of the total number of members and make decisions with the absolute majority of the total number of members attending the meeting. In case of equality, the vote of the chairman of the board is decisive.
- **Item 12.** The sponsor of the research and the ethics committee member(s) who are related to or have a role in the research under review cannot participate in the discussions and voting of this research in the ethics committee and cannot sign the board decision.
- **Item 13.** While the Ethics Committee examines applications;  
Suitability of the responsible investigator and assistants who will conduct the research,  
Suitability of the unit where the research will be carried out for the research, Whether

the research topic is supported by sufficient literature information, Justification and purpose of the study, Proper planning, Formation of the working group, Protection of the rights, safety, dignity and health of volunteers, It evaluates the informed consent form in terms of the adequacy and suitability of its content in terms of the designed research. In studies carried out using the survey or interview method, the survey or interview forms are requested to be added to the projects. In studies requiring permission from any institution or organization, care is taken to obtain permissions, add them to the project, and ensure that the processes followed regarding the permission are clearly stated in the method section of the project. In addition, evaluations include the protection of the rights, safety, dignity and health of volunteers, the adequacy and suitability of the content of the “Informed Consent Form” in terms of the designed research, the presence of a declaration of no conflict of interest signed by the researchers and the health assurance provider. It also includes evaluations of whether social security institutions and revolving funds are used as financial resources.

- **Item 14.** The Ethics Committee determines whether the research/thesis projects applied for approval comply with ethical standards; It evaluates the purpose and justification of the study, its method, benefits and harms of the study, possible dangers, and budget, and, if appropriate, gives approval indicating the feasibility of the study. Ethics committee decisions are made by consensus or majority vote. The decision text contains the wet signatures of the members. The justification for dissenting votes is written in the decision text. The decision text is given in Turkish and English.
- **Item 15.** The ethics committee is obliged to finalize the applications that do not require correction and the decision must be evaluated at the meeting within the

following calendar month at the latest and the result must be reported in writing. The ethics committee notifies the researcher in writing about any issues it finds deficient and/or incorrect regarding the research. The decision is notified to the researcher in writing within the calendar month after the requested correction or information is submitted to the ethics committee. The decision regarding research rejected by the ethics committee is notified in writing along with the justification.

### **ETHICS COMMITTEE SECRETARIAT:**

- **Item 16.** Ethics Committee Secretariat is carried out by the secretariat appointed by the Faculty Deanery. Receiving applications to the ethics committee, informing researchers, archiving documents, making necessary correspondence, arranging application forms, organizing meetings and similar tasks are carried out by the ethics committee secretariat. The Chairman of the Ethics Committee coordinates the work of the Secretariat.

### **BINDING AND OBLIGATIONS:**

- **Item 17.** Financial and legal responsibility for the positive or negative decision of the Non-Interventional Clinical Research Ethics Committee belongs to the researchers who conducted the research. **Ethics Committee Decisions are advisory. It never has any legally binding force. The ethics committee and its members are not subject to criminal or legal liability for the decisions they make.**
- **Item 18.** If the ethics committee deems it necessary, it may inspect the research site for ongoing studies, request oral or written information about the research, request the application or research to be stopped by stating the reason, and withdraw its approval. If a stopped study is to be restarted, the ethics committee can re-evaluate and decide whether the reasons requiring the study to be stopped have been eliminated. When deemed necessary, the ethics committee may invite researchers to its meetings to listen

and obtain information, or may seek the opinions of experts other than its members regarding the research. Exchange of views, discussions and objections made during ethics committee meetings are confidential.

- **Item 19.** In the design, conduct, completion and termination of non-interventional clinical research, the use of data for scientific and/or educational purposes and publication, the researcher order declared in the application is the author order. If researchers do not comply with the principles and rules of publication ethics and the promises they made on the project, the unethical behavior of the researcher is reported to the relevant Faculty Deanery.
- **Item 20.** The ethical, legal and administrative responsibility of research conducted without the approval of the Ethics Committee or for which a negative opinion is given belongs to the responsible researcher who conducted the research.
- **Item 21.** There is no obligation for the ethics committee to meet in July and August. The Chairman may evaluate the agenda and call the committee to a meeting in July and August with the approval of the Faculty Deanery. Meeting dates are announced to the board members in advance by the chairman.
- **Item 22.** This directive comes into force after being approved by the Selçuk University Senate.
- **Item 23.** The provisions of the directive shall be enforced by the Dean of the Faculty of Health Sciences on behalf of the Rector of Selçuk University.