**SELÇUK UNIVERSITY FACULTY OF MEDICINE**

**LOCAL ETHICS COMMITTEE DIRECTIVE**

## Aim

**Article 1 –** Purpose of this Directive; In applications to be made from **academic units** affiliated to Selçuk University and from outside the institution to be evaluated scientifically and ethically , clinical research projects that will be carried out on patients and/or human volunteers, in which there is no intervention to patients and/or volunteers and/ or their treatments, and that **are non-drug and medical device clinical research** projects shall be carried out in accordance with ethical principles and To evaluate in terms of rules, to express opinions, to monitor, to create new principles and rules when necessary, and to protect the dignity, rights, safety and well-being of patients and/or volunteers, taking into account the scientific method and the concerns of the society.

## Rest

**Article 2 –** This directive; Based on the additional article 10 of the Health Services Basic Law No. 3359 dated 7/5/1987 and Articles 27 and 40 of the Decree Law on the Organization and Duties of the Ministry of Health and Affiliated Organizations No. 663 dated 11/10/2011 and European In accordance with the directives 2001/20/EC and 2005/28/EC on Good Clinical Practices of the Union's legislation on medicines and the Regulation on Clinical Research of Pharmaceuticals and Biological Products published by the Ministry of Health in the Official Gazette dated 13/4/2013 and numbered 28617 and numbered 06/06. The Regulation on Medical Device Clinical Research published in the Official Gazette No. 09/2014 and 29111 was prepared based on the Standard Operating Method Principles of the Clinical Research and Bioavailability/Bioequivalence Studies Ethics Committees of 14.05.2020.

## Scope

**Article 3 – (1)** All research conducted on humans without requiring the direct intervention of a physician constitutes the scope of non-drug and medical device clinical research. These studies are stated below:

**a)** Survey studies,

**b)** Retrospective archive scans and similar observational studies using files and image records,

**c)** Studies to be carried out with biochemistry, microbiology, pathology and radiology collection materials such as blood, urine, tissue and images, or materials obtained during routine examination and treatment

procedures, **ç)** Cell or tissue culture studies,

**d)** Research to be carried out with genetic material for identification purposes, other than gene therapy clinical research

**e)** Research to be conducted within the boundaries of nursing activities,

**f)** Research on body physiology such as exercise (research on therapeutic effects is out of scope)

**g)** Studies based on anthropometric measurements,

**h)** All research to be conducted on a human being without requiring the direct intervention of a physician, such as research on the evaluation of living habits,

**i)** Other: Other research that is not included in the above groups and that will be conducted on humans without requiring the direct intervention of a physician.

**(2)** Even if a license or permission has been obtained, drug clinical studies, observational drug studies, observational medical device studies to be conducted on humans with drugs and compounds, traditional herbal medicinal products, cosmetic raw materials or products, and all other substances and products that may be tested on humans. clinical trials; research with industrial advanced medicinal products and non-industrial advanced medicinal products; Stem cell transplantation research, organ and tissue transplantation research, surgical research, gene therapy research on humans are outside the scope of this Directive. For studies within this scope, it is necessary to apply to the relevant ethics committees affiliated with the Ministry of Health.

**Definitions**

**Article 4.** (1) The concepts and terms used in the directive are as

follows: **a) Ethics:** The limits of the actions that can be taken in the sciences that concern human life are a set of guiding and limiting rules before the behavior.

**b) Ethics committee:** Protection of the rights, health safety and well-being of volunteers who will participate in the research; In order to ensure that the research is carried out and followed in accordance with the legislation, 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 to inform the volunteers, and the relevant institutions according to the clinical research fields, to provide scientific and ethical opinions on other issues related to the research. These are independent boards to be formed and approved by. **c) Non-drug and medical device clinical research:** Observational

clinical studies to be conducted on humans without requiring the direct intervention of a physician, survey studies, retrospective archive scans such as files and image records, biochemistry, microbiology, pathology and radiology studies such as blood, urine, tissue and radiological images. Research and cell or tissue culture studies to be carried out with collection materials or materials obtained during routine examination, examination, analysis and treatment procedures; Research on genetic material for identification that is outside of gene therapy clinical research, research to be carried out within the limits of nursing activities, research on body physiology such as exercise (research on therapeutic effects is out of scope), studies based on anthropometric measurements and research on the evaluation of living habits, etc. These are studies that do not require the direct intervention of a physician.

**d) Responsible researcher:** The person who has completed his/her specialization or doctoral education, is responsible for the conduct of the research, has sufficient scientific experience and education regarding the research subject, and works in academic educational institutions.

**d) Volunteer:** In accordance with the provisions of this directive and the relevant legislation, the patient or healthy person who will participate in the clinical trial by obtaining written consent from himself or his legal representative.

**e) Informed volunteer consent form:** After the volunteer who will participate in the research or, when necessary, his/her legal representative is informed about the importance of all kinds of information, practices and risks related to the research in terms of human health (in a way that the volunteer can understand, medical terms are expressed in Turkish as much as possible), the volunteer is fully informed. with free will

It is a written document signed and dated by the parties showing that they have decided to participate in the research. If the volunteer or his/her legal representative is illiterate or the volunteer is visually impaired, it is a document showing the verbal consent of the volunteer in the presence of at least one witness independent of the research and by obtaining the signature of the witness. **f) Sponsor:** The person,

institution or organization responsible for initiating, conducting and/or financing a clinical trial.

**g) Multicenter clinical trial:** It is a clinical trial conducted in more than one center according to a single protocol, and therefore has more than one responsible investigator. **g) Good clinical practices:** Designing,

conducting, monitoring, budgeting, evaluating and reporting research in order to ensure that research is carried out in accordance with international scientific and ethical standards; protection of all rights and physical integrity of the volunteer; These are the rules that cover regulations on issues such as ensuring the reliability of research data and maintaining their confidentiality, and that must be followed by the parties participating in the research. **h) Restricted:** Patients in intensive care, including privates and non-commissioned officers doing their military duty, are people within the scope of the restrictions defined in Articles 405 to

408 of the Turkish Civil Code No. 4721 dated 22/11/2001.

**i) Coordinator:** In a multi-center research, the researcher who has completed his/her specialty or doctorate degree carries out the coordination between the responsible researchers of these centers, the ethics committee and the sponsor.

**Establishment and Working**

**Principles Article 5 -** Selçuk University Faculty of Medicine Local Ethics Committee members consist of 11 (eleven) members who have received "Basic Good Clinical Practices Training" and will be selected by the Faculty of Medicine Executive Board from among the faculty members of the Faculty of Medicine.

**Article 6 –** Selçuk University Faculty of Medicine Local Ethics Committee members are elected by the Faculty of Medicine Board of Directors for 3 (three) years. Members begin their duties by signing the Local Ethics Committee confidentiality agreement. Members whose term of office has expired can be re-elected. Membership of members who fail to attend three consecutive meetings or five intermittent meetings without an excuse during their membership period will be automatically terminated. A new member is elected using the same method to replace the member who has resigned.

**Article 7 – (1)** After the board members are determined, they convene within the first 15 days and the president, vice president and rapporteur are elected among them by secret ballot. In order for voting to take place, there must be at least 7 (seven) people present at the meeting. The main thing in the election is to get the most votes. First the president, then the vice president, and finally the rapporteur are elected. In case of a tie, another vote is held. If there is a tie again, the Dean makes a choice. The Chairman represents the Local Ethics Committee. In the absence of the president, the vice president represents him.

**(2)** The Board meets with at least 7 (seven) people and makes decisions by the majority of the number of members attending the meeting. The voting procedure is open voting. In case of equal votes, the chairman's vote is decisive. Commission members cannot participate in voting during the evaluation of their own work.

**Article 8 –** The Board holds the first meeting within 15 days following the appointment of the members and determines the method and documents to be used in the preparation of the application file and the appropriate format for notification of the result and makes announcements to the necessary places. The board meets at least once a month. There is no obligation to meet in July and August. Meeting dates are announced to board members and researchers in advance by the secretariat.

**Article 9 –** The secretariat of the Board is carried out by at least one officer appointed by the Dean. Receiving applications, informing researchers, archiving documents, making correspondence, arranging application forms, organizing meetings and similar tasks are carried out by the secretariat.

**Article 10 –** Studies implemented before the application to the Ethics Committee are not evaluated and no Ethics Committee permission is given retroactively.

**Article 11 – (1)** In order for the Board to carry out its services, the Deanship provides the appropriate physical environment, archive unit, photocopier, telephone, fax and computer systems with internet access.

**(2)** Receiving the applications made to the ethics committee, informing the sponsor or the contract research organization or the responsible researcher, archiving the documents, making the necessary correspondence, organizing the meetings and similar tasks are carried out by the ethics committee secretariat. Personnel working in the ethics committee secretariat must comply with the confidentiality principle for all information they receive.

**General principles of the research, obtaining consent for the research**

**Article 12 – (1)** General principles regarding the protection of volunteers who will participate in the research are as follows:

**a.** In children, during pregnancy, puerperium and breastfeeding periods and in case of restriction; If it is expected that the volunteers will benefit directly from the research and the research does not pose a foreseeable serious risk to the volunteer's health, the research may be allowed with the approval of the relevant Ethics Committee along with a duly obtained informed consent form.

**b.** The person or his/her legal representative who wants to volunteer to participate in the research must: He is informed sufficiently and in a way that he can understand by a researcher from the research team about the purpose of the research, its methodology, expected benefits, foreseeable risks, difficulties, aspects that are not suitable for the person's health and personal characteristics, and the conditions under which the research will be conducted and continued, and that he has the right to withdraw from the research at any time.

**c.** The volunteer's consent to be included in the research with his/her free will is obtained and this is documented with the Informed Volunteer Consent Form. The Informed Volunteer Consent Form is prepared in two copies. One of these copies is given to the volunteer for signature, and the other remains with the researcher. The Informed Volunteer Consent Form is open to Ethics Committee review. **c.** During the research, it is essential not to use

methods that will cause pain to the volunteer that is incompatible with human dignity.

**D.** At least one person from the research team (at least two people for studies with more than one researcher) is assigned to ensure that the volunteer can obtain information about his or her health and the progress of the research at any time and to contact him for this purpose. **to.** The volunteer can withdraw

from the research at any time, with or without justification, with his/her own consent, and therefore cannot lose any of his or her existing rights during subsequent medical follow-up and treatment.

**f.** Expenses that will arise from the participation of volunteers in the research are stated in the research budget and covered from this budget. These expenses are not paid to the volunteer or the social security institutions to which he/she is affiliated.

**g.** There is no research on disrupting the genetic structure of volunteer germ cells.
It cannot be done.

**h.** In case the information obtained as a result of the research is published, the identity of the volunteer
information cannot be disclosed.

**(2) The general principles regarding obtaining voluntary consent in research are as follows:**

**a.** The volunteer is informed about the research adequately and in a way that he/she can understand.
After being informed, written consent is obtained and this situation becomes the Informed Volunteer.
It is documented with a Consent Form. In cases where a witness is needed, his/her relevance to the research
Those present cannot testify.

**b.** In cases where the volunteer cannot give consent, his/her legal representative is authorized.

**c.** Any samples and other data obtained from individuals other than routine examinations are
It cannot be used without the permission of the legal representative.

**(3)** Informed Volunteer Consent Form must be obtained from the volunteer participating in the research,
It eliminates the volunteer's right to compensation for damages suffered as a result of the research.
does not lift.

**Children's participation in research**

**Article 13 – (1)** Research on children is permitted within the framework of the following:
permissible:

a. The child will be able to evaluate the information given to him and
If the child is capable of reaching a conclusion, all necessary information about the research will be provided to the child in an appropriate manner.
It is explained as follows. The child's refusal to participate in the research or any part of the research
If the student requests to withdraw from the research at some stage, his/her parent or
may not be included in the research and may not be excluded from the research, regardless of the approval of the legal representative.
is removed.

**b.** A child health and disease specialist is required for any clinical research to be conducted on children.
A physician (other than researchers) regarding the conduct of research on children
The ethics committee cannot approve this research without a positive opinion. Research for these studies
A physician or dentist who has a doctorate or specialization in the relevant field of science
His/her opinion is taken and it is evaluated as a result of this opinion whether the research will be allowed or not.

**c.** General medical advice indicates that the research has no known risks to children.
There must be an opinion. **c.** Legal

representative: "Within the framework of general principles regarding the protection of volunteers"
After being informed, written consent is obtained. The legal representative gives written consent,
Even if the research does not cause a negative impact on the child's health, it can be withdrawn at any time.
can take.

**D.** For research to be conducted on children, the results will be revealed through the participation of children in the research.
any convincing incentive and/or financial offer other than covering mandatory expenses
cannot be found.

**Participation of pregnant women, postpartum women and breastfeeding women in the research**

**Article 14 – (1)** Pregnant women, postpartum women and breastfeeding women within the framework of the following:
Research on it may be allowed.

**a.** Pregnant, postpartum or breastfeeding women may refuse to participate in the study or
If they request to withdraw from the research at any stage
is excluded from the research.

b. In terms of fetus/baby health, a perinatologist should be consulted for research on pregnant women.
a physician or a gynecologist and obstetrician, postpartum women and breastfeeding women
In research to be carried out on the patient, a neonatologist or child health and
Without the positive opinion of a physician who specializes in diseases, the Ethics Committee
cannot approve research.

**c.** Pregnant, postpartum or breastfeeding women should be advised that this directive 'Concerning the protection of volunteers'
Written consent is obtained after being informed within the framework of general principles.

**c.** The research does not have any known effects on pregnant women, postpartum women, breastfeeding women and the fetus/infant.
There must be a general medical opinion that there is no risk.

**D.** For studies to be conducted on pregnant, postpartum or breastfeeding women,
any convincing other than covering the mandatory expenses incurred by participating
No incentives and/or financial offers can be made.

**Participation of people in intensive care and unconscious people in the research**

**Article 15 – (1)** Persons in intensive care and unconscious within the framework of the following
Research on it may be permitted.

**a.** The research does not have any known effects on people in intensive care and unconscious.
There must be a general medical opinion that there is no risk.

b. Legal representatives of people in intensive care and those who are unconscious, if any, or their relatives, 12
They are informed in accordance with subparagraph (b) of the first paragraph of the article and their written consent is obtained.

**c.** Persons in intensive care and unconscious should evaluate the information given to them.
If they have the capacity to reach an opinion on this issue by doing this, they can participate in the research.
refuse or want to withdraw from the research at any stage of the research.
In such cases, they are immediately removed from the research.

**c.** Regarding clinical, ethical, psychological and social problems related to research,
without the positive opinion of a physician who has expertise in the relevant field.
Research is not approved.

**D.** For research on people in intensive care and unconscious people,
Covering the mandatory expenses arising from the participation of unconscious persons in the research
No other convincing incentive or financial offer can be made.

**Participation of people with restrictions in research**

**Article 16 – (1)** Research on restricted individuals is permitted within the framework of the following:
can be given.

**a.** Limited, evaluates the information given to him and makes an opinion on this issue.
If he/she has the capacity to participate in the research, he or she refuses to participate in the research or
taking into consideration the request to withdraw from the research at any stage.
is removed immediately.

**b.** The relevant ethics committee is informed about the clinical, ethical, psychological and social problems related to the research by a physician who has expertise in the field of research and a physician who is a psychiatrist, and the protocol is evaluated accordingly.

**c.** Written consent is obtained after the person and/or his/her legal representative are informed within the framework of this directive "General principles regarding the protection of volunteers".

**c.** There must be a general medical opinion that the research does not pose any known risk to the disabled.

**D.** No convincing incentives and/or financial offers can be made for research to be conducted among people with disabilities, other than covering the mandatory expenses that will arise from the participation of people with disabilities in the research.

**Application and evaluation Article**

**17 –** Responsible researchers working in academic educational institutions can apply to Selçuk University Faculty of Medicine Local Ethics Committee. Applications made otherwise will not be accepted.

**Article 18 –** In order for the application file to be included in the meeting agenda, it must be delivered to the secretariat at least 5 (five) business days before the meeting date. Urgent investigative files may be submitted to the board under the authority of the president.

**Article 19 –** While the Board examines the applications;

**a)** Suitability of the responsible investigator and assistants who will conduct the research,

**b)** Analysis of the expected benefits, harms and risks from the research

**c)** Suitability of the unit where the research will be carried out for the research,

**ç)** Whether the research is based on scientific data and a new hypothesis

**d)** Whether the research topic is supported by sufficient literature information, **e)** The justification and

purpose of the study,

**f)** Protection of the rights, safety, dignity and health of volunteers,

**g)** The adequacy and suitability of the content of the Informed Volunteer Form in terms of the designed research,

**h)** The adequacy of the justification for research to be carried out on children and limited persons who cannot give consent.

**i)** It evaluates whether social security institutions and revolving funds that provide health insurance are used as financial resources.

**Article 20 – (1)** The Board is obliged to evaluate the applications that do not require corrections in the appropriate number of meetings, according to the application order, and notify the result in writing. Urgent investigative files may be discussed before the normal order under the authority of the President.

**(2)** The Board notifies the investigator of any issues it finds deficient and/or incorrect regarding the research. After the requested correction or information is presented to the board, it is re-evaluated and the decision is notified to the investigator. The results of rejected research are reported with justification.

**Article 21 – (1)** When deemed necessary, the Board may inspect the research site for ongoing studies and request oral or written information about the research,

may request the application or research to be stopped by stating the reason, and may withdraw approval.

**(2)** When deemed necessary, the Board may invite researchers to its meetings to listen and obtain information, or may seek the opinions of experts other than members regarding the research.

**Article 22 – (1)** Despite the positive opinion of the Board, legal responsibility belongs to the people who conducted the research. The Board does not assume any criminal, legal or medical liability for its decisions.

**(2)** Exchange of views, discussions and objections made during Board meetings are confidential.

**Article 23 –** If there is an Ethics Committee at the institution where the responsible researcher is located, at the higher institution to which he/she is affiliated, or at the place where the study is conducted, and if the study can be evaluated by this committee, applications made to the Local Ethics Committee of Selçuk University Faculty of Medicine will not be accepted.

**Article 24 –** If the subject of the study concerns another medical field other than the responsible researcher's own field, a researcher from the relevant field must be among the researchers.

**Article 25 – 1)** The approvals and decisions of the boards are only related to the ethical and scientific aspects of the research and do not replace the permission and license of the competent authority, especially the Ministry of Health. In addition, it does not eliminate the need for other permissions, approvals and decisions that must be obtained from the competent authorities in accordance with the current legislation.

**2)** After the positive opinion of the Board is received, research cannot be started without obtaining the necessary permission in studies subject to the permission of the Ministry of Health. Legal and administrative responsibility for research conducted without the approval of the Board or, in relevant cases, the permission of the Ministry, for which a negative opinion is given, belongs to the responsible investigator who conducted the research. Action is taken in accordance with the provisions of the Disciplinary Regulation for Administrators, Faculty Members and Civil Servants of Higher Education Institutions against researchers who conduct a research for which a negative decision has been made by the Board or for which an application has not been made to the Board or to another Ethics Committee in multi-center research, or whose practices are detected outside the ethical framework determined at the acceptance of the project during controls while the study is ongoing. .

**Repealed directive Article 26 –** Selçuk

University Faculty of Medicine Local Ethics Committee Directive, which was accepted by the Selçuk University Senate on 07/02/2019, has been abolished.

**Force**

**Article 27 –** This directive enters into force on the date it is accepted in the Senate.

**Executive**

**Article 28 –** The Dean of the Faculty of Medicine enforces the provisions of this directive.

**Provisional Article 1 –** The duties of the Local Ethics Committee members who are on duty on the date this directive comes into force shall terminate.