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**ISTANBUL MEDIPOL UNIVERSITY**

INSTRUCTION ON ANIMAL EXPERIMENTS LOCAL ETHICS COMMITTEE

FIRST SECTION

Aim, Scope, Basis, and Definitions

**Aim**

**ARTICLE 1 –** (1) This instruction is for expressing opinions in line with ethical principles on methods and materials used in basic activities such as scientific research, experimental study, health care practices, education, and publication to be carried out with experimental animals at Istanbul Medipol University and to evaluate research proposals from this perspective. It was organized to determine the establishment and working principles of the “Istanbul Medipol University Animal Experiments Local Ethics Committee” (IMU HADYEK).

# Scope

**ARTICLE 2 –** (1) This instruction covers the permissions required before the use of animals to be used for experimental purposes at Istanbul Medipol University, the establishment of the Animal Experiments Local Ethics Committee, the working principles, duties, training, inspection and obligations of this committee.

(2) This instruction does not cover;

1. Non-experimental clinical veterinary medicine practices,
2. Clinical trials required to be authorized to market veterinary health products,
3. Applications whose primary purpose is the identification of an animal.

# Base

**ARTICLE 3 –** (1) This instruction is based on the 9th, and 17th articles of the Animal Protection Law dated 24/6/2004 and numbered 5199 and the "Welfare and Protection of Animals Used for Experimental and Other Scientific Purposes" published in the Official Gazette dated 13/12/2011 and numbered 28141 of the Ministry of Food, Agriculture and Livestock. It has been prepared following the Regulation on the Protection of Animals and the Regulation on the Working Procedures and Principles of Animal Experiments Ethics Committees dated 15/02/2014 and numbered 28914 of the Ministry of Forestry and Water Affairs.

# Definitions

**ARTICLE 4 –** (1) The definitions in this instruction refer to;

1. Principle 3R: Use a scientifically valid alternative method or testing strategy to replace live animals whenever possible, reduce as much as possible the number of animals to be used without compromising the project objectives, improve animal welfare by improving procedures that will cause suffering, suffering, suffering, and permanent damage to animals. ,
2. President: President of IMU-HADYEK,
3. Study: All research projects, training, and testing activities carried out on experimental animals and approved by IMU-HADYEK with a protocol number for research, training and testing purposes,

ç) Experiment: Any procedure or set of procedures to be performed on animals for scientific purposes,

1. Experimental animal: Any non-human vertebrates, including free-living or reproductive larval forms, viviparous cephalopods, and mammals from the last third of normal fetal development, used in procedures.
2. Experimental Animal Breeding and Research Laboratory: Istanbul Medipol University Experimental Medical Research Center,
3. Ethics: Limits of actions that can be made in sciences that concern human and animal life concerning animals to be used in research, universal rules guiding the attitude and behaviour towards animals,
4. HADMEK: Animal Experiments Center Ethics Committee,

ğ) Animal welfare unit: At least one person who has the title of veterinarian, veterinary health technician or veterinary health technician, responsible for the welfare and care of animals, obligatory to be established in producers, suppliers, users and institutions authorized to research, and a person holding one of these titles in user organizations. A unit consisting of a maximum of three people, one of which is a member of the local ethics committee, in addition to the individual,

1. Humane killing method: Ending the animal's life in such a way that it is exposed to the least physical and sensory pain, suffering and distress unique to its species,

ı) Istanbul Medipol University Animal Experiments Local Ethics Committee (IMÜ-HADYEK): Istanbul Medipol University Animal Experiments Local Ethics Committee, which was established according to the conditions specified in the Regulation on Working Procedures and Principles of Animal Experiments Ethics Committees,

1. User: Person authorized to use animals in procedures,
2. User Organization: Istanbul Medipol University and its affiliates,
3. Procedure: Animals; Experimental, other experimental, other, with known or unknown consequences, which, in accordance with a good veterinary practice, may cause pain, suffering, suffering, or lasting damage equal to or greater than that caused by the insertion of a needle, including the processes of giving birth, hatching, or maintaining a genetically modified animal lineage. To be used for scientific or educational purposes,
4. Rector: Refers to the Rector of Istanbul Medipol University.

# SECOND SECTION

The Purposes of Using the Experimental Animal, Establishment, Term of Office, Working Method, Duties and Authorities of the Ethics Committee

The Purposes of Using the Experimental Animal

**ARTICLE 5 –** (1) The purposes of using experimental animals are stated below:

1. Basic research.
2. Translational or applied research with any of the following purposes:
3. Prevention, diagnosis, treatment or avoidance of disease, health disorders and other abnormalities in humans, animals or plants.
4. The study, identification, correction or modification of physiological disorders in humans, animals or plants.
5. Improvement of animal welfare and production conditions of animals raised for agricultural purposes.
6. Development, manufacture and testing of the quality, efficacy and safety of medicines, food raw materials, feedstuffs, other substances and products for any of the purposes specified in (b).

ç) Protection of the natural environment for human and animal health and welfare.

1. Research aimed at species conservation.
2. Higher education or training for the acquisition, maintenance or development of professional skills.
3. Forensic investigations.

**ARTICLE 6 –** (1) IMU-HADYEK is installed as follows:

1. IMU-HADYEK must have members whose qualifications are stated below as a minimum:
2. A veterinarian with at least one year of experience in animal experiments, responsible for raising and producing experimental animals within the institution or organization, has a certificate of use of experimental animals, works in the unit full-time.
3. A representative from the units working with experimental animals within the institution or organization.
4. He and his first-degree relatives are citizens of the Republic of Turkey who do not conduct experimental studies on animals and have no interest in the organization.

ç) A citizen of the Republic of Turkey who is a member of a non-governmental organization that has no interest in the institution or organization

1. At least one member of IMU-HADYEK must have at least one year of experience in animal experiments and have a doctorate or medical speciality degree. If necessary, IMU-HADYEK may seek opinions from experts in other fields and invite them to meetings. IMU-HADYEK consists of at least five and at most 21 members.
2. Regarding the assignment of IMU-HADYEK members;
3. The president, vice president and members of IMU-HADYEK are appointed by the Rector.
4. The head of IMU-HADYEK and the veterinarian must be full-time employees of the institution or organization. Other members may also be appointed from outside the institution or organization.

ç) Persons who are found to act in violation of the provisions of this Regulation cannot be appointed as IMU-HADYEK members.

1. IMU-HADYEK secretariat is appointed by the Rector.
2. The term of office for HADYEK members is four years. The member whose term of office expires can be reappointed or assigned with approval. The membership of a member who does not attend three consecutive meetings without permission and excuse within a calendar year is forfeited. If the membership status is terminated for any reason such as death, retirement or resignation, a new member who has the same qualifications as the resigned member is appointed in the same manner and to complete the remaining term.
3. IMU-HADYEK works as follows:
4. IMU-HADYEK convenes at least once a month, with the participation of at least two-thirds of the members, with the agenda to be determined by the chairman of the board.
5. At the IMU-HADYEK meeting, decisions are taken by a majority vote. In the case of equality of votes, the decision is made in the direction of the chairman's vote.
6. Records of all experimental animals used in institutions are kept by the veterinarian in charge of breeding, production and care of experimental animals in the animal welfare unit. The number of animals provided, their species, where they were obtained, the date the user came to the organization and all the transactions carried out are included in the said records. These records are kept for at least five years.

ç) IMU-HADYEK prepares a form to evaluate the applications to be made. The form must contain the following information:

* 1. Project Name.
  2. Name, address, place of duty, the signature of the project coordinator and other researchers.
  3. The place and duration of the procedure.
  4. Training certificates for those who will perform procedures on live animals.
  5. Application Date.
  6. Project Proposal.
  7. Non-technical project summary in everyday language.
  8. Animal resources, estimated number, species and age of animals.
  9. Procedures to be performed on animals.
  10. The level of pain, suffering, suffering and permanent damage that the procedures will cause.
  11. The way the 3R principle is applied in procedures.
  12. Anesthesia, analgesia and other pain relief methods are planned to be used.
  13. Measures are to be taken to ensure that animals do not experience pain and suffering during their lifetime or to reduce the suffering they suffer.
  14. Determination of humane killing method in termination of procedures.
  15. Experimental or observational strategies and data analysis procedures to minimize the number of animals and the pain, suffering, suffering, or potential environmental effects of the procedures.
  16. Whether the animals will be used in multiple projects.
  17. Conditions of housing, rearing and care of animals.
  18. Competence of those involved in the project.
  19. Letter of Undertaking.

1. Projects are allowed by IMU-HADYEK for a maximum period of five years. In the case of an extension request, additional time may be granted if the request is justified.
2. All applications and decisions taken are recorded by giving the date and issue number. These records are kept for at least five years.
3. Applications are made by the project coordinator. He is the coordinator and advisor faculty member for thesis studies.
4. As a result of its evaluation, IMU-HADYEK decides whether it is appropriate, needs to be corrected, conditionally appropriate or not. Decisions are notified to the applicant in writing within forty working days from the date of application. This period also includes project evaluation. In cases where the complexity of the project or if it concerns more than one discipline, IMU-HADYEK can extend the aforementioned period to fifteen working days for once

May extend beyond. An executor is informed before the expiry of the extension, by justifying the reason and duration of the extension. IMU-HADYEK may request preliminary experiments on a small number of animals to test the feasibility of a project. In this case, the final decision is made according to the procedures in the projects for which the "conditionally appropriate" decision is given.

ğ) While the applications of IMU-HADYEK members are being discussed, the relevant board member cannot participate in the meetings and cannot vote.

1. Projects that have been given a "need to be fixed" decision are re-evaluated after they are fixed. Projects that are determined as “conditionally suitable” are followed by the animal welfare unit for a period to be determined by IMU-HADYEK. After evaluating whether the required conditions are fulfilled, it is decided as appropriate or not appropriate, and a report is given to IMU-HADYEK regarding the project.

ı) IMU-HADYEK inspects whether there are any changes that may adversely affect animal welfare in the permitted projects. IMU-HADYEK cancels the granted permission in case of non-compliance with the approved project. In case the permission is cancelled; It is ensured by the animal welfare unit that the welfare of the animals used or anticipated to be used in the project is not adversely affected.

1. After the approval of IMU-HADYEK, the changes in the project and the people who will participate in the study are notified to HADYEK in writing by the project coordinator and its approval is obtained.
2. The following interventions are not subject to the permission of IMU-HADYEK:
   1. Clinical applications for diagnosis and treatment.
   2. Procedures with dead animals or tissue, slaughterhouse materials, waste fetuses.
   3. Milking.
   4. Collecting a stool or litter sample.
   5. Sampling with a swab.
3. If field surveys are carried out in more than one province, it is sufficient to obtain HADYEK approval for only one place.
4. Records are kept open to the inspection of HADMEK and the Ministry. IMU-HADYEK can get the written opinions of experienced experts when necessary, or invite them to IMU-HADYEK meeting and ask for oral or written opinions.

# Duties of IMU-HADYEK

**ARTICLE 7 –** (1) The duties of IMU-HADYEK are as follows:

1. To prepare the instruction that determines its working procedures and principles and make suggestions for changes when necessary.
2. To approve or reject the protocols regarding the procedures to be carried out by determining the ethically acceptable limits of all procedures be performed on experimental animals.
3. To supervise the continuation of the process of using experimental animals within the institution following the 3R principles and ethical rules to make the necessary arrangements for this purpose.

ç) To carry out practices that can provide the same or higher level of information than those obtained by using experimental animals but will contribute to the development and validation of alternative methods that do not use animals, or that use the least number of animals or less painful procedures, and that will encourage research in this field.

1. To ensure that the procedures to be performed on experimental animals are carried out in accordance with the approved protocol and to decide to terminate them when necessary.
2. To ensure that the personnel who will work with experimental animals receive the necessary training and to allow animal experiments to be carried out, provided that they have an experimental animal use certificate. To organize certificate programs when necessary for this purpose.
3. To control whether the production, breeding, housing and transportation conditions of the experimental animals and the laboratory conditions and equipment in which the experiments are carried out are ethically appropriate.
4. To prepare statistical data tables and annual activity reports regarding experimental animals and present them to HADMEK.

ğ) To ensure the disposal of wastes and medical wastes resulting from experimental studies in accordance with the Environmental Law No. 2872 dated 9/8/1983 and the relevant legislation.

1. To ensure that experimental animals are registered and monitored within the framework of the Animal Protection Law No. 5199 and the relevant legislation.

ı) Notifying HADMEK of the training certificate programs to be organized thirty days in advance.

1. To inform HADMEK about the certificate training programs they have organized and the trainees who have been successfully certified at the end of the training.
2. To decide whether the animals used in the experiment are inconvenient to adopt after the procedure or return to the farming system.

# Working Principles of IMU-HADYEK

**ARTICLE 8 –** (1) IMU-HADYEK works in accordance with the following principles:

1. To prevent ill-treatment of experimental animals, which are obligatory to be used in scientific research.
2. To ensure that the experimental animals are used within the scope of the purposes specified in Article 5.
3. To ensure that an animal is not used more than once in experiments that cause severe pain, stress, or the equivalent, and that if necessary, it is based on sound scientific justification.

ç) To ensure that painful and painful experiments are not carried out in educational congresses, conferences and seminars.

1. To ensure that scientifically reliable data is obtained with as little suffering and stress to animals as possible.
2. To prepare suitable conditions for the experimental animals used during the research and provide the best physiological, behavioural and environmental conditions.
3. To provide experimental animal care under appropriate conditions by suitably trained personnel.
4. To ensure that experimental studies on live animals are carried out under the supervision of a responsible veterinarian.

ğ) To ensure that the investigators determine the target points regarding the conditions under which the experiments will be terminated.

1. To not consider animal experiments ethically appropriate if there are alternative methods with proven validity in obtaining the researched information and to prevent the repetition of experiments that have been done in detail before.

ı) To ensure that the most appropriate animal species and method are selected for the experiment and that the least number of animals can produce scientifically meaningful results are used.

1. To ensure that an appropriate anaesthesia method is applied in experiments that will cause unnecessary pain and pain to experimental animals and that appropriate painkillers and anaesthesia are used in research.
2. To prevent anaesthesia from being performed if it is more traumatic for the animal than the experiment itself and is not suitable for the purpose of the experiment.
3. In order for the experiment to be conducted within the framework of ethical principles and to be suitable for its purpose, with the decision of the veterinarian;
   1. The animal that will be exposed to significant pain when it comes out of anaesthesia should be treated with painkillers; if it is not possible to be treated, it should be killed with a humane method,
   2. The process of ending the life of the experimental animal during or at the end of the research is carried out for appropriate reasons,
   3. To ensure that the experimental animals that suffer from severe and constant pain or that cannot maintain their normal life and that may pose a risk to their health and environment are put to an

end with a humane method.

1. To ensure the provision of healthy living conditions at the end of the experiment for the experimental animals used in the research and continuing their lives.
2. Deciding to carry out experiments that will expose animals to severe and long-term pain, taking into account ethical principles, the benefit to be obtained from the research and the suffering of the animals
3. To reduce the number of animals used in the experiment by performing more than one application on animals, as long as the scientific goal is not strayed from and the welfare of the animal is not impaired.
4. To ensure that other applications are also evaluated within the scope of sharing the tissues and organs of animals that died by using them in the experiment.

ö) Avoiding practices that are likely to result in long-term severe pain, torment, and suffering that cannot be corrected.

1. Allowing procedures to be carried out only under the supervision of its animal welfare unit.

r) To follow up on the changes to be made in the approved projects, the content and the people who will participate in the study, and ensure that the necessary permissions are obtained.

# THIRD SECTION

Experimental Animals and Applications Related to Research Experimental animals

**ARTICLE 9 –** (1) Issues regarding the animals to be used in the studies of IMU-HADYEK:

1. IMU-HADYEK must approve all procedures to be performed on experimental animals.
2. Unless there is a general or special exception taken following the regulations made by IMU-HADYEK, it will be used in the experiments;
   1. Mouse (Mus musculus),
   2. Rat (Rattus norvegicus),
   3. Guinea pig (Cavia pocellus),
   4. Syrian (golden) hamster (Mesocricetus auratus),
   5. Chinese hamster (Cricetulus griseus),
   6. Mongolian gerbil (Meriones unguiculatus),
   7. Rabbit (Oryctolagus cuniculus),
   8. Dog (Canis familiaris),
   9. Cat (Felis catus),
   10. All species of non-human primates
   11. Frog [Xenopus (laevis, tropicalis), Rana (temporaria, pipiens)],
   12. Zebrafish (Danio rerio),

required that the species and all animals to be used in the experiment have been purchased from registered legal experimental animal producers and suppliers.

1. The strays of domesticated species such as cats and dogs on the street are not used in the experiments. However, these animals can be used in experiments if studies on the health and welfare of animals are needed, pose a serious danger to the environment, human and animal health, and there is scientific justification that the purpose of the study can be achieved using only stray animals.

ç) The use of non-human primates in experiments is permitted in exceptional cases and if there is scientific justification that the purpose of the procedure cannot be achieved using a species other than non-human primates.

1. Great apes cannot be used in experiments.
2. The use of endangered and protected species within the framework of national legislation and international conventions and the species in the Annex-1 List of the CITES Convention are permitted in the following cases:
   1. If the procedure has one of the objectives specified in sub-clause (1) of subparagraph (b) of the first paragraph of Article 5 and sub-paragraphs (ç) and (d).
   2. If there is a scientific justification that the purpose of the procedure cannot be achieved with species other than the species in question.
3. The experiment to be carried out on wild animals taken from nature is for a scientific reason; approved only if other animals are not sufficient for the purpose of the experiment. After the approval of IMU-HADYEK, permission is obtained from the General Directorate for studies on this subject.

# Procedures related to anaesthesia and administration of anaesthesia, killing and severity classification in experiments

**ARTICLE 10 –** (1) Procedures related to anaesthesia and application of anaesthesia, killing and severity classification in experiments are made in accordance with Articles and 22nd and Annex-8 and Annex-9.

# Re-Use of Animals in Experiments

**ARTICLE 11 –** (1) Re-use of an animal that has been used in one or more experiments is permitted in the following cases:

1. If the actual severity of previous experiments was “mild” or “moderate”.
2. If the general state of health of the animal is completely restored.
3. If the new experiment is classified as "mild", "moderate" or "uncorrectable".

ç) If approved by a veterinarian who can evaluate the previous procedures performed on the animal.

(2) In exceptional cases, an animal may be allowed to be reused provided that the animal is not used more than once in an experiment involving severe pain, suffering or the equivalent after the animal has been examined by a veterinarian, excluding subparagraph (a).

# Termination of the Experiment

**ARTICLE 12 –** (1) The experiment is terminated when no further observations can be made regarding the experiment, or if genetically modified animal strains and progeny are no longer traced, or if they are expected to experience pain, suffering, suffering and permanent damage equivalent to or greater than a continuous needle stick.

(2) At the end of the experiment, the decision on the survival of an animal is taken by a veterinarian. In case an animal continues to be kept alive, care and shelter services are provided in accordance with its health condition. If the animal continues to experience moderate or severe pain, suffering, suffering and permanent damage, it is killed.

**Evaluation of the Projects**

**ARTICLE 13 –** (1) Projects;

1. Scientific, educational or legal grounds,
2. Reasons for animal use,
3. Designing the procedures to be carried out in the most humane and environmentally friendly manner possible,

ç) Its estimated scientific benefits and educational value,

1. Compliance with the 3R principle,
2. Classification of procedure severity,
3. The benefit to be gained and the suffering of the animals,
4. Compliance of killing methods, procedures, anaesthesia, reuse, care and accommodation conditions with the current legislation,

ğ) Deciding whether and when a retrospective assessment will be made,

it is evaluated by IMU-HADYEK according to the criteria.

1. Experts who will make the project evaluation by IMU-HADYEK; 3R principle, experimental design, practical applications of animal experiments, practical applications of wild animals or animal care and nutrition should be chosen according to competence.
2. Project evaluation should be transparent. To protect intellectual property and confidential information, project evaluation is carried out impartially and may include the views of independent parties.

**FOURTH SECTION**

**Training of the Personnel Who Will Deal with the Experimental Animals**

**ARTICLE 14 –** (1) The points to be followed in the training of the personnel who will deal with the experimental animal are as follows:

1. IMU-HADYEK is responsible for the organization of training programs for the training of researchers who deal with or will deal with experimental animals, and the opening, organization and execution of certificate programs for the use of experimental animals. Those who are successful in these programs are given an experimental animal use certificate by IMU-HADYEK.
2. Students, researchers, academic, health, technical and administrative personnel who want to do all kinds of education, research, practice, and testing using experimental animals or who contribute to making these programs by touching experimental animals are considered experimental animal users.
3. Users of experimental animals cannot operate on these animals for experimentation, training or testing without obtaining a certificate, and they cannot house these animals in their working areas. It is obligatory to have a veterinarian in the research team in researches to be carried out with farm animals. In this case, the veterinarian doesn't need to have a certificate for the use of experimental animals.

ç) IMU-HADYEK; It prepares an in-service training program that includes the minimum information of the personnel responsible for the production and breeding of experimental animals and the procedures and principles to be followed, and periodically supervises its implementation.

1. In the study submitted for the approval of IMU-HADYEK, if the person using the experimental animal does not have a certificate of use, this study is not approved.
2. If a researcher does not have his certificate, he can apply to IMU-HADYEK to collaborate with other people as a research director. Researchers who participate but do not directly perform procedures with experimental animals can continue their experiments with the help of certified experimental animal users.
3. It is obligatory to attend 80% of the courses in experimental animal use certificate programs.
4. For the trainees to receive a certificate, they must get at least 70 points out of 100 in the exam to be held at the end of the course.

ğ) How the certificate training programs will be carried out is determined by IMU-HADYEK.

1. "Experimental Animal Use Certificate" is given to the trainees who fulfil the attendance and success conditions by registering in the experimental animal use certificate programs organized in accordance with the provisions of this Regulation. Experimental animals use certificate is signed by the President of IMU-HADYEK and the Rector.

ı) İMÜ-HADYEK is obliged to notify HADMEK about the certificate training programs it will organize thirty days in advance.

1. IMU-HADYEK is obliged to inform HADMEK about the trainees who have successfully received certificates at the end of the certificate training programs it organizes.
2. IMU-HADYEK decides whether the training received on the use of experimental animals at the undergraduate or graduate level is equivalent to the certificate program and issues certificates to those who complete the training programs determined to be appropriate.

# FIFTH SECTION

Miscellaneous and Final Provisions

Confidentiality

**ARTICLE 15 –** (1) The correspondence of IMU-HADYEK is confidential, and no information is given to third parties other than the authorized institutions specified in this Regulation.

**Permission Obligation**

# ARTICLE 16 -(1)

1. All researchers who will practice in Istanbul Medipol University units regarding the activities in Article 1 must apply in writing

and obtain Ethics Committee Approval. Work without approval requires administrative and legal investigation, and work is stopped immediately. No approval certificate is issued for the studies started without the permission of IMU-HADYEK.

1. The protocol number of IMU-HADYEK and the statement "Approval of the Ethics Committee" must be included in all kinds of national or international scientific publications related to the researches related to the activities included in Article 1.
2. Ethics Committee permissions are valid for a fixed period to be determined by the applicants and approved by IMU-HADYEK. Study coordinators have to notify IMU-HADYEK of the start date of the experiments.
3. Following the end of the study, the study coordinator prepares a report on the results obtained and the study's contributions to animal welfare and the 3R principle and submits it to IMU-HADYEK.

# Change in Experimental Studies

**ARTICLE 17** – (1) After obtaining approval from IMU-HADYEK, a written application is made to IMU-HADYEK for changes (adds and subtractions) in the study protocol and the people participating in the study, and its approval is obtained.

# Validity Duration

**ARTICLE 18** – (1) IMU-HADYEK approvals are valid for the given period.

Additional time may be requested for unfinished projects.

# Supervision

**ARTICLE 19** – (1) IMU-HADYEK experiment, production, breeding, housing and transportation conditions and the shelter where the experiments are carried out, laboratory conditions and equipment ethically

checks for suitability; It prevents the use of experimental animals when it is not found appropriate.

# Cases without Provisions

**ARTICLE 20** – (1) Regarding the matters not covered in this instruction, the provisions of the Regulation on the Working Procedures and Principles of Animal Experiments Ethics Committees published in the Official Gazette dated February 15, 2014, and numbered 28914 are applied.

# Enforcement

**ARTICLE 21** – (1) This instruction is submitted to the Animal Experiments Center Ethics Committee (HADMEK) after it is accepted by the Istanbul Medipol University Senate Decision and becomes effective after it is approved by this committee.

# Execution

**Article 22** (1) The provisions of this instruction are executed by the Rector of Istanbul Medipol University.