

**ATILIM UNIVERSITY**  
**DIRECTIVE ON THE LOCAL ETHICS COMMITTEE FOR ANIMAL**  
**EXPERIMENTATION**

**SECTION ONE**

**Purpose, Scope, Basis and Definitions**

**Purpose**

**ARTICLE 1** - (1) This directive aims to determine the minimum ethical standards regarding the methods and materials used in the basic activities such as scientific research, health care service practices, education, and publications involving laboratory animals within the academic units of Atılım University, to create new principles when necessary, to provide regulations regarding their implementation, and opinions in line with ethical principles; and to determine the principles regarding the submission of planned procedures, examination and permission of research and study proposals, monitoring of applications, recording of all procedures performed on laboratory animals and ensuring the traceability of these procedures, ensuring the auditability of all procedures and termination of the relevant procedures when necessary in applications for research and publication studies to be undertaken from within or outside the university. This document has been prepared to regulate the establishment and operating principles of the Atılım University Local Ethics Committee for Animal Experimentation (*ATUHADYEK*), established to evaluate research proposals through these perspectives.

**Scope**

**ARTICLE 2** – (1) This directive covers the permits required for the use of animals for experimental purposes under scientific studies within Atılım University, as well as the establishment, authority, duties and working principles of the Atılım University Local Ethics Committee for Animal Experimentation.

(2) This Directive does not include the following:

- a) Non-experimental agricultural practices,
- b) Non-experimental clinical veterinary medicine practices,
- c) Clinical trials required for the granting of marketing authorization for veterinary health products,
- d) Practices that registered or approved livestock farms are obliged to execute,
- e) Practices where the primary purpose is the identification of an animal.

**Basis**

**ARTICLE 3** – (1) This Directive is based on Higher Education Law no. 2547; and “Regulations on the Welfare and Protection of Animals Used in Experiments and for Other Scientific Purposes” published in the Official Gazette dated December 13, 2011, no. 28141, based on Articles 9 and 17 of Law no. 5199 on “Animal Protection” published in the Official Gazette dated 24.06.2004 no. 25509; and the relevant articles of “Regulations on the Working Procedures and Principles of Ethics Committees for Animal Experimentation” published in the Official Gazette dated February 15, 2014, no. 28914; as well as European Union Directive 2010/63/EU on the Protection of Animals Used for Scientific Purposes.

**Definitions**

**ARTICLE 4** - (1) The definitions for this Directive are:

- 1) **Ministry:** Ministry of Agriculture And Forestry,
- 2) **Chairperson:** Chairperson of Atılım University HADYEK
- 3) **Deputy Chairperson:** Deputy Chairperson of Atılım University HADYEK
- 4) **Application Form:** The form completed by researchers regarding their proposed project, and submitted to the Ethics Committee.

- 5) **CITES Convention:** The Convention on International Trade in Endangered Species of Wild Animals and Plants, published in the Official Gazette dated 20.06.1996, no. 22672.
- 6) **Authorization:** The document issued by the Ministry of Agriculture and Forestry to organizations that handle, produce, and supply laboratory animals.
- 7) **Farm animal:** Sheep, goats, horses, and cattle raised for the purpose of utilizing their products and services.
- 8) **Experiment:** All scientific procedures to be executed on animals.
- 9) **Laboratory animal:** Any non-human vertebrate animal including free-living or reproducing larval forms, cephalopods, and mammals from the last third of their normal fetal development onwards, used in procedures.
- 10) **Laboratory Animal Unit:** Atılım University Laboratory Animal Application and Research Center.
- 11) **Experimentation Unit:** Units authorized by the Ministry of Agriculture and Forestry to undertake any procedure or processes on animals under scientific studies.
- 12) **Ethics:** The limits of actions that may be taken in sciences concerning human and animal life regarding the use of animals in research, and the universal rules to guide attitudes and behaviors towards animals.
- 13) **General Directorate:** General Directorate of Nature Conservation and National Parks.
- 14) **HADMEK:** Central Ethics Committee for Animal Experimentation.
- 15) **HADYEK:** Local Ethics Committee for Animal Experimentation.
- 16) **Animal Welfare Unit:** The unit consisting of up to three people, including at least one person with the title of veterinarian, veterinary health technician or technologist responsible for animal welfare and care; and one person who is a member of the local ethics committee; obligatory to be established at the facilities of the producer, the supplier, the user and the research authorized organizations.
- 17) **In-Vivo Experiment:** An experiment conducted in a live environment.
- 18) **Humane Method of Euthanasia:** Ending the life of an animal in a way that minimizes physical and sensory pain, suffering, and distress, specific to its species.
- 19) **Good Laboratory Practices:** The quality system regarding the planning, conduct, monitoring, recording, archiving, and reporting requirements and management procedures of health and environmental safety studies outside of clinical trials.
- 20) **Authorized Person:** The individual authorized to use animals in procedures.
- 21) **Organization:** Any fixed or portable facility, laboratory building or group of buildings, including its annexes, whether open, closed, or semi-open, that holds an authorization from the Ministry of Agriculture and Forestry.
- 22) **Project:** A work program that has a defined scientific purpose and includes one or more procedures.
- 23) **Procedure:** The use of animals for experimental, scientific, or educational purposes, with known or unknown consequences, in accordance with good veterinary practices, including processes such as delivery, hatching or continuation of genetically modified animal breeds, which may cause pain, suffering, distress or permanent damage equal to or greater than the pain of a needle prick.
- 24) **President:** The President of Atılım University,
- 25) **Secretariat:** The individual(s) who undertake(s) the necessary coordination, correspondence, and records for Atılım University HADYEK,
- 26) **Species:** A biological group containing related organisms that share common characteristics and is able to interbreed.
- 27) **ATUHADYEK:** The Atılım University Local Ethics Board for Animal Experimentation
- 28) **Wild Animal:** Vertebrate and invertebrate animals that live freely in nature and are not domesticated or cultured.
- 29) **3R Principle:** Choosing a scientifically-valid alternative method or experimental strategy instead of live animals whenever possible, minimizing the number of animals used without compromising project objectives, improving procedures that cause pain, suffering, distress, and permanent damage to animals to increase animal welfare, and being aware of and acting

accordingly with regard to laboratory animals, and increasing personal responsibility through the development of new methods and technologies. (The three “R”s stand for Replacement, Reduction, and Refinement.)

## **SECTION TWO**

### **Purposes of Using Laboratory Animals, Members of the Ethics Committee, Appointment and Terms of Office, Working Methods, Duties, and Principles of Operation**

#### **Purposes of using laboratory animals**

**ARTICLE 5** – (1) Laboratory animals may be used for the following purposes:

- a) Basic research,
- b) Translational or applied research with any of the following purposes:
  - 1) Prevention, diagnosis, treatment or avoidance of health disorders and other abnormalities in humans, animals or plants,
  - 2) Identification, correction, investigation or modification of physiological disorders in humans, animals or plants,
  - 3) Improvement of animal welfare and production conditions of animals raised for agricultural purposes,
- c) Improvement, production and testing of the quality, efficacy and safety of medicines, food raw materials, feed raw materials, other substances and products for any of the purposes specified in Subparagraph (b),
- ç) Protection of the natural environment for human and animal health and welfare,
- d) Scientific studies aimed at the conservation of species,
- e) Higher education or training for the acquisition, maintenance or development of professional skills,
- f) Forensic investigations.

#### **Members of ATUHADYEK, appointment and terms of office**

**ARTICLE 6-** (1) ATUHADYEK consists of seven (7) members.

(2) The appointment of ATUHADYEK members working at Atılım University and the approval to appoint members assigned from outside the University are made by the President.

(3) ATUHADYEK is required to include members with the following conditions:

- a) A Veterinarian working full-time at the Atılım University Laboratory Animal Application and Research Center, with at least one year of experience in animal experiments; responsible for the production, breeding and care of laboratory animals within the institution,
- b) A Turkish citizen who, along with their immediate family members, does not conduct experimental studies on animals and has no conflict of interest with the institution.
- c) A Turkish citizen who is a member of a non-governmental organization that has no conflict of interest with the institution.
- ç) A veterinary ethics or medical ethics expert may also be a member.

(4) At least one member of HADYЕК is required to have at least one year of experience in in-vivo animal experiments and hold a doctorate or medical specialization degree. It is preferable for HADYЕК to include experts in medical or veterinary ethics.

(5) The President appoints a full-time faculty member from Atılım University as the chairperson from among the ATUHADYЕК members.

(6) The term of office for all members, including the chairperson, is four years. Changes regarding appointments or assignments with approval are to be reported to HADMEK within one month. A member whose term has expired may be reappointed or assigned with approval. The membership status of a member failing to attend three consecutive meetings without permission or a valid excuse within a calendar year will automatically be terminated. In the event that the membership ends due to death, retirement, resignation, or any other reason, or if the membership is terminated, a new member with the qualifications of the departing member will be appointed by the President in the same manner to complete the remaining term. Persons found to have acted contrary to the provisions of this Directive may not be appointed as members of ATUHADYЕК.

(7) The ATUHADYЕК secretariat is appointed by the President and is responsible for the regular operation of ATUHADYЕК, such as the duties of receiving, evaluating and archiving applications.

(8) The ATUHADYЕК chairperson and veterinarian are full-time employees of Atılım University. Members other than these may be from outside Atılım University.

(9) ATUHADYЕК may seek opinions from experts in other fields when necessary. These individuals may be invited to meetings.

### **The working method of ATUHADYЕК**

**ARTICLE 7 -** (1) ATUHADYЕК shall convene at least once a month with an agenda determined by the chairperson, with the participation of at least two-thirds of the members. In the absence of the chairperson, committee meetings shall be conducted by the deputy chairperson. Additional meetings may be held upon the invitation of the chairperson where necessary.

a) Decisions at the ATUHADYЕК meeting shall be taken by majority vote. The chairperson's decision shall be taken in case of tie.

b) Applications to and decisions made by ATUHADYЕК are logged with a date and a number. Logs are kept for at least five years.

c) Records are open to inspection by HADMEK and the relevant Ministry. Where necessary, ATUHADYЕК may obtain written opinions from its experienced experts or request oral or written opinions by inviting them to an ATUHADYЕК meeting.

ç) In the use of wild animals from nature for species identification, the permission obtained from the General Directorate replaces the permission of ATUHADYЕК.

d) Applications to ATUHADYЕК are made by the project manager. The executer for thesis studies is the faculty member undertaking the duties of an advisor.

e) ATUHADYЕК prepares application forms for application evaluation purposes. The prepared application form, along with the documents specified in Article 16, is filled out by the project manager and submitted to ATUHADYЕК.

f) ATUHADYЕК may grant permits for projects for a maximum period of five years. If an extension is requested, it shall be granted on the condition that the request is justified.

g) ATUHADYEK members may not attend or vote at the evaluation meetings for applications submitted by their members.

ğ) ATUHADYEK members may not remove application files from the meeting without the decision of the ethics committee.

h) Obtaining ATUHADYEK approval is mandatory for scientific studies and other matters involving laboratory animals to be conducted within Atılım University. Studies without ATUHADYEK approval may not be conducted within Atılım University.

ı) ATUHADYEK is not responsible for any situations requiring punitive measures arising from studies it has approved. The researcher accepts the liability.

ii) After ATUHADYEK approval is obtained, any changes made to the project scope, methodology, or the individuals participating in the study must be reported to ATUHADYEK in writing by the project manager for their approval. Unapproved changes may not be implemented; if unapproved changes are detected in a study, the project in question will be terminated.

j) ATUHADYEK may invite the project manager who submitted the application or experts experienced in the relevant field to attend the meeting to provide their opinion, either verbally or in writing, if deemed necessary.

k) If field research is conducted in more than one province, obtaining HADYEK approval for only one location shall be sufficient.

l) The following procedures are not subject to ATUHADYEK approval:

1. Clinical applications for diagnosis and treatment,
2. Procedures involving dead animals or their tissues, slaughterhouse materials, and aborted fetuses,
3. Milking,
4. Collection of fecal or litter samples,
5. Swab sampling.

m) ATUHADYEK shall deem projects as “**suitable**”, “**requires correction**”, “**conditionally suitable**” or “**not suitable**” as a result of the evaluation. The decision will be notified to project managers in writing within 40 (forty) working days from the date of application. This period also includes the project evaluation. If the project is complex or involves more than one scientific discipline, ATUHADYEK may extend the aforementioned period once, for a maximum of 15 (fifteen) working days. The reason and duration of the extension shall be justified, and the project manager shall be informed before the deadline.

n) For projects planned to use archival tissue previously used in another study, the ethics committee approval letter obtained for the archival tissue is requested, examined, and if deemed appropriate, the committee decides that “**no ethics committee decision is required**”.

o) ATUHADYEK may request preliminary experiments on a small number of animals to determine the feasibility of a project. In this case, the final decision is made according to the procedures for projects that have been deemed “**conditionally suitable**”. The conditions and situations accepted are added to the resolution. Studies concerning wildlife and endangered animals may also be evaluated. However, in addition to the decision that the project is “**appropriate**”, the phrase “**General Directorate permission required**” is added.

ö) In applications for studies to be conducted on farm animals in locations, species, and farm conditions where there is no authorization issued by the Ministry of Agriculture and Forestry, ATUHADYEK

may request that “project-based permission” be obtained from the Ministry of Agriculture and Forestry before conducting an ethical evaluation of the application. However, if the content of the project is deemed not to require ethics committee approval, the committee may decide that an “**ethical committee approval is not required**”.

p) Applications that are deemed to require correction are re-evaluated by ATUHADYEK after the decision that they “**require correction**”.

r) Applications that are deemed “**conditionally suitable**” are monitored by the Animal Welfare Unit for a period to be determined by ATUHADYEK, and after determining whether the required conditions have been met, a decision that they are “**suitable**” or “**not suitable**” is made, with a report submitted to ATUHADYEK.

s) ATUHADYEK monitors for any changes in the approved projects that may affect animal welfare. If ATUHADYEK determines that the approved project is not being complied with, their permit shall be revoked. In case of revocation of the permit, the animal welfare unit ensures that the welfare of the animals used or planned to be used in the project is not negatively affected.

ş) Records regarding all laboratory animals used within the ATUHADYEK organization are kept or commissioned by the veterinarian responsible for the breeding, production and care of laboratory animals in the animal welfare unit. These records include the number of animals obtained, their types, the places where they were obtained, the date they arrived at the user organization, and all procedures performed. Logs are kept for at least 5 (five) years.

t) In projects that have been duly approved, any requested changes to the project or procedures are submitted to the committee by the project manager via a written application. In the initial meeting, ATUHADYEK deems projects as “**suitable**”, “**requires correction**”, “**conditionally suitable**” or “**not suitable**”.

### **Duties of ATUHADYEK**

**ARTICLE 8** – (1) The duties of ATUHADYEK are as follows:

a) To prepare guidelines on its own working procedures and principles within the framework of Regulations on the Working Procedures and Principles of Ethics Committees for Animal Experimentation, and the ethical principles and good laboratory practices determined by HADMEK, and to submit them to HADMEK for approval,

b) To determine the ethically acceptable limits of all scientific procedures to be performed on laboratory animals and to approve or disapprove, with justification, the protocols for the project to be executed,

c) To supervise the use of laboratory animals within the institution in accordance with the 3R principles and ethical rules and to make the necessary arrangements,

d) To contribute to the development and validation of alternative methods that provide the same or higher level of information as the data obtained using laboratory animals without using them, or using a minimum number of animals, or involving less painful procedures; and to implement practices to encourage research in this regard,

d) To ensure that procedures on laboratory animals are done in accordance with the approved protocol, and to decide on the termination of studies that are not executed in accordance with the protocol,

e) To ensure that the personnel working with laboratory animals receive the necessary training, to permit animal experiments provided that they have an experimental animal use certificate, and to organize certificate training programs when necessary for this purpose,

- f) To report to the Presidency in order to initiate legal proceedings against those responsible, if any procedures are detected to be performed within the institution by individuals without ATUHADYEK approval or certification,
- g) To inspect whether the production, breeding, housing and transportation conditions of laboratory animals and the laboratory conditions and equipment where experiments are conducted are ethically appropriate, and to stop the use of laboratory animals until corrections are made if found to be inappropriate,
- ğ) To prepare and submit to HADMEK the annual activity report with statistical data tables regarding the use of experimental animals,
- h) To ensure the disposal of waste and medical waste resulting from experimental studies in accordance with Environmental Law No. 2872 dated 09.08.1983 and the relevant legislation,
- ı) To ensure the registration and traceability of experimental animals within the framework of the provisions of Animal Protection Law No. 5199 and the relevant legislation,
- i) To notify HADMEK 30 (thirty) days in advance of the training certificate programs that ATUHADYEK is to organize, and to inform HADMEK about the information regarding the trainees who are certified at the end of certificate training programs,
- j) To decide whether there is any objection to the animals used in experiments being adopted or returned to the farming system after a procedure.

### **The principles of operation of ATUHADYEK**

**ARTICLE 9-** (1) ATUHADYEK operates under the following conditions:

- a) To prevent mistreatment and abuse of laboratory animals that are necessary for use in scientific research,
- b) To ensure that laboratory animals are used within the scope of the purposes specified in Article 5 of “Regulations on the Working Procedures and Principles of Ethics Committees for Animal Experimentation”,
- c) To ensure that an animal is not used more than once in experiments that cause severe pain, stress or equivalent suffering, and that if its use is necessary, it is based on sound scientific grounds,
- ç) To ensure that experiments causing pain and suffering are not conducted in educational congresses, conferences and seminars,
- d) To ensure that scientifically reliable data is obtained by causing as little suffering and stress as possible to animals,
- e) To prepare conditions suitable for the species of laboratory animals used during research and to ensure the best physiological, behavioral and environmental conditions,
- f) To ensure the care of laboratory animals under appropriate conditions by appropriately trained personnel,
- g) To ensure that procedures on live animals in scientific studies are performed under the supervision of a responsible veterinarian,
- ğ) To ensure that conditions provided during the experiment are suitable for the species of animals used,

- h) To ensure that researchers determine the target points for when to terminate experiments,
- i) To consider animal experiments ethically inappropriate if there are proven alternative methods for obtaining the researched information and to prevent the repetition of experiments that have been previously conducted in detail,
- i) To ensure that the most appropriate animal species and management are selected and the minimum number of animals are used in order to obtain meaningful results in scientific studies.
- j) To ensure that an appropriate anesthesia method is applied in experiments that would cause unnecessary pain and suffering to laboratory animals, and that appropriate analgesics and anesthetics are used in research,
- k) To prevent the application of anesthesia if it is more traumatic for the animal than the experiment itself and is not in line with the purpose of the experiment,
- l) In order for the experiment to be conducted within the framework of ethical principles and remain appropriate for its purpose, and subject to the decision of a veterinarian, to ensure the following:
  1. That the animal to receive significant pain when coming around from anesthesia be treated with painkillers, and if treatment is not possible, be euthanized humanely;
  2. That the procedures for ending the life of a laboratory animal during or at the end of the research be executed with appropriate justifications;
  3. That laboratory animals that are experiencing severe and continuous pain or that are unable to lead a normal life, and that may pose a risk to their health and the environment, be euthanized humanely.
- m) To ensure healthy living conditions for laboratory animals used in research that are alive at the end of the experiment,
- n) To decide whether to conduct experiments that will expose animals to severe and prolonged pain during the experiment, taking into account ethical principles, the benefits to be obtained from the research, and the pain the animals will suffer,
- o) To ensure that the number of animals used in the experiment is reduced by performing more than one procedure on the animals, as long as the scientific goal is not deviated from and the welfare of the animal is not compromised,
- ö) To ensure that the tissues and organs of animals that died as a result experiments are evaluated in other applications,
- p) To avoid practices that result in severe pain, torture and suffering that are likely to be long-term and irreversible,
- r) To only allow procedures under the supervision of its own animal welfare unit,
- s) To monitor changes to be made in the approved projects, content and the people who will participate in the study and to ensure that the necessary permissions are obtained.

### **SECTION THREE**

#### **Laboratory Animals, Practices Related to Experimental Research, Animal Welfare Unit**

##### **Laboratory animals**

**ARTICLE 10** - (1) All procedures on laboratory animals must be approved by ATUHADYEK.

(2) Issues on the animals to be used in experiments:

a) Unless there is a general or special exception, the animals to be used in experiments approved by ATUHADYEK are:

1. Mice (*Mus musculus*)
2. Rats (*Rattus norvegicus*)
3. Rabbits (*Oryctolagus cuniculus*)
4. Guinea pigs (*Cavia pocellus*)

It is required that these species and all animals to be used in the experiment be obtained from legal, licensed laboratory animal producers and suppliers.

b) Domestic animals such as cats and dogs that roam freely in the streets may not be used in experiments. However, these animals may be used in experiments if there is a need for studies on the health and welfare of the animals, if they pose a serious threat to the environment, human and animal health, and if scientific justification is provided that the purpose of the study is only achievable with stray animals.

c) The use of non-human primates in experiments is permitted only in exceptional circumstances and if there is a scientific justification that the purpose of the procedure may not be achieved using a species other than non-human primates.

ç) Great apes may not be used in experiments.

d) The use of endangered and protected species under national legislation and international conventions, as well as species listed in Annex 1 of the CITES Convention, is permitted under the following conditions:

1. If the procedure has one of the purposes specified in Subparagraph (i) of Paragraph (b), and Paragraphs (c) and (d) of the first paragraph of Article 5.
2. If there is a scientific reason why the procedure may not be performed on species other than those in question.

e) In the Laboratory Animals Unit, procedures and other treatments to be applied to the animals must be performed under the supervision and control of a veterinarian.

f) Experiments on wild animals taken from nature are approved only if there is a scientific justification and other animals are not suitable for the purpose of the experiment. In studies conducted in this regard, permission is required through the General Directorate, upon the approval of ATUHADYEK.

#### **Anesthesia, using anesthesia, euthanasia, and classification of severity in experiments**

**ARTICLE 11** - (1) Procedures related to anesthesia, euthanasia, and classification of severity in experiments are executed in accordance with Articles 21 and 22 and Appendices 8 and 9 of Regulations on the Welfare and Protection of Animals Used for Experimental and Other Scientific Purposes, published in the Official Gazette dated 13/12/2011 no. 28141 by the Ministry of Agriculture and Forestry.

#### **Reuse of animals in experiments**

**ARTICLE 12** - (1) The reuse of an animal previously used in one or more experiments is permitted in the following cases:

- a) If the actual severity of the previous experiments was “mild” or “moderate”.
- b) If the general health of the animal has completely returned to its previous state.
- c) If the new experiment is classified as “mild”, “moderate”, or “irreversible”.

ç) If the procedures previously performed on an animal have been deemed appropriate by a veterinarian able to evaluate the procedures.

(2) In exceptional circumstances, the reuse of an animal is permitted provided that the animal is not used more than once in an experiment involving severe pain, suffering or equivalent, and after the animal has been examined by a veterinarian, in a way that excludes clause (a).

### **Experiment termination**

**ARTICLE 13** - (1) The experiment shall be terminated if further observations may not be made regarding the experiment, or if genetically modified animal strains and generations are no longer being monitored, or if the animal is expected to suffer pain, distress, suffering, or permanent damage equivalent to or greater than that of a needle prick.

(2) At the end of the experiment, a veterinarian shall make the decision regarding the animal's continued life. If the animal is to be kept alive, appropriate care and housing services suitable to its health condition shall be provided. If the animal continues to suffer moderate or severe pain, distress, suffering, or permanent damage, the animal should be euthanized.

### **Animal Welfare Unit**

**ARTICLE 14** - (1) The Animal Welfare Unit consists of a veterinarian and a veterinary technician working full-time within the institution and experienced in the care, feeding, production, and welfare of laboratory animals, as well as a faculty member assigned to the Atılım University Local Ethics Committee for Animal Experimentation who is experienced in laboratory animal research and holds a certificate in the use of laboratory animals.

(2) Members of the Animal Welfare Unit are appointed by the President. Their term of office is 4 years. At the end of their term of office, members may be re-appointed.

(3) In case of termination of membership due to reasons such as resignation, death, or retirement, a new member with the qualifications of the departing member is appointed to complete the term in the same way.

### **Duties of the Animal Welfare Unit**

**ARTICLE 15** - (1) The animal welfare unit is responsible for the following duties:

a) To identify situations that may negatively affect animal welfare during and after procedures in units where laboratory animals are used, and if necessary, to make recommendations to the project manager and unit manager to improve animal welfare,

b) To report to the Presidency on any units and situations unsuitable for the use and housing of laboratory animals,

c) To provide training to personnel/ staff working in units using laboratory animals and to assistant researchers working on the project on improving animal welfare and keeping records,

ç) To monitor animal experiments for the duration set by ATUHADYEK in projects that ATUHADYEK has deemed “conditionally suitable” and to report to ATUHADYEK at the end of the period whether the determined conditions regarding animal welfare have been met,

d) To decide on the fate of animals used or awaiting use in projects the permits for which have been revoked by ATUHADYEK,

e) To conduct on-site inspections of projects requested to be inspected by ATUHADYEK and to submit an opinion report on animal welfare in the project to ATUHADYEK,

f) To ensure that all laboratory animals in the laboratory animal use and/ or production units within the university are recorded, specifying the number, types, place/ organization from which they were obtained, the date they arrived at the unit, and all procedures performed,

g) To prepare a written opinion on whether animals used in experiments and intended for adoption instead of being euthanized should be adopted or, if so, what conditions must be met,

ğ) To obtain the animal records kept in the laboratory animal use and/or production units from the relevant units at the end of the year and prepare the annual “Atılım University Laboratory Animal Application and Research Center Report on Laboratory Animal Use Report”.

## **SECTION FOUR**

### **Ethics Committee Applications, Project Summary and Evaluation Procedures, Researcher Responsibilities**

#### **Ethics committee applications**

**ARTICLE 16 - (1)** The project manager applies by filling in **the information presented below and requested in the Application Form** prepared by ATUHADYEK completely and appropriately, along with their application letter and declaration:

1. Project name,
2. Names of the project executive and other researchers, their addresses, workplaces, signatures, and roles in the project,
3. Location and duration of the procedure,
4. Training certificates of those to perform the procedure on live animals,
5. Application date,
6. Project proposal,
7. Non-technical project summary in everyday terms,
8. Where to obtain the animal(s) in question, the number, type and age of these animals,
9. Procedures to be performed on animals,
10. The level of pain, suffering, distress, and permanent damage that the procedures are to cause,
11. How the 3R principle is followed throughout the procedures,
12. The anesthesia, analgesia, and other pain relief methods intended to be used,
13. Measures to be taken to prevent animals from experiencing pain and suffering throughout their lives or to reduce the suffering they experience,
14. Experimental or observational strategies and data analysis methods to be applied to minimize the number of animals and the suffering, pain, distress, or potential environmental impacts caused by the procedures,
15. Determining the humane method of euthanasia in terminating the procedures,
16. Determining whether animals will be used in more than one project,
17. The housing, breeding and care conditions provided to the animals,
18. The competencies of those involved in the project.
19. Covenant

#### **Project abstract**

**ARTICLE 17** - (1) Subject to the protection of intellectual property rights and confidential information, the project summary, prepared in non-technical, everyday terms, shall include the following:

- a) Information about the objectives of the project, including the estimated damages and benefits and the identity of the animals used.
- b) Compliance with the 3R principle.

(2) The non-technical project summary is prepared anonymously and does not include the names and addresses of the users and personnel.

(3) ATUHADYEK may request that the non-technical project summary specify whether the project will be subject to a retrospective evaluation process and the time limit for this process. In this case, it is ensured that the non-technical project summary is updated with the results of the retrospective evaluation.

(4) If a database is created by the Ministry of Agriculture and Forestry; the non-technical project summaries of the authorized projects, and the updates made, are published in this database.

### **Project evaluation**

**ARTICLE 18-** (1) ATUHADYEK evaluates the projects in line with the following criteria:

- a) Justifications for animal use,
- b) Scientific, educational, or legal justifications,
- c) Whether the procedures are designed to be carried out in the most humane and environmentally sensitive way possible,
- ç) Estimated scientific benefits and educational value,
- d) Compliance with the 3R principle,
- e) Classification of the severity of the procedure and the benefits to be obtained, as well as the suffering to be endured by the animals,
- f) Compliance of euthanasia methods, procedures, anesthesia, reuse, care, and housing conditions with current legislation,
- g) Decision on whether and when to conduct a retrospective evaluation.

(2) Projects are evaluated by the Committee in a transparent manner. To protect intellectual property rights and confidential information, project evaluation is done impartially and may include the opinions of independent parties.

(3) ATUHADYEK may seek the written and oral opinion of an external expert when necessary. In addition, the project manager may be invited to the meeting if deemed necessary.

(4) ATUHADYEK ensures that the experts who will evaluate the project are selected based on their competence in the 3R principle, experimental design, practical applications of animal experiments, practical applications of wild animal experiments, or animal care and nutrition.

(5) In order for an application file to be considered and discussed, it must be submitted in its entirety to the Atılım University HADYEK Secretariat at least 10 (ten) working days before the announced meeting date.

### **Retrospective evaluation**

**ARTICLE 19** - (1) All projects involving non-human primates and procedures deemed “severe”, including procedures involving long-term, irreversible severe pain, suffering, and distress, are subject to retrospective evaluation.

(2) Projects other than those mentioned in the first paragraph may be exempt from retrospective evaluation.

(3) If a decision is made to conduct a retrospective evaluation of projects completed with the permission of ATUHADYEK, the following aspects will be evaluated based on the documents submitted to ATUHADYEK:

- a) Whether the project achieved its objectives,
- b) The number of animal species used, the harm inflicted on the animals, and the severity of the procedures,
- c) Elements that may contribute to the execution of the 3R principle.

### **Researcher responsibilities**

**ARTICLE 20** - (1) Project executives applying to ATUHADYEK are deemed to have committed to the following:

- a) The accuracy of the information presented in their application form,
- b) That the persons to conduct the animal experimentation have received the necessary training and that they will not allow any procedures to be performed on laboratory animals by persons who do not have an Animal Experimentation Authorization,
- c) That the relevant animal experiment will not be started without the approval of ATUHADYEK,
- ç) That the experiments will be performed in accordance with the approved protocol and ethical principles,
- d) That the experiments are open to the supervision of ATUHADYEK and that the necessary information will be provided promptly when requested,
- e) That they will immediately inform ATUHADYEK of any protocol changes.

**ARTICLE 21** - (1) Applications where some or all of the animal experiments will be conducted at an institution or settlement outside the Atılım University campus will only be considered after the applicant accepts and undertakes that the animal experimentation site will remain open to the supervision of ATUHADYEK, and will provide all necessary conditions to allow for supervision (necessary permits for the members to conduct the supervision, transportation, travel expenses, etc.). Where deemed necessary by ATUHADYEK, the Committee may also request the approval of this undertaking from the head of the institution where the animal experiments will be conducted through the applicant.

(2) An application cannot be made to ATUHADYEK with an animal experiment protocol that has been previously rejected by another local ethics committee.

(3) If an application is made with changes to an animal experiment protocol that has been previously rejected by another local ethics committee, the previous application file and the reasoned decision of the other ethics committee must be attached to the file.

## **SECTION FIVE**

### **Training**

#### **Training the personnel to work with laboratory animals**

**ARTICLE 22** - (1) ATÜHADMEK may organize a certificate program in accordance with the curriculum and other provisions determined by the “Circular on the Certificate Program for the Use of Laboratory Animals” published by the Ministry, and may issue “Laboratory Animal Authorizations” to successful trainees.

(2) The content of the laboratory animal authorization program is organized according to the programs updated by HADMEK.

(3) For courses to be organized for internal or external certificate purposes, the course coordinator must submit an application to ATUHADMEK at least 60 days before the start of the course, including information on the course content, topics, and total class hours. ATUHADMEK notifies HADMEK of the course(s) approved for certificate purposes at least 30 (thirty) days in advance. Certificates are issued by ATUHADMEK to those who successfully complete these courses. In case of any changes in the content, topic, or class hours of the approved course(s), the course coordinator must notify ATUHADMEK of the change, and reapply. Courses approved by ATUHADYEK are announced on the official web page for the institution.

(4) Trainees are required to attend 80% of the courses in the Animal Experimentation Authorization Program and must obtain at least 70 points out of 100 in both the theoretical and practical exams at the end of the program.

(5) ATUHADYEK notifies HADMEK of the trainees who successfully complete the training program. Students, researchers, academic staff, health care personnel, technical and administrative personnel intending to conduct training, research, application and testing using animals, or who contribute to these programs by interacting with animals, are considered animal experimenters.

(6) Animal experimenters may not perform experiments, training or testing on these animals or keep them in their workplaces without a certificate.

(7) In research involving farm animals, it is mandatory for a veterinarian to be part of the research team. In this case, the veterinarian must have an animal experimentation certificate.

(8) If a researcher does not have their own certificate, they may apply to ATUHADYEK to work in collaboration with other people as a research director. Researchers who participate but do not perform procedures on laboratory animals may continue their experiments with the assistance of certified animal experimenters in the research team.

(9) If the individual(s) to perform the procedures on laboratory animals do not have the relevant authorization for the study submitted for ATUHADYEK approval, the study will not be approved.

(10) HADMEK decides whether animal experimentation authorizations or similar certificates from other institutions are equivalent.

(11) ATUHADYEK prepares an in-service training program that includes the basic information and procedures to be followed by the personnel responsible for the production and breeding of experimental animals and periodically supervises its implementation.

(12) How the certificate programs will be conducted is determined by ATUHADYEK.

(13) ATUHADYEK decides whether the training received at the undergraduate/ graduate level regarding the use of experimental animals is equivalent to the certificate program.

## **SECTION SIX**

### **Miscellaneous and Final Provisions**

#### **Logging and identification of laboratory animals**

**ARTICLE 23** - (1) Logging and identification of laboratory animals shall be done in accordance with Articles 34, 35 and 36 of Regulations on 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. Logs cover the information in statistical formats required by the Ministry, as per the relevant HADMEK resolution.

**Auditing and monitoring**

**ARTICLE 24** - (1) Decisions by ATUHADYEK are subject to the supervision of HADMEK and the Ministry of Agriculture and Forestry.

**ARTICLE 25** - (1) ATUHADYEK supervises whether the laboratories where all training, studies, procedures, and tests permitted under its jurisdiction take place, as well as the production, care, feeding and transfer stages of laboratory animals, are managed in a way that is ethically appropriate.

**Confidentiality**

**ARTICLE 26** - (1) ATUHADYEK correspondence is confidential and no information will be provided to third parties other than the authorized institutions specified in the relevant regulation.

**Effective Date**

**ARTICLE 27** - (1) This Directive shall take effect upon HADMEK approval, following its approval by the Atılım University Senate.

**Execution**

**ARTICLE 28** - (1) This Directive is executed by the President of Atılım University.

Protocol No.: ..... Appl. Date:..... Comm. Appr. No.:..... Approval Date:.....	<b>APPLICATION FORM FOR THE ATILIM          UNIVERSITY LOCAL ETHICS          COMMITTEE FOR ANIMAL          EXPERIMENTATION</b>				
1.	PROJECT TITLE	The title of the research in Turkish			
		Keywords (Turkish)			
		The title of the research in English			
		Keywords (English)			
2.	PROJECT EXECUTIVE	Full Name	Certificate: (HADYEK Name/ Year/ No.)		
		Title	Available		
		Place of Duty	.....HADYEK		
		Office Phone	../20.. - ..		
		Mobile Phone	Signature:		
		E-mail Address			
		Address			
Role and Competence in the Project					
3	PROJECT TEAM	<b>RESEARCHER'S</b>		Signature	Certificate (HADYEK NAME/ YEAR/ NO.)
		1. Full Name: Title: Place of Duty: Address: E-mail: Mobile Phone: Role and Competence in the Project			Available
					.....HADYEK/ 20../.....
		2. Full Name: Title: Place of Duty: Address: E-mail: Mobile Phone: Role and Competence in the Project			Available
					.....HADYEK/ 20../.....
		3. Full Name: Title: Place of Duty: Address: E-mail: Mobile Phone: Role and Competence in the Project			Available
					.....HADYEK/ 20../.....
		4. Full Name: Title: Place of Duty: Address: E-mail: Mobile Phone: Role and Competence in the Project			Available
					.....HADYEK/ 20../.....
		5. Full Name: Title: Place of Duty: Address: E-mail: Mobile Phone: Role and Competence in the Project			Available
					.....HADYEK/ 20../.....

		6. Full Name: Title: Place of Duty: Address: E-mail: Mobile Phone: Role and Competence in the Project			Available
		.....HADYEK/ 20.../.....			
		7. Full Name: Title: Place of Duty: Address: E-mail: Mobile Phone: Role and Competence in the Project			Available
		.....HADYEK/ 20.../.....			

<b>4. ADVISING VETERINARIAN</b>		
Full Name		Signature:
Title		
Department of Employment		
Mobile Phone		
Phone		
E-mail		

<b>5. PROJECT SUPPORT</b>
( ) <i>Scientific Research Project Committee</i>
( ) <i>International (Please specify):</i>
( ) <i>TÜBİTAK</i>
( ) <i>Other (Please specify):</i>

<b>6. PROJECT TYPE</b>	
<i>THESIS:</i>	
( ) <i>Graduate Degree Thesis</i>	( ) <i>Individual Research</i>
( ) <i>Doctorate Degree Thesis</i>	( ) <i>Preliminary Study</i>
( ) <i>Medical Specialization</i>	( ) <i>Educational</i>
( ) <i>Specialization in Dentistry</i>	( ) <i>Other (Please specify):</i>

<b>7. APPLICATION TYPE</b>
( ) New application
( ) Correction (Atılım HAYDEK Application no.: ) (Please mark the corrections requested by the Ethics Committee in bold, use a dark color, and underline them)
( ) Correction (Accepted as per Atılım HADYEK Resolution dated /.../20..., no. ETİK 20.../....) (Please provide the justification in details): .....
( ) Additional Study (Accepted as per Atılım HADYEK Resolution dated /.../20..., no. ETİK 20.../....) (Please provide the justification in details): .....
( ) Primary Study Application Following an Additional Study (Accepted as per Atılım HADYEK Resolution of “Conditional Appropriateness” dated /.../20..., no. ETİK 20.../....) (Please detail the results of your preliminary study in the Method section)



b) How will the animal groups be formed and how many animals will be in each group?

	Experiment Control Groups	Total Number of Animals per Group	Number of Repetitions	Number of Animals Used per Group
Preliminary Study Group				
Study Group				
TOTAL				

c) Please detail the procedures to be performed throughout the study, using a working schedule.

12. PROCEDURES TO BE PERFORMED ON ANIMALS:

a. Methodology (*In detail*)

b. Citations (*At least 3 citations on laboratory animal procedure methodology*)

13. PLEASE SPECIFY THE LEVEL OF PAIN, SUFFERING, DISTRESS, AND PERMANENT DAMAGE THAT THE PROCEDURES ARE TO CAUSE.

14. DESCRIBE THE PRECAUTIONS TO BE TAKEN TO ENSURE THAT THE PROCEDURES IN THE STUDY DO NOT CAUSE THE ANIMALS FEAR AND STRESS.

15. MEASURES TO BE TAKEN TO PREVENT ANIMALS FROM EXPERIENCING PAIN AND SUFFERING THROUGHOUT THEIR LIVES OR TO REDUCE THE SUFFERING THEY EXPERIENCE

**16. THE METHOD OF EXECUTION OF THE 3R PRINCIPLES THROUGHOUT THE PROCEDURES**

**a) Why is the use of laboratory animals necessary in this study? Is it possible to conduct this study without using laboratory animals?**

**b) Will a preliminary study be conducted in this study? Please explain why this study may not be conducted using a smaller number of animals.**

**c) Please explain why you selected the specified species, breed, gender, age/ weight of animals.**

This species is preferred, because:

- There are extensive databases that allow comparison with previously obtained data.
- As stated below, the anatomical and physiological characteristics of the proposed species are the only suitable model for the study.  The proposed species has the most suitable tissue, size, and anatomy for this study and is the lowest phylogenetically.
- This species constitutes a very suitable physiological model for simulating the situation in humans.  The same species was used in previous studies from which this project originated.
- The characteristics of this species, as stated below, are the most suitable choice for the study.  Other (Please specify).

**d) Will any restrictions (physical restraint, water, food, etc.) be exercised on the animals in the experiments, or, will they be exposed to abnormal conditions?**

Yes                       No

1. Which of the following restrictions will be exercised?

- Water Restriction
- Food Restriction
- Physical Restriction
- Exposure to abnormal conditions
- Other:.....

2. Please specify the period of restriction:  
.....

3. Please provide details on the intended restrictive procedures:  
.....

4. Please specify the possible undesirable behavioral, health, and well-being changes that may occur in restrained animals.  
.....

5. Please specify the procedures to be followed to help animals adapt to the restrictive conditions.  
.....

6. Please specify the frequency with which animals are to be monitored under restrictive conditions.  
.....

7. Please specify the abnormal condition(s). (Cold, heat, fear, stress etc.)  
.....

**17. ANESTHESIA, ANALGESIA, AND OTHER PAIN RELIEF METHODS TO BE USED**

**a) Please specify the method, frequency, and schedule of researchers monitoring the depth of anesthesia and subsequent vital signs during the procedure.**

- Method of monitoring depth of anesthesia (check all that apply)

Not suitable for application to the protocol.  Skin or finger pinch responses.

Palpebral or corneal reflex (not suitable for rodents)  Monitoring jaw or skeletal muscle tone.

Monitoring physiological response.  Other. Please explain:

- Monitoring frequency

Not possible to apply to the protocol.

Every 2-3 minutes.

Every 4-5 minutes.

Other duration (Please explain):

Please explain researchers' monitoring schedules.

**b) Please specify the analgesics, sedatives, tranquilizers and anesthetics; or other medications to administer to animals to prevent pain and suffering during procedures; including their method of administration, frequency, and doses.**

**Analgesic agents**

AGENT	DOSE	METHOD OF ADMINISTRATION	VOLUME	FREQUENCY	DURATION OF EFFECT

**Sedatives, Anesthetic agents**

AGENT	DOSE OF INDUCTION	ADDITIONAL DOSES	METHOD OF ADMINISTRATION	PROCEDURE	DURATION UNDER ANESTHETICS




**b) Specify the hazardous substances and/ or situations that may arise or be used during the experiment.**

1. Risk of microbiological contamination.  YES  NO  
*If yes, please specify* :  
*If yes, is there a risk of human transmission?* :

2. Carcinogenic substances.  YES  NO  
*If yes, please specify* :  
*If yes, is it hazardous to humans?* :

3. Radioisotopes  YES  NO  
*If yes, please specify* :  
*If yes, is it hazardous to humans?* :

4. Biological toxins  YES  NO  
*If yes, please specify* :  
*If yes, is it hazardous to humans?* :

5. Antineoplastic/ cytotoxic agents.  YES  NO  
*If yes, please specify* :  
*If yes, is it hazardous to humans?* :  
:

Other agents. Please list:

<b>19. DETERMINING THE HUMANE METHOD OF EUTHANASIA IN TERMINATING PROCEDURES</b>
<b>a) What are your humane termination point standards? Criteria for removing animals from the experimental protocol (please check all that apply)</b>
<input type="checkbox"/> <i>Weight loss exceeding ...% of body weight</i> <input type="checkbox"/> <i>Inability to walk properly</i> <input type="checkbox"/> <i>Inability to eat and drink properly</i> <input type="checkbox"/> <i>Significantly reduced response to stimuli</i> <input type="checkbox"/> <i>As deemed appropriate by the veterinarian (humane reasons)</i> <i>Please describe:</i> <input type="checkbox"/> <i>Other. Please describe:</i>
<b>b) Will euthanasia be performed in the study? If so, please indicate the method of euthanasia.</b>

- Euthanasia will not be performed.  Euthanasia will be performed.
- High-dose anesthetic*
  - Decapitation under anesthesia/tranquilizer*
  - Cervical dislocation under anesthesia/tranquilizer*
  - Exsanguination during surgery*
  - Carbon dioxide*
- inhalation*
- Other. Please describe:*

**20. PLEASE DESCRIBE THE EXPERIMENTAL OR OBSERVATIONAL STRATEGIES AND DATA ANALYSIS METHODS TO MINIMIZE THE NUMBER OF ANIMALS AND THE SUFFERING, PAIN, OR POTENTIAL ENVIRONMENTAL IMPACTS CAUSED BY THE PROCEDURES.**

**21. PLEASE SPECIFY WHETHER THE ANIMALS WILL BE USED IN MULTIPLE PROJECTS.**

**22. HOUSING, BREEDING, AND CARE CONDITIONS PROVIDED TO ANIMALS**

For each topic, describe the characteristics and schedules of the living space, feeding, watering, lighting, heating, and ventilation to be provided in the study. Indicate what the ideal working environment is for the animal in the experimental study.

- a.  No special conditions will be applied.
- b. The following practices will be carried out in the experiments (indicate all that are valid):
  - Prolonged exposure to high/ low temperatures*
  - Prolonged exposure to substandard humidity/ dryness*
  - Prolonged exposure to substandard atmospheric pressure*
  - Prolonged exposure to substandard atmosphere*
  - Housing in a substandard cage*
  - Prolonged non-standard light/ dark cycle*
  - Water deprivation for more than 12 hours*
  - Food deprivation for more than 24 hours (48 hours for ruminants)*
  - Other. Please explain:*

**23. DO YOU HAVE ANY ONGOING RESEARCH INVOLVING LABORATORY ANIMALS? IF SO, PLEASE SPECIFY.**

**24. HOW WILL ORGANIC AND MEDICAL WASTE GENERATED DURING AND AFTER THE STUDY BE DISPOSED?**

**ATILIM UNIVERSITY  
LOCAL ETHICS COMMITTEE COVENANT FOR ANIMAL EXPERIMENTATION**

**Title of Study:**

I have read the Atılım University Local Ethics Committee Directive on Animal Experimentation, and declare that I / We will commit to the following:

- Working in accordance with the guidelines;
- Not allowing individuals without an Animal Experimentation Authorization to perform any procedures on experimental animals in the approved study;
- Obtaining permission from the Atılım University Local Ethics Committee for Animal Experimentation for any changes to the procedures and the project team during the study;
- Reporting the situation to the Atılım University Local Ethics Committee for Animal Experimentation by the last working day of the third month following the completion of the study;
- Complying with the ethical principles contained in the Atılım University Local Ethics Committee Guidelines on Animal Experimentation during this study, and immediately reporting any unexpected adverse effects or events to the Local Ethics Committee.

	<b>Full Name</b>	<b>Title</b>	<b>Workplace</b>	<b>Signature</b>
<b>Executive responsible</b>				
<b>Project team</b>				
<b>Other officials</b>				

**Project Executive's:**

**Address :**

**Phone (office) :**

**Phone (mobile) :**

**E-mail :**