FIRAT UNIVERSITY ANIMAL EXPERIMENTS LOCAL ETHICS COMMITTEE DIRECTIVES

This directive was approved in accordance with the decision of the Central Ethics Committee of Animal Experiments dated 02/10/2015 and numbered 41.

FIRAT UNIVERSITY ANIMAL EXPERIMENTS LOCAL ETHICS COMMITTEE DIRECTIVES

PART ONE

Purpose and Scope, Basis, Definitions and

Abbreviations Purpose and Scope

ARTICLE 1- (1) This directive aims to evaluate the procedures to be carried out with experimental animals in basic activities such as scientific research, testing, health care practices, education-training and publication at Fırat University and its affiliated units within the framework of minimum ethical principles, to express opinions, to examine the proposed protocols, to grant permission, and to monitor the applications, This regulation was issued in order to determine the establishment and working principles of Fırat University Animal Experiments Local Ethics Committee (FÜHADYEK) which will be established to ensure that all procedures performed on experimental animals are recorded and that these procedures can be monitored immediately or retrospectively and to examine research proposals in this respect.

(2) This directive;

- a) Non-experimental agricultural practices,
- b) Non-experimental clinical veterinary medicine practices,
- c) Clinical trials required for marketing authorization of veterinary health products,
- ç) Practices that registered or approved livestock enterprises are obliged to carry out,
- d) It does not cover applications whose primary purpose is the identification of an animal.

Basis

ARTICLE 2- This directive is based on the following laws, regulations, international and national declarations and guidelines:

- a) Law No. 5199 on the Protection of Animals,
- b) "Regulation on the Working Procedures and Principles of Animal Experimentation Ethics Committees" of the Ministry of Forestry and Water Affairs published in the Official Gazette dated February 15, 2014 and numbered 28914,
- c) Good Laboratory Guide, d) Universal Declaration of Animal Rights,

- d) CITES Convention: Convention on International Trade in Endangered Species of Wild Fauna and Flora published in the Official Gazette dated 20/6/1996 and numbered 22672.
- e) "Regulation on the Welfare and Protection of Animals Used for Experimental and Other Scientific Purposes" published in the Official Gazette dated 13/12/2015 and numbered 28141

Definitions and Abbreviations

ARTICLE 3- (1) In this Directive:

- a) Institution: Fırat University,
- b) Establishment: Open, closed, semi-open, all kinds of fixed or movable facilities, buildings or group of buildings with outbuildings, which have a work permit by the Ministry of Food, Agriculture and Livestock,
- c) Rector: Rector of Fırat University,
- ç) Chairman: Chairman of

FÜHADYEK,

- d) Deputy Chairman: Deputy Chairman of FÜHADYEK,
- e) FÜDAM Fırat University Experimental Research Center,
- f) FÜHADYEK Fırat University Animal Experiments Local Ethics Committee,
- g) HADMEK Animal Experimentation Center Ethics Committee,
- ğ) Secretariat: The person or persons who ensure the necessary coordination of FÜHADYEK, conduct correspondence and keep records,
- h) Application Form: The form prepared for the project and submitted to FÜHADYEK,
- Supplier organization: A natural or legal person, other than the producer organization, authorized or registered by the relevant official authorities from whom animals are supplied for use in experiments,
- i) Producer organization: A real or legal person authorized or registered by the Ministry of Food, Agriculture and Livestock where animals are raised until they are large enough to be used for experimental purposes and produced for use in experiments,
- j) Authorized person: A person who has the training and ability to perform the practices defined in this Directive on animals and who is qualified to train experimental animal users,
- k) Experimentation: Any procedure or set of procedures to be performed on animals for

- scientific purposes, other than non-experimental animal husbandry, agricultural or clinical veterinary medicine practices,
- Experimental animal: Any non-human vertebrate used in experiments, including freeliving or reproducing larval forms, live cephalopods and mammals from the last third of their normal fetal development,
- m) Species: A biological group of related organisms that share common characteristics and can reproduce by fertilization among themselves,
- n) Experimental animal user: Students, researchers, academic, health, technical and administrative personnel who will perform any procedure using an experimental animal,
- o) Experimental Unit: Units with a work permit from the Ministry of Food, Agriculture and Livestock where all kinds of procedures or procedures are performed on animals,
- ö) Ethics: The limits of actions that can be taken in sciences related to human and animal life regarding animals to be used in research, universal rules guiding the attitude and behavior towards animals,
- p) Animal welfare unit: The unit in FÜDAM consisting of at least one person with the title of veterinarian, veterinary health technician or veterinary health technician responsible for the welfare and care of animals, and a maximum of three people, at least one of whom must be a member of FÜHADYEK,
- r) Humane method of killing: The termination of an animal's life in a way that is typical of its species and causes the least physical and sensory pain, suffering and distress,
- s) In vivo experiment: An experiment conducted in a living environment,
- §) Good laboratory practices: The quality system related to the conditions and management procedures for planning, conducting, monitoring, recording, archiving and reporting of health and environmental safety studies other than clinical studies,
- t) Project: A program of work that has a defined scientific objective, involves one or more procedures, and has not begun to be implemented,
- u) Procedure: The use of animals for experimental, other scientific or educational purposes, including the breeding, hatching, or genetically modified animal lineage maintenance processes, with known or unknown consequences, including the use of animals for experimental, other scientific or educational purposes, with known or unknown consequences that may cause pain, suffering, anguish or permanent damage equal to or greater than that caused by the insertion of a needle in accordance with

- good veterinary medical practice,
- ü) 3R (Replacement, Reduction, Refinement) principle: Wherever possible, substitute live animals with scientifically valid alternative method or trial strategy, without compromising the project objectives.
 - to reduce the number of animals as much as possible, to improve animal welfare by improving procedures that cause pain, suffering, anguish and permanent damage to animals, refers to.

PART TWO

Establishment of FÜHADYEK and Qualifications of Members, Appointment and Term of Office of Members, Purposes of Using Experimental Animals, Working Method of FÜHADYEK, Duties of FÜHADYEK, Working Principles of FÜHADYEK

Establishment of FÜHADYEK and Qualifications of Members ARTICLE 4- (1) FÜHADYEK;

- a) President of FÜDAM
- b) A veterinarian who is responsible for the breeding and production of experimental animals within the institution and who has a certificate for the use of experimental animals, who works full-time in the unit and has at least one year of experience in animal experiments,
- c) At least one representative from the units working with experimental animals within the institution,
- ç) A citizen of the Republic of Turkey who does not perform experimental work on animals and does not have a relationship of interest with the organization,
- d) A citizen of the Republic of Turkey who is a member of a non-governmental organization with no vested interest in the institution,

It consists of a minimum of 5 and a maximum of 21 members.

(2) At least one member of FÜHADYEK must have at least one year of experience in in vivo animal experiments and a PhD or medical specialty degree. It is preferable to have medical or veterinary ethics experts in the FÜHADYEK. The institution may determine the composition of the FÜHADYEK according to its needs and administrative structure. When necessary, FÜHADYEK may receive opinions from experts in other fields and invite them to meetings.

Appointment and Term of Office of Members

ARTICLE 5- The President, Vice President and members of FÜHADYEK are appointed by the Rector. Appointments or changes in appointments with approval shall be notified to HADMEK within one month. The chairman of FÜHADYEK and the veterinarian must be full-time employees of the institution. FÜHADYEK secretariat is appointed with the approval of the rector. The term of office of FÜHADYEK members is 4 (four) years. A member whose term of office expires may be reappointed. One calendar

A member who fails to attend 3 (three) consecutive meetings within the year without permission or excuse shall automatically cease to be a member. In the event of termination of the membership for any reason such as death, retirement, resignation, or in the event that the membership falls, a new member bearing the qualifications of the departed member is appointed in the same manner and to complete the remaining period.

Purposes of use of Experimental Animals ARTICLE 6- Experimental animals;

- a) Basic research,
- b) Translational or applied research with any of the following objectives,
- 1) The prevention, diagnosis, treatment or avoidance of disease, health disorders and other abnormalities in humans, animals or plants,
- 2) The study, identification, correction or modification of physiological disorders in humans, animals or plants,
- 3) Improving animal welfare and production conditions for animals raised for agricultural purposes,
- c) the development, 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 referred to in point (b),
- ç) Protection of the natural environment for human and animal and welfare,
- d) Research aimed at species conservation,
- e) Higher education or training for the acquisition, maintenance or development of professional skills,
- f) It is used for forensic investigations.

Working Method of FÜHADYEK

ARTICLE 7- FÜHADYEK works as follows:

- a) FÜHADYEK convenes at least once a month with the participation of at least twothirds of the members, with the agenda to be determined by the chairman of the board. Additional meetings may be held upon the invitation of the chairperson when necessary.
- b) Ethics Committee meetings shall be chaired by the acting chairman in the absence of the chairman. Decisions are taken by majority of votes. In case of equality of votes, the chairman's vote shall prevail.
- c) Records of all experimental animals used in the studies, responsible for the breeding, production and care of the experimental animal—in charge of the animal welfare unit kept or made to be kept by the veterinarian. These records shall include the number of animals procured, their species, the places where they were procured, the date they arrived at the user organization and all procedures performed. These records shall be kept for at least 5 (five) years.
- ç) FÜHADYEK prepares an application form to evaluate the applications.

In the application form;

- 1) Project name,
- 2) Name, address, position and 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) Date of application,
- 6) Project proposal,
- 7) Non-technical project summary written in everyday language,
- 8) Animal resources, estimated number, type and age of animals,
- 9) Procedures to be performed on animals,
- 10) The level of pain, suffering, anguish and permanent damage caused by the procedures,
- 11) How the 3R principle is applied in procedures,
- 12) Anesthesia, analgesia and other pain relief methods planned to be used,
- 13) Measures to be taken to prevent or reduce pain and suffering of animals throughout their lives,
- 14) Determining the humane method of killing to terminate procedures,
- 15) Experimental or observational strategies and data analysis procedures to minimize the number of animals and the pain, suffering, suffering or potential environmental

impacts of the procedures,

- 16) Whether animals will be used in more than one project,
- 17) Conditions of housing, breeding and care of animals,
- 18) Competence of those involved in the project,
- 19) Undertaking information must be available.
- d) All applications and decisions taken are recorded by giving date and number numbers. Records are kept for at least 5 (five) years.
- e) Projects are authorized by FÜHADYEK for a maximum period of 5 (five) years, and in case of a request for extension, additional time may be granted provided that the request is justified and approved by FÜHADYEK.
- f) As a result of its evaluation, FÜHADYEK decides as appropriate, needs to be corrected, conditionally appropriate or not appropriate. Decisions are notified to the applicant in writing within 40 (forty) working days from the date of application. This period also covers the project evaluation. In cases where the project is complex or involves more than one scientific discipline, FÜHADYEK may extend the aforementioned period not exceeding 15 (fifteen) working days for one time only. The reason and duration of the extension shall be justified and the executive shall be informed before the expiration of the period. FÜHADYEK 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 for projects that are deemed "conditionally eligible".
- g) While the applications of FÜHADYEK members are being discussed, the relevant board member cannot participate in the discussions and cannot vote.
- ğ) Projects that are deemed "needs to be corrected" are re-evaluated after correction. Projects that are deemed "conditionally suitable" are monitored by the animal welfare unit for a period of time to be determined by FÜHADYEK, and after evaluating whether the required conditions are fulfilled, it is decided as "suitable" or "not suitable" and a report on the project is submitted to FÜHADYEK.
- h) FÜHADYEK audits whether there are any changes in the authorized projects that may adversely affect animal welfare. the approved project is not complied with, FÜHADYEK the permission granted. In case the permit is canceled, the animal welfare unit ensures that the welfare of the animals used or intended to be used in the project is not adversely affected.

- 1) After the approval of FÜHADYEK, changes in the project and the people who will participate in the study are notified in writing to FÜHADYEK by the project coordinator after obtaining the signed approval of the other researchers in the project and their approval is obtained.
- i) The following interventions are not subject to FÜHADYEK authorization:
 - 1) Clinical applications for diagnostic and therapeutic purposes,
 - 2) Procedures with dead animals or tissue, slaughterhouse materials, waste fetuses,
 - 3) Milking
 - 4) Collection of urinefeces or litter samples,
 - 5) Swab sampling,
 - 6) Studies with animal products.
- j) For the use of wild animals from nature for species identification, the permission obtained from the General Directorate of Nature Conservation and National Parks replaces the permission of FÜHADYEK.
- k) In case field surveys are conducted in more than one province, it is sufficient to obtain the approval of HADYEK for only one location.
- l) Records are kept open to the inspection of HADMEK and the Ministry. When necessary, FÜHADYEK may receive the written opinions of experienced experts or invite them to the FÜHADYEK meeting and request oral or written opinions.

Duties of FÜHADYEK

ARTICLE 8- The duties of FÜHADYEK are as follows:

- a) To prepare a directive on its own working procedures and principles within the framework of ethical principles and good laboratory practices determined by HADMEK.
- b) To determine the ethically acceptable limits of all procedures to be performed on experimental animals and to approve or reject study protocols with justification,
- c) To supervise the continuation of the process of using experimental animals within the institution in accordance with the 3R principles and ethical rules, and to make the necessary arrangements for this purpose,
- ç) To carry out practices that will contribute to the development and verification of alternative methods that can provide the same or higher level of information than those obtained by using experimental animals, but that do not use animals, or that use a minimum number of animals, or that involve less painful procedures, and to

- encourage research in this field,
- d) 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,
- e) 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 there is a certificate for the use of experimental animals, and to organize certification programs when necessary for this purpose,
- f) To inspect whether the production, breeding, housing and transportation conditions of experimental animals and the laboratory conditions and equipment where experiments are carried out are ethically appropriate,
- g) To examine and decide on research applications according to the principles in the relevant articles of this directive,
- ğ) To examine and decide on proposals for changes in experimental research protocols for which it has previously granted permission and approval,
- h) Accepting applications for multi-center studies, one of which is carried out at our University, and giving opinions,
- 1) To supervise and ensure that the working conditions of the personnel dealing with experimental animals comply with the workplace health rules,
- i) Advising researchers on ethical issues, organizing conferences and seminars on ethical issues when necessary, and preparing guidelines,
- j) Preparing statistical data tables and an annual activity report on the use of experimental animals and submitting it to HADMEK,
- k) To ensure the disposal of wastes and medical wastes resulting from experimental studies within the framework of the Environmental Law No. 2872 dated 9/8/1983 and the relevant legislation,
- To ensure that the experimental animals are registered and monitored within the framework of the provisions of the Animal Protection Law No. 5199 and the relevant legislation,
- m) To determine new ethical principles when necessary and ensure that they are included in the FÜHADYEK Directive,
- n) To decide whether the animals used in the experiment should be adopted or returned to the farming system after the procedure.

Working Principles of FÜHADYEK

ARTICLE 9- (1) FÜHADYEK works in line with the principles stated below:

- a) To prevent the mistreatment of experimental animals that must be used in scientific research,
- b) To ensure that experimental animals are used for the purposes specified in Article 6 of this Directive.
- 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 it must be used, it is based on sound scientific justification,
- ç) To ensure that experiments that cause pain and suffering are not conducted in educational congresses, conferences and seminars,
- d) To ensure that scientifically reliable data is obtained with as little pain and stress to the animals as possible,
- e) To prepare conditions suitable for the experimental animals used during the researches and to provide the best physiological, behavioral and environmental conditions,
- f) To ensure the care of experimental animals under appropriate conditions by appropriately trained personnel,
- g) To ensure that experimental studies on live animals are carried out under the supervision of the responsible veterinarian,
- ğ) To ensure that the reasons/criteria for termination of experiments are determined in advance by the investigators,
- h) To deem animal experiments ethically inappropriate if there are proven alternative methods for obtaining the information being researched and to prevent the repetition of experiments that have already been conducted in detail,
- 1) To ensure that the most appropriate animal species and method is selected for the experiment and that the minimum number of animals that can give scientifically meaningful results is used,
- To ensure that an appropriate anesthesia method is applied in experiments that will cause unnecessary pain and pain to experimental animals and that appropriate painkillers and anesthesia are used in research,
- j) To prevent the experiment from being carried out if the anesthesia is more traumatic for the animal than the experiment itself and is not in accordance with the purpose of

- the experiment,
- k) With the decision of the veterinarian, to ensure that the experiment is carried out within the framework of ethical principles and is suitable for its purpose; to ensure that the animal, which will be exposed to significant pain when it comes out of anesthesia, is treated with painkillers, if it is not possible to treat it, it is killed by a humane method, the termination of the experimental animal's life during or at the end of the research process is carried out on appropriate grounds, and the experimental animals that suffer severe and continuous pain or are unable to maintain their normal life and the experimental animals that may pose a risk to their health and environment are terminated by a humane method,
- 1) Providing healthy living conditions for the experimental animals used in the research at the end of the experiment,
- m) To decide on the conduct of experiments that will expose animals to severe and prolonged suffering, taking into ethical principles, the benefit to be obtained from the research and the suffering of animals,
- n) Reducing the number of animals used in experiments by performing more than one experiment on animals, as long as the scientific objective is not compromised and the animal's welfare is not impaired,
- o) To ensure that the tissues and organs of animals that die in experiments are shared and evaluated in other applications,
- ö) Avoiding practices that result in severe pain, suffering and anguish that are likely to be prolonged and that cannot be remedied,
- p) Only allow procedures to be carried out under the supervision of its in-house animal welfare unit,
- r) Approved projects, in content and to work will attend in people To follow the changes to be made and to ensure that the necessary permissions are obtained.
- (2) Principles regarding the members of the Board:
- a) While fulfilling the duties assigned to them in this directive, the members of the Board may not use their powers to prevent, delay or stall an investigation.
- b) Board members may not take sides in scientific competition and rivalry between units, and may not use their authority in a way that gives priority to their colleagues,

- other members of the board or themselves. They evaluate and finalize the application files according to the order of application.
- c) Board members cannot request to be assigned for a specific file during the examination of application files. Member(s) who have been stated in writing by the research supervisor for any reason that they "will not act impartially" cannot be assigned to review the relevant file and cannot act as a rapporteur.
- ç) The members of the Board cannot take review duties for the files belonging to them and cannot vote for the decision.
- d) Board members may not take the application files out of the meeting, examine them privately or prepare reports without the written permission of the Board.
- e) Board members may not discuss the contents of the application files with others outside the board meeting and may not provide information about the contents of the files. They may not take copies of the whole or part of the application file for any purpose whatsoever and may not give them to others.
- f) Board members may not, while in office and within the first year after leaving office, take part in or work on any research that is similar in content to an application file that they have not authorized and approved.
- g) Board members may not ask questions or request information on matters that are not required to be included in the application file according to the provisions of this directive, and may not prolong or delay the examination for reasons that are not mandatory for the application.
- ğ) The Board has no legal responsibility for the studies it approves and any criminal liability arising from them. All responsibility belongs to the responsible investigator.

PART THREE

Practices Related to Experimental Animals and Research

Experimental Animals

ARTICLE 10- (1) Issues regarding the animals to be used in the studies of FÜHADYEK:

- a) All procedures to be performed on experimental animals must be approved by FÜHADYEK.
- b) Mice (*Mus musculus*), rats (*Rattus norvegicus*), guinea pigs (*Cavia pocellus*), Syrian (golden) hamster (*Mesocricetus auratus*), Chinese hamster (*Cricetulus griseus*),

Mongolian gerbil (*Meriones unguiculatus*), rabbits (*Oryctolagus cuniculus*) to be used in experiments, unless a general or special exception has been obtained in accordance with the regulations made by FÜHADYEK, dog (*Canis familiaris*), cat (*Felis catus*), all species of non-human primates, frog [xenopus (*Laevis, tropicalis*), rana (*Temporaria pipiens*)], zebrafish (*Danio rerio*) and all animals to be used in the experiment must be obtained from registered legal experimental animal producers and suppliers.

- c) Stray domestic animals such as cats and dogs are not used in experiments. However, these animals can be used in experiments if there is a need for studies on the health and welfare of animals, if they pose a serious danger to the environment, human and animal health, and if scientific justifications are presented that the purpose of the study can only be realized using stray animals.
- ç) The use of non-human primates in experiments is permitted in exceptional circumstances and where there is scientific justification that the purpose of the procedure cannot be achieved using a species other than non-human primates.
- d) Greater tailless monkeys cannot be used in experiments.
- e) The use of endangered and protected species within the framework of national legislation and international conventions and species listed in Appendix-1 of the CITES Convention is permitted in the following cases:
 - 1) The procedure shall be based on subparagraph (1) of paragraph (b) of Article 6 of this directive and paragraphs (c) and has one of the purposes specified in subparagraphs (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,
- f) The experiment to be carried out on wild animals taken from the wild is approved on scientific grounds; only if other animals are not sufficient for the purpose of the experiment. In studies on this subject, permission is obtained from the General Directorate of National Parks after the approval of FÜHADYEK.

Procedures Related to Anesthesia and Anesthesia Administration, Killing and Violence Classification in Experiments

ARTICLE 11- (1) Procedures related to anesthesia and anesthesia administration, killing and severity classification in experiments are carried out according to Articles 21 and 22 and Annex-8 and Annex-9 of the Regulation on the Welfare and Protection of Animals Used for Experimental and Other Scientific Purposes published by the Ministry of Food, Agriculture and Livestock in the Official Gazette dated 13/12/2011 and numbered 28141.

Reuse of Animals in Experiments

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

- a) If the actual severity of previous experiments was "mild" or "moderate",
- b) The animal's general state of health is completely restored,
- c) If the new experiment is classified as "mild", "moderate" or "irrecoverable",
- ç) If deemed appropriate by a veterinarian who can evaluate the procedures previously performed on the animal,
- (2) In exceptional circumstances, the re-use of an animal may be permitted, subject to the exclusion of subparagraph (a) and after examination of the animal by a veterinarian, provided that the animal is not used more than once in an experiment involving severe pain, suffering or its equivalent.

Termination of the Experiment

- **ARTICLE 13-** (1) The experiment shall be terminated if no further observations can be made in relation to the experiment, or if the genetically modified animal lineages and generations are no longer being monitored, or if it is expected to experience pain, suffering, anguish and permanent damage equivalent to or greater than needle sticks in an ongoing manner.
- (2) At the end of the experiment, the decision on whether to keep an animal alive shall be taken by a veterinarian. If an animal is kept alive, it shall be provided with care and housing appropriate to its state of health. If the animal continues to experience moderate or severe pain, suffering, anguish and permanent damage, it is killed.

Evaluation of Projects

ARTICLE 14- (1) Projects:

- a) Scientific, educational or legal grounds,
- b) Justifications for animal use,
- c) Designing procedures to be carried out in the most humane and environmentally sound manner possible,
- ç) Estimated scientific benefits and educational value,
- d) Compliance with the 3R principle,
- e) Classification of procedure severity,
- f) The benefit to be gained and the suffering of the animals,
- g) Compliance of killing methods, procedures, anesthesia, reuse, care and housing conditions with applicable legislation,
- ğ) Deciding whether and when to conduct a retrospective evaluation, evaluated by FÜHADYEK according to the criteria.
- (2) FÜHADYEK pays attention to the selection of experts who will evaluate the project according to the 3R principle, experimental design, practical applications of animal experiments, practical applications of wild animal experiments or competence in animal care and nutrition.
- (3) Project evaluation must be transparent. To protect intellectual property rights and confidential information, the project evaluation is carried out in an impartial manner and may include the views of independent parties.

Project Summaries

- **ARTICLE 15-** (1) to the protection of intellectual property rights and confidential information, the non-technical project brief shall include the following
 - a) Information on the objectives of the project, including estimated damages and benefits and the identity of the animal used,
 - b) That the 3R principle is followed,
 - (2) The non-technical project summary is prepared anonymously and does not include the names and addresses of users and staff.
 - (3) FÜHADYEK may request that the non-technical project summary indicate whether the project will be subjected to a retrospective evaluation process and the limit of this period. In this case, it ensures that the non-technical project summary is updated with the results of the retrospective evaluation.
 - (4) In the event that a database is established by the Ministry, the non-technical project summaries of the authorized projects and the updates made to them are published in this database.

Retrospective Evaluation

- **ARTICLE 16-** (1) In case a decision is taken to make a retrospective evaluation regarding the projects finalized with the permission of FÜHADYEK, the following issues are evaluated according to the documents submitted to FÜHADYEK:
 - a) Whether the objectives of the project were achieved,
 - b) The number of animal species used, the harm caused to animals and the severity of the procedures,
 - c) Elements that can contribute to the implementation of the 3R principle,
 - (2) All projects using non-human primates and projects involving procedures classified as "severe including procedures involving prolonged and unrelieved severe painsuffering and anguishare subject to retrospective review.
 - (3) Projects outside the provisions of the second paragraph may be exempted from retrospective evaluation.

SECTION FOUR

Training of Personnel to Deal with Experimental Animals, Approval of Working Protocols, Application Procedures, Responsibilities of Applicants

Training of Personnel to Deal with Experimental Animals

ARTICLE 17- The issues to be complied with in the training of the personnel who will deal with experimental animals are specified below:

- a) FÜHADYEK is responsible for the organization of training programs within the institution for the training of researchers who deal or will deal with experimental animals, and for the opening, organization and execution of experimental animal use certificate programs. Those who are successful in these programs organized within the institution are given an experimental animal use certificate by FÜHADYEK.
- b) Students, researchers, academic, health, technical and administrative personnel who want to conduct any kind of education, research, application and testing using experimental animals or who contribute to these programs by touching experimental animals are considered as experimental animal users.
- c) Experimental animal users may not perform experiments, training or testing on these animals and may not keep these animals in their workplaces without obtaining a certificate. In research to be conducted with farm animals, it is mandatory to have a veterinarian in the research team. In this case, it is not necessary for the veterinarian to have a certificate for the use of experimental animals.
- ç) FÜHADYEK prepares and periodically supervises the implementation of an on-thejob training program that includes the procedures and principles to be followed and minimum information for the personnel responsible for the production and breeding of experimental animals. Training programs are conducted by authorized persons. The authorized persons are determined by FÜHADYEK.
- d) In the study submitted for FÜHADYEK approval, if the person using the experimental animal does not have a certificate of use, this study will not be approved.
- e) A researcher may apply to FÜHADYEK to collaborate with others as a researcher if he/she does not have his/her own certificate. Researchers who participate but do not directly perform procedures with experimental animals may continue their experiments with the help of certified experimental animal users.

- f) The experimental animal use certificate program to be organized by FÜHADYEK is created according to the current content reported by HADMEK.
- g) It is compulsory to attend 80% of the courses in experimental animal use certificate programs.
- ğ) In order to receive a certificate, trainees must score at least 70 points out of 100 in the exam to be held at the end of the course.
- h) How the certificate programs will be conducted is determined by FÜHADYEK.
- 1) Trainees who enroll in the experimental animal use certificate programs organized in accordance with the provisions of this Directive and fulfill the attendance and success conditions are given "Experimental Animal Use Certificate". The certificate for the use of experimental animals is signed by the President of FÜHADYEK and the Rector.
- i) FÜHADYEK is obliged to notify HADMEK at least 30 (thirty) days in advance of the certificate training programs it will organize.
- j) FÜHADYEK is obliged to inform HADMEK about the trainees who have successfully received a certificate at the end of the certificate training program it organizes.
- k) FÜHADYEK decides whether the trainings on the use of experimental animals at undergraduate or graduate level are equivalent to a certificate program, and those who complete the training programs decided to be appropriate are awarded certificates by FÜHADYEK.

Approval of Working Protocols

ARTICLE 18- The studies that require approval from FÜHADYEK are as follows:

- a) Animal experiments and observations for all kinds of research projects, thesis (specialization, master and doctorate) studies,
- b) Student practices and demonstrations for educational purposes, which are specified in the curriculum (to be approved once at the beginning of each academic year),
- c) Tests and studies to be conducted for learning a method and manual dexterity, ç) All other scientific research to be conducted at FÜDAM.

Application procedures

ARTICLE 19- (1) Applications are made by the project coordinator to the secretariat of

- FÜHADYEK by filling out the "Fırat University Animal Experiments Local Ethics Committee Application Form". For thesis studies, the coordinator is the advisor faculty member.
- (2) The research supervisor whose application is not granted permission and approval may appeal the decision within 1 (one) month at the latest after the decision is notified to him/her in writing, or may reapply by correcting the deficiencies and making corrections justified by the rejection decision. The appeal and re-application shall be discussed and decided by the Board at the first meeting.
- (3) In experimental research for which permission and approval have been obtained, it is necessary to obtain permission and approval for changes in the project and the people who will participate in the study during the conduct of the studies. Applications for changes are made using the relevant form.

Responsibilities of applicants

ARTICLE 20- Personal declaration is essential for applications to FÜHADYEK and applicants:

- a) The accuracy of the information provided in their application forms,
- b) That they will not start experiments without FÜHADYEK approval,
- c) They will carry out the procedures to be performed on experimental animals in accordance with the issues specified in the application form,
- ç) In case FÜHADYEK wishes to monitor their work, they are deemed to have agreed to open their working environments and all kinds of practices related to their work to the control of FÜHADYEK members.

SECTION FIVE

Miscellaneous and Final Provisions

Privacy

ARTICLE 21- The correspondence of FÜHADYEK is confidential and no information is given to third parties other than the authorized institutions specified in this Directive.

Repealed Directive

ARTICLE 22- The previous "Directive of the Ethics Committee on Animal Experiments of Fırat University" has been repealed.

Enforcement

ARTICLE 23- This directive enters into force on the date it is accepted by Fırat University Senate and HADMEK.

Execution

ARTICLE 24- The provisions of this directive shall be executed by the Rector of Fırat University.