Pursuant to article 51 of the Law on Animal Welfare ("Official Gazette RS", vol. 41/09) and article 119 of the Statutes of the Faculty of Medicine, at the meeting held on 21 June 2011 the Academic Staff Board of the Faculty of Medicine University of Belgrade hereby passes the following

**Rules of Operation of the Ethics Committee for Experimental Animals Welfare Protection**

**Article 1**

These Rules govern the composition, competencies and mode of operation of the Ethics Committee for the Experimental Animals Welfare Protection of the Faculty of Medicine University of Belgrade (hereinafter: School).

**Article 2**

The Ethics Committee for the Experimental Animals Welfare Protection (hereinafter: Ethics Committee) is made up of 7 members, as follows:

- Three representatives from the ranks of full-time academic staff of the Faculty;
- One representative of association, i.e. organization dedicated to protection of animal welfare;
- One doctor of veterinary medicine, specialized in veterinary surgery;
- One doctor of veterinary medicine in charge of protection of welfare of experimental animals at the Faculty of Medicine; and
- One expert in application of statistics in research.

At least one third of the Ethics Committee members may not be employed at the Faculty

**Article 3**

Ethics Committee members employed at the Faculty (representatives of the academic staff, veterinary doctor in charge of protection of welfare of experimental animals, and expert in application of statistics in research) are appointed by the Dean upon advice of Academic Staff Boards of pertinent departments.

Ethics Committee members are required to have pertinent scientific qualifications and experience in work with experimental animals.

**Article 4**

Upon request of the Faculty, the Dean shall appoint an Ethics Committee member representing associations, i.e. organization dedicated to protection of animal welfare proposed by an NGO pursuing animal protection.
Article 5

Upon request of the School, the Dean shall appoint an Ethics Committee member who is a doctor of veterinary medicine, specialized in veterinary surgery proposed by the Faculty of Veterinary Medicine, University of Belgrade.

Article 6

The Ethics Committee members are appointed for a 3 (three)-year term, and may be re-appointed.

Ethics Committee members shall elect a Chairperson and Vice-Chair from their own ranks.

Election of the Chairperson and Vice-Chair shall be accomplished by an open vote, and the candidate receiving over a half of the total number of members of the Ethics Committee for Experimental Animals Welfare Protection shall be deemed elected.

Article 7

The Ethics Committee Chairperson has the following rights and duties:

- To prepare, convene and chair the meetings;
- To propose the meeting agenda;
- To sign decisions, proposals/motions, conclusions, expert opinions and other documents;
- To sign annual reports.

Article 8

The Ethics Committee Vice-Chairperson has the following rights and duties:

- To substitute the Chairperson of the Ethics Committee for Experimental Animals Welfare Protection in case of his/her absence or inability to perform his/her duties, and for the duration of such substitution has the same rights and duties as the Chairperson of the Ethics Committee for Experimental Animals Welfare Protection;
- To assist the Chairperson in discharging his/her duties;
- To perform any task delegated by the Chairperson of the Ethics Committee for Experimental Animals Welfare Protection.

Article 9

Ethics Committee members have the following rights and duties:

- To attend the meetings and participate in discussion on the items on the agenda;
- To have access to documentation within the purview of the Ethics Committee for Experimental Animals Welfare Protection;
- To have access to documentation relating to the items on the agenda of Ethics Committee for Experimental Animals Welfare Protection;
- Not to disclose information they obtained at the meetings of the Ethics Committee for Experimental Animals Welfare Protection, which represent a business secret.

If a member of the Ethics Committee for Experimental Animals Welfare Protection is absent unjustifiably from three consecutive meetings, his/her membership shall be terminated.

Article 10

Ethics Committee mandate:
1) to establish the manner in which testing is conducted on animals, pursuant to the Law on Animal Welfare;
2) to provide expert monitoring of tests/experiments conducted on animals;
3) to organize training of persons conducting tests/experiments on animals;
4) to provide expert opinion to the Minister on ethical and scientific rationale for conducted/conducting tests/experiments;
5) to submit regular annual reports to the Minister.

Article 11
In fulfilling its mandate, the Ethics Committee for Experimental Animals Welfare Protection is guided by provisions of the Law and other secondary legislation governing this area, as well as pertinent scientific-research methods and procedures.

Article 12
Tests on animals for educational purposes may be conducted only if they do not inflict unnecessary pain, suffering, fear, distress, injury or death of animals.

At the undergraduate studies practical exercises are allowed if they do not violate life and welfare, i.e. physical, psychological and genetic integrity of animals.

Article 13
Ethics Committee is required to terminate any test without delay if provisions of the Law are violated in the course of such tests on animals, and notify the Ministry accordingly.

Article 14
Tests on animals may be performed pursuant to a decision approving tests on animals passed by the Minister upon expert opinion of the Ethics Committee for Experimental Animals Welfare Protection.

Article 15
Upon written request of a scientist/researcher, the Ethics Committee for Experimental Animals Welfare Protection is required to pass opinion on ethical and scientific justification of the test, in writing and within 15 (fifteen) working days.

Article 16
Upon advice of the Ethics Committee, the Faculty applies to the Ministry for approval of tests on animals, where such application contains the following information:

1) description of the research area formulated in a clear and unequivocal manner, to elucidate understandably the study purpose;
2) advantages and importance of the test, potential hazards and discomfort for experimental animals, as well as classification of severity, i.e. invasiveness of the test;
3) Detailed description of materials and methods to be used;
4) Proof of alternative methods to conduct the test and reasons why they are not used;
5) The total number of animals and their kind, by testing stages;
6) Types and doses of anesthetics and analgesics to be used;
7) Description of possible expected animal reactions;
8) Description of possible adverse effects of the tests on animals, severity and duration of such impacts, and methods to be undertaken to mitigate or prevent such impacts;
9) How the experimental animals will be deprived of life, if this is planned during or at the end of such tests;
10) Name of person in charge of experimental animals welfare protection and his/her qualifications;
11) Names of persons participating in the tests.

Notwithstanding paragraph 1 of this article, the decision referred to in paragraph 1 of this article shall be issued on the basis of opinion of the Ethics Council for Welfare of Experimental Animals.

**Article 17**

Application Form to be filed for approval of tests on animals, which is prescribed by the Minister, is enclosed to these Rules for information purposes as Annex 1.

**Article 18**

Documentation and opinions of Ethics Committee for Experimental Animals Welfare Protection and issued approvals for tests on animals shall be kept permanently for operational purposes.

**Article 19**

Ethics Committee is required to submit regular annual report to the Minister, which shall be stored with other documentation.

**Article 20**

Ethics Committee for Experimental Animals Welfare Protection discusses issues within its purview at regular meetings that are held at least quarterly (once in three months).

Chairperson of the Ethics Committee for Experimental Animals Welfare Protection convenes these meetings. In case of his temporary inconvenience, the Vice-Chairperson of Ethics Committee shall convene a meeting.

Invitations for meetings of the Ethics Committee for Experimental Animals Welfare Protection, as well as materials for the meetings should be furnished to the members no less than three days before the scheduled meeting. The materials for the meeting should be furnished to the committee members by regular mail or e-mail.

If necessary, the Chairperson of the Ethics Committee for Experimental Animals Welfare Protection may convene a meeting within a shorter term (less than three days). In these cases, the material for the meeting has to be forwarded by e-mail.

All issues not regulated by these Rules, when they pertain to mode or organizing and holding the Ethics Committee meetings, shall be regulated by direct application of provisions of the Rules of Procedure of the Academic Staff Board of the School of Medicine.

**Article 21**

The quorum necessary for deliberation and decision making of the Ethics Committee is set at the presence of over a half of the appointed members at the meeting.

At the meetings the members will vote by a show of hands (open vote).

A proposal shall be deemed adopted is majority of Ethics Committee members vote for it.

**Article 22**

Minutes shall be taken on Ethics Committee meeting/deliberations.
Minutes of the Ethics Committee for Experimental Animals Welfare Protection shall be kept by a person assigned by the dean, upon advice of the Ethics Committee.

The minutes shall include the number of the meeting, agenda, time and place of the meeting, list of present and absent Ethics Committee members, stating whether an absence is justified or not, and conclusion of discussion held by the items on the agenda.

The minutes shall include dissenting opinions of individual members of the Ethics Committee for Experimental Animals Welfare Protection.

**Article 23**

After the agenda is adopted, the meeting proceeds to adoption of the minutes from the previous meeting.

The meeting is adopted by an open vote. The minutes are deemed adopted if majority of the present members Ethics Committee approve it.

**Article 23a**

Administrative support to the Ethics Committee operations is provided by the logistics service appointed by the Dean

**Transitional and final provisions**

**Article 24**

These Rules come into force 8 (eight) days after they are posted on the School Bulletin Board and website.

These Rules supersede provisions of the Rules for the Use of Experimental Animals at the Faculty of Medicine in Belgrade of 25 March 2008 except for provisions relating to approvals for the use of experimental animals (article 11) which remain in force until the tasks in the are taken over by the line Ministry.

FACULTY OF MEDICINE
ACADEMIC STAFF BOARD
D E A N
Prof. dr Nebojša Lalić
APPLICATION FOR APPROVAL TO CONDUCT TESTS ON ANIMALS

Approval no: _______________________

APPLICATION FOR APPROVAL TO CONDUCT TESTS ON ANIMALS OR ANIMAL ORGANS AND TISSUES

PART I : DETAILS ON WORK WITH ANIMALS

1. STUDY TITLE:

2. KEY WORDS (up to 5 key words):
   1. 
   2. 
   3. 
   4. 
   5. 

3. PERSONS CONDUCTING TESTS

3.1. Responsible person

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<th>TITLE INITIALS:</th>
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QUALIFICATIONS:

TRAINING/EXPERIENCE:

ADDRESS AT WORKPLACE:

PHONE.: FAX: E-MAIL ADDRESS:

3.2. Other persons
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(Copy this page if more persons participate)
3.3. Person in charge of animal wellbeing and care

<table>
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<tr>
<th>FULL NAME:</th>
<th>TITLE:</th>
<th>TITLE INITIALS:</th>
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</table>

QUALIFICATIONS:

TRAINING / EXPERIENCE:

ADDRESS AT WORKPLACE:

PHONE.: FAX: E-MAIL ADDRESS:

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4. PLANNED DURATION OF TEST: From: to:

5. IS THIS A NEW TEST? YES/NO

5.1 IF NOT:

5.1.1 Decision number approving the previous test:

5.1.2 Previous test title (if different from the currently proposed)

5.1.3 Name of person previously conducting the test: (if different from the currently proposed)
1. **Test purpose (check with X):**

<table>
<thead>
<tr>
<th>Purpose</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Setting up breeding pairs of experimental animals which will not be used for testing, research, educations. Instead, their offspring may be used for such purposes.</td>
</tr>
<tr>
<td>1</td>
<td>Fundamental research relating to basic structure and functions of bodies, organs, tissues, cells, molecules...</td>
</tr>
<tr>
<td>2</td>
<td>Medical tests relating to health disorders and diseases, their causes, genesis, diagnostics, treatment, prevention, etc.</td>
</tr>
<tr>
<td>3</td>
<td>Studies of efficacy, toxicity, and safety of drugs, vaccines, biocide and other products used in human and veterinary medicine, plant protection, environmental protection, etc.</td>
</tr>
<tr>
<td>4</td>
<td>Developmental studies of new products which may be used in diagnostics and treatment of diseases in humans and animals, health protection of humans and environmental protection, etc.</td>
</tr>
<tr>
<td>5</td>
<td>Testing the quality of food for animals, food obtained from animals and products obtained from animals.</td>
</tr>
<tr>
<td>6</td>
<td>Education and training of students and experts in biomedical sciences.</td>
</tr>
</tbody>
</table>

5.3. **Categorize the level of invasiveness (circle appropriate category!):**

<table>
<thead>
<tr>
<th></th>
<th>A</th>
<th>B</th>
<th>C</th>
<th>D</th>
<th>E</th>
</tr>
</thead>
</table>

6. **TYPE AND NUMBER OF ANIMALS TO BE USED IN TESTS:**

| Common name of the species | | | | | |
|---------------------------|---|---|---|---|
| Latin name of the species | | | | |
| Race/strain, breed | | | | |
| Special name of the race/strain, breed | | | | |
| Sex | | | | |
| Age | | | | |
| Body weight | | | | |
| Origin (source of procurement) | | | | |
| Number during the 1st year of study | | | | |
| Number during the 2nd year of study | | | | |
| Number during the 3rd year of study | | | | |
| Total number for 3 years | | | | |

6.1. **Is the use of this species prohibited/restricted in any manner by a law or other regulation of the Republic of Serbia?**

   YES/NO
If YES, specify:

If YES, specify the number of animals exempted from the prohibition, i.e. restriction:

7. PLACEMENT AND CARE OF ANIMALS:

| Building: | ............................................... |
| Floor:    | ............................................... |
| Room:     | ............................................... |

7.1. Accommodation of animals during the testing:

7.2 Person in charge of daily animal care: (who can be contacted after working hours and during weekends)

| Full name: | .......................................................................................................................... |
| Title/position: | .......................................................................................................................... |
| Phone at work: | ........................................... Phone at home:.............. Mobile................................. |

7.3. Mode of placement of animals during testing (check with X):

<table>
<thead>
<tr>
<th>Laboratory conditions</th>
<th>Farm conditions</th>
<th>Vivarium</th>
</tr>
</thead>
<tbody>
<tr>
<td>Floor system - individual</td>
<td>Floor system - individual</td>
<td>Floor system - individual</td>
</tr>
<tr>
<td>Floor system - group</td>
<td>Floor system - group</td>
<td>Floor system - group</td>
</tr>
<tr>
<td>Cage system - individual</td>
<td>Cage system - individual</td>
<td>Cage system - individual</td>
</tr>
<tr>
<td>Cage system - group</td>
<td>Cage system - group</td>
<td>Cage system - group</td>
</tr>
<tr>
<td>Individual pen</td>
<td>Individual pen</td>
<td>Individual pen</td>
</tr>
<tr>
<td>Group pen</td>
<td>Group pen</td>
<td>Group pen</td>
</tr>
<tr>
<td>Shoe box cage</td>
<td>Box</td>
<td>Box</td>
</tr>
<tr>
<td>Tub</td>
<td>Tub</td>
<td>Tub</td>
</tr>
<tr>
<td>Pool</td>
<td>Pool</td>
<td>Pool</td>
</tr>
<tr>
<td>Fish-farm</td>
<td>Fish-farm</td>
<td>Fish-farm</td>
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<tr>
<td>Other (specify)</td>
<td>Other (specify)</td>
<td>Other (specify)</td>
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</tbody>
</table>

7.4. Testing is conducted at (institution, organizational unit, department) specify:
7.5. Monitoring of health and wellbeing of animals intended for testing during the day, on weekends and holidays (specify how many times a day the animals are observed for change in health and behavior, at what times, and how their health and wellbeing are monitored during weekends and holidays).

8. PURPOSE OF ANIMAL TESTING (describe briefly in up to 50 words)

8.1. Description of test design in language understandable to lay persons

9. RATIONALE FOR THE USE OF ANIMALS (describe briefly in up to 50 words)
10. ARE YOU AWARE OF ANY ALTERNATIVE FOR THIS TEST?  

YES  NO

11. LIST 5 REFERENCES OF FOREIGN AUTHORS WHO PUBLISHED RESULTS OF SIMILAR STUDIES AND SUBMIT COPIES OF THESE PUBLICATIONS WITH THE FORM ORIGINAL.
12. ILLUSTRATE THE ANIMAL TEST ALGORITHM/FLOWCHART (control group, experimental group, mode of treatment, applied substances, mode of application, and everything else that is relevant for the test)
13. **TEST PURPOSE**

13.1 Main purpose of the test (check, x)?

- research
- treatment
- training

(check one)

Ancillary means for physiological function

Investigational product (drug/vaccine/biocide/food/produce/other products)

13.2. For which area of study is the test relevant or in which area it may be applicable

(choose one)

- conservation / ecology
- veterinary medicine
- fundamental biology
- Agriculture (husbandry, features, production)
- medicine/stomatolog(y)
- other (specify !)

14. **AREA OF RESEARCH**

(check only one)

- behavior
- malignant diseases
- study of drugs/biocides
- gastrointestinal system
- immunology
- skeleton/muscular system
- oral biology
- reproduction
- biological materials
- cardiovascular system/blood
- ecology
- genetics/genetic manipulations
- Communicable disease
- neurobiology/senses
- parasitology
- respiratory system
- developmental biology
- endocrinology
- growth
- molecular biology
- nutrition
- Renal function
- toxicology
- other (specify !)

15. **SPECIES**

- mouse
- cat
- sheep
- wild animal/mammal
- rat
- dog
- pig
- bird
- rabbit/hare
- horse
- cattle
- Amphibian/reptile
- guinea pig
- primate
- fish
- goat
- cephalopods
- Other species (specify !)

16. **STUDY CATEGORY**

16.1. Are the studies conducted ?

- A. for observation of animals in nature, at their own habitat, zoological gardens, farms, etc.
- B. on animals previously deprived of life for sampling of blood, lymph, CSF and solid tissues for growing cultures of tissues, cells or for isolation and study of organs *in vitro*
- C. on animals in general anesthesia without recovery upon completion of test
- D. on animals which will remain alive after testing which did not induce stress in these animals (application of non-toxic and other harmless substances, venepunction, brief restraint of animals, submitting animals to deprivation of food and water within the limits of physiological endurance, etc.)
- E. on animals which will remain alive after testing based on minimum level of brief stress (cannulation of blood vessels on anesthetized animals, administration of pharmacological substances, laparoscopy, brief restraint of wild animals, submitting animals to deprivation of food and water beyond the limits of etc.)
- F. on animals which will remain alive after testing which induce substantial stress or chronic stress (after major surgical interventions, induced changes in animal behavior by way of biological, physical or chemical means, extended restraint of animals, application of toxic or other substances that inflict pain, etc.)
16.2. Specify the level of test invasiveness

(check only one)

- algesia
- genetic manipulation
- neoplasms
- behavioral deprivation
- social isolation
- inducing communicable disease
- Inducing parasitic disease
- applying toxic substances
- applying pyrogenic substances
- teratogenicity
- bodily injury
- amputation
- Removing whole organs or their parts
- radiation
- Intervention on fetuses
- qualitatively improper diet
- quantitatively improper diet
- water deprivation
- other (specify)

17. DOES THE TEST AFFECT STRUCTURE OR FUNCTION OF ANIMAL BODY?

18. DOES THE TEST REQUIRE THE USE OF ANESTHETICS?

19. IF YES, SPECIFY:

(a) type of anesthetic, dosage, mode of administration:
(b) how long the animals will be observed in general anesthesia?

20. DOES THE TEST REQUIRE THE USE OF ANALGESICS?

21. IF YES, SPECIFY:

(a) type of analgesic, dosage, mode of administration:
(b) for which part of the test the analgesic is administered and how long does its effect last?
(c) person administering the analgesic:
(d) reason why the analgesic is administered:

22. Observation of animal recovery, occurrence of pain and symptoms of stress

(a) how frequently will animals be observed/checked after the test?
(b) which signs will be monitored?
(c) person in charge of monitoring pain and stress after the test:

23. IMPACT OF TEST ON ANIMALS (check one)

- Complete recovery
- Partial recovery
- Deprivation of life

24. TREATMENT OF ANIMAL SURVIVING THE TEST

- Finding a home
- Returning to original breeding site
25. IF THE ANIMAL IS DEPRIVED OF LIFE SPECIFY HOW


26. IF A PHYSICAL METHOD IS USED FOR DEPRIVATION OF LIFE, SPECIFY WHICH AND WHY (up to 50 words)


27. DOES THE TEST CARRY RISK FOR PERSON(S) CONDUCTING IT AND OTHER STAFF?

| YES | NO |

If it carries a risk, which measures will be undertaken to reduce or prevent the risk?


28. MODE OF DISPOSAL OF DECEASED OR KILLED ANIMALS (describe in up to 50 words)


29. MODE OF DISPOSAL OF OTHER TEST MATERIALS (describe in up to 50 words)


ANIMALS TO WHICH APPLICATION FOR APPROVAL TO CONDUCT TESTING APPLIES

ANIMALS FOR WHICH APPROVAL IS REQUIRED

Application for approval to conduct tests is required for the following classes of animals:
1. All vertebrates, including fish to be used in research, testing and for educational purposes
2. cephalopods (octopus, cuttlefish)
3. all animals caught for whatever reason
4. all animals caught to be marked, to take body measurements, or samples of fluids and tissues,
5. animals hunted
6. protected, endangered and rare species

ANIMALS FOR WHICH APPROVAL IS NOT REQUIRED

Application for approval to conduct tests is not required for the following classes of animals:
1. all invertebrates
2. all invertebrates that are not cephalopods
3. dead animals which are not deprived of life for research purposes
4. eggs, embryos, larvae, except for larvae of fish expected to develop completely to adult fish
5. animals observed at natural habitat, reservations, zoological gardens, without any manipulation of animas.
6. test animals grown in laboratory conditions for reproduction
7. domestic animals kept under standard conditions
8. animals with known owners, undergoing treatment if they are used for teaching purposes with students
9. animals deprived of life or slaughtered for commercial reasons
10. fish from fish-farms used for stocking other waters with fish
11. fish caught to establish the size of population, migrations, etc.
12. fish caught /sampled already dead (disease, poisoning…)