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în Domeniul Patologiei și Științelor Biomedicale
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Ethical and Legal Consultancy for Laboratory Animal Experiments

1. Service Objective

Assessment of the ethical and legal compliance of experimental protocols involving the use of laboratory mice, together with support in preparing the documentation required to obtain the approvals and authorizations set out in national and European legislation on the protection of animals used for scientific purposes.

2. Applicable Legal Framework

Law No. 43/2014 on the protection of animals used for scientific purposes, republished, as subsequently amended and supplemented.
Order No. 97/2015 on the Methodological Norms of application, approved by order of the National Sanitary Veterinary and Food Safety Authority (ANSVSA), concerning the authorization of user establishments and experimental projects, as subsequently amended and supplemented.
Directive 2010/63/EU of the European Parliament and of the Council on the protection of animals used for scientific purposes, as subsequently amended and supplemented.
The 3R Principle (Replacement, Reduction, Refinement), applied as a mandatory ethical standard in the design and evaluation of animal experiments.

3. Methodology

Analysis of the experimental protocol submitted by the client, identifying the species, number of animals, procedures applied, and the estimated severity level (mild, moderate, severe, non-recovery).
Verification of the application of the 3R principle: possibilities for replacing the animal model, reducing the number of animals through appropriate statistical design, and refining procedures to minimize pain, suffering, and stress.
Assessment of the housing, care, and welfare conditions of the animals (space, enriched environment, qualified staff, veterinary supervision), in accordance with applicable legal requirements.
Verification of the existence and quality of the required documentation: the operating authorization of the user establishment, and the documentation prepared for requesting the approval of the institution's Research Ethics Committee or the authorization of the project by the competent authority.
Drafting of comments and recommendations regarding the compliance of the protocol, as well as, upon request, support in completing the forms required to apply for approval/authorization of the project.

4. Deliverables

Ethical and legal compliance report, including the analysis of the experimental protocol, the assessment of the application of the 3R principle, the identification of any non-conformities and the necessary recommendations, as well as a checklist of the documents required to obtain the approvals and authorizations.

5. Estimated Duration

Approximately 10 working days from receipt of the complete experimental protocol and related documentation.

6. Estimated Budget– analysis and consultancy for one experimental protocol: 250 Euro

7. Terms and Conditions

The experimental protocol and related documentation (information on the species, number of animals, procedures applied, Ethics Committee approval, relevant forms) will be made available by the client before the analysis begins.

The consultancy report is advisory in nature and does not replace the approval or authorization issued by the competent authorities (the Research Ethics Committee, the competent authority), which remain the only bodies empowered to approve the experimental project.