GUIDELINES FOR THE OPERATION OF THE ANIMAL WELFARE BODY (OpBA) OF THE HUMAN TECHNOPOLE FOUNDATION

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Indice

1) Object

These guidelines regulate the operation of the Animal Welfare Body (OpBA) of the Human Technopole Foundation in accordance with the provisions of Legislative Decree No. 26 of March 4, 2014, which implements Directive 2010/63/EU on the protection of animals used for scientific purposes. The primary function of the OpBA is to ensure the welfare of animals used for scientific purposes and to promote and monitor full compliance with the current regulations on this matter.

In particular, the OpBA performs the following tasks:

a) Advises personnel responsible for animal care on matters relating to their welfare, including acquisition, housing, care, and use;

b) Provides guidance to personnel on applying the 3Rs principle (Replacement, Reduction, Refinement), keeping them informed of technical and scientific developments, and promoting their professional development and education in the field;

c) Defines and reviews internal operational processes for monitoring, communication, and verification related to the welfare of animals housed or used at the facility;

d) Issues reasoned opinions on research projects and any subsequent modifications, notifying the project leader;

e) Submits research project authorization requests to the Ministry of Health, while keeping the project leader informed;

f) Monitors the development and outcomes of research projects, taking into account the effects on the animals used, and identifying and advising on further elements to support the principles of Replacement, Reduction, and Refinement;

g) Provides advice on rehoming programs, including the appropriate socialization of animals that are to be rehomed.

The OpBA of the Human Technopole Foundation also performs the following additional activities:

h) Records consultations and decisions in registers made available to the competent authority and ensures their retention for at least six years.

[1] For the purpose of issuing a reasoned opinion, the OPBA evaluates:

- the correct application of the current decree;
- the technical-scientific relevance of the project;
- the obligations deriving from European and international regulations or pharmacopoeias regarding the development and safety -of drugs and toxicological tests related to chemical and natural substances;
- the possibility of replacing one or more procedures with alternative methods;
- the adequate training and appropriateness of the professional roles of the personnel involved in the project;
- the harm/benefit assessment.

2) Definitions

The following definitions are adopted from Legislative Decree No. 26/2014 in force at the time of approval of these guidelines. In case of subsequent legislative amendments or additions, reference shall be made to the definitions contained in the newest version of the legal text.

“Animal Welfare Body”: As described in Article 25 of Legislative Decree No. 26/2014, which must consist of at least the person or persons responsible for the welfare and care of the animals (Animal Welfare Officer), the designated veterinarian as described under Article 24 of Legislative Decree No. 26/2014, and a scientific member;

“Animal Welfare Officer”: The individual responsible for the welfare and care of the animals and for the correct operation of the equipment, across one or more establishments;

“Designated Veterinarian”: A veterinarian specializing in laboratory animal medicine, with specific training and experience, responsible for prescribing methods for the welfare and treatment of animals;

“User”: A physical or legal person authorized to operate an establishment where procedures are carried out, whether for profit or not;

“Breeder”: A physical or legal person authorized to breed the animals listed in Annex I of Legislative Decree No. 26/2014 for use in procedures or to supply their organs or tissues for scientific purposes or to breed other animals primarily for such purposes, whether for profit or not;

“Research Project Leader” The individual authorized to manage the research project, responsible for the procedures and projects, as well as for their administrative and scientific aspects;

“Scientific Member”: A researcher or scientist, theoretical or technical, in various fields of scientific investigation, who belongs to the scientific community and communicates the results of their work through publications.

3) Regulatory references

- Legislative Decree No. 26 of March 4, 2014, implementing Directive 2010/63/EU on the protection of animals used for scientific purposes”;
- Ministerial Decree (DM) of August 5, 2021, regarding training for staff involved in tasks and functions under Article 23, paragraph 2, of Legislative Decree No. 26/2014, related to the protection of animals used for scientific purposes.

4) Appointment and Composition

1. The OpBA of the Human Technopole Foundation is composed of at least:

- The animal welfare officer, as described under Article 3, paragraph 1, letter (h), and Article 22, paragraph 3, of Legislative Decree No. 26/2014;
- The designated veterinarian, as described under Article 24 of Legislative Decree No. 26/2014;
- One scientific member as described under Article 3, paragraph 1, letter (i), of Legislative Decree No. 26/2014.

The Head of the Preclinical Research Facility is an ex-officio member of the OpBA, serving as its President. If absent, the President may delegate functions to another OpBA member.

2. The OpBA is appointed by the Director of the Foundation.
3. The OpBA can consult external experts to delve deeper into specific issues or assess particular aspects of research projects.
4. Each OpBA member performs their duties with confidentiality, ensuring no conflicts of interest.
5. Any OpBA member involved in a research project being evaluated is excluded from voting on matters related to that project.
6. The President or a delegated member records the meeting minutes, which must be approved by a majority of the present members.

5) Operation

1. The President convenes OpBA meetings via email at least five days before the meeting date.
2. The OpBA meets at least every two months or with a frequency necessary to perform its duties.
3. Meetings are valid if the majority of members are present. However, if research project evaluations are on the agenda, the presence of the Chair or delegate, the Animal Welfare Officer, and the designated veterinarian is mandatory for the meeting's validity.
4. Members who miss three meetings without justification in a calendar year, barring serious and proven reasons submitted in writing and evaluated by the Chair, are considered to have resigned and are replaced by the Director.
5. Decisions are made by a majority vote of the members present.
6. Meetings are held at the Foundation’s headquarters, though remote participation is permitted if members can be properly identified and are able to follow and participate in discussions in real-time.