

National charter on the ethics of animal experimentation *

PREAMBULE

Given that animals are sensitive beings, capable of suffering, with cognitive and emotional functions and physiological and behavioural specific needs for each species;

given that an alternative method avoiding the use of animals for research, teaching and development of regulatory tests is not always available;

given that in all experimental activities, man should do more than simply apply the animal protection regulations to animals used for experimental and other scientific purposes;

given that, in response to this need, ethical committees for animal experimentation have been created in public and private establishments and that such committees should be more generally established according to common principles;

given that these committees must take into account the principles of the charter as described in article R214-122 of the rural code to formulate their recommendations;

the Comité National de Réflexion Ethique sur l'Expérimentation Animale (French national committee for consideration of ethics in animal experimentation) proposes the following Charter to serve as a reference for researchers and their collaborators as well as institutions and ethical committees.

Article 1 : Respect for the animal

The ethics of animal experimentation is based on the duty that Man has to respect animals as living and sensitive beings.

Article 2 : Individual responsibility

Any use of an animal for experimentation involves the moral responsibility of each person implied.

Article 3 : Responsibility of institutions

The institutions are morally responsible for experiments carried out on animals in their establishments.

Article 4 : Skills

This responsibility involves, at all levels of intervention, an ethical training and regulatory scientific and technical skills proper to the species used and regularly updated.

Experts with specialised skills in physiology, ethology or medicine should be sought whenever necessary for the animals concerned.

Article 5 : General Principles

Careful consideration of a sound scientific, ethical and societal basis justifying the use of the animal must precede any experimental procedure.

The use of methods and techniques aiming to eliminate or reduce to an absolute minimum the suffering of animals must be considered systematically. The development and promotion of such methods must be encouraged.

Optimisation of living conditions, accommodation and care of the animals used must be permanent and continued throughout the animal's life.

The recommendation of an ethical committee must be sought before any experiment on animals

Article 6 : Ethical procedure

The use of animals for any experimental procedure must be preceded by careful consideration of:

- the usefulness of the planned experiment with respect to studies performed by others;

- the pertinence of the chosen methods and the probability of them yielding tangible results;
- the lack of alternative methods to achieve the same goal;
- the adequacy between the animal models envisaged and the scientific objectives;
- the extent of animal suffering relative to the expected benefit from the results;
- the biological and cognitive characteristics of the species concerned;
- the need to ensure that the choice of species, in the case of nondomesticated animals, does not threaten biodiversity;
- limiting to a minimum the number of animals required;
- the choice of living conditions, accommodation, care and use of animals, such that their physiological and behavioural needs are respected as much as possible.

Article 7 : The role of the ethical committees

Each ethical committee serves to ensure discussion and consideration of issues.

It gives recommendations on the use of animals in research projects submitted to it, referring to the principles stated in this Charter.

These recommendations are justified and can include additional recommendations.

Each ethical committee contributes to the promotion of the ethical principles laid out in this Charter.

Article 8 : Composition of ethical committees

Each ethical committee brings together multidisciplinary skills, to issue competent advices. Civil society (lay members) and veterinary medicine are represented.

Article 9 : Professional conduct of the ethical committees

Any ethical committee must be independent, impartial and must guarantee confidentiality of documents submitted to it.

It must take into account the advice or recommendations of the *Comité National de Réflexion éthique sur l'Expérimentation animale*.

Annexe

Ethical committees for animal experimentation

The ethical committees for animal experimentation are consulting bodies, with the objective of promoting ethical principles and practices in animal experimentation.

In this annexe, the Comité national de réflexion éthique sur l'expérimentation animale (the French national committee for consideration of ethics in animal experimentation) proposes to these committees, researchers and institutions on which they are dependent, ways of applying their national Charter on the ethics of animal experimentation (the Charter).

I - RÔLE

The fundamental role of an ethical committee, defined by article 7, is to provide recommendations to all researchers intending to undertake experiments on living vertebrate animals, according to current legislation. Article 7 also indicates that ethical committees must promote the principles formulated in the Charter.

All animal experimentation establishments must refer to one, and only one, ethical committee. Several establishments may depend on the same committee by associating with each other to create a joint committee

II - STRUCTURE

The composition and organisation of an ethical committee must ensure its essential **reliability**.

To achieve this, they require:

- A multidisciplinary representation allowing expression of the diverse views. For this purpose, an ethical committee must be composed of, at least:

- A researcher,
- An individual undertaking the experiments,
- An individual involved in housing and caring for animals,
- A veterinary surgeon,
- An individual external to the animal experimentation establishment(s) and who demonstrates real interest in animal protection

- competence appropriate in the area of activity of animal experimentation establishment(s) referring to the committee. If necessary, the committee can call upon the skills of persons external to the establishment,

- the obligation of its members to respect the strict confidentiality of discussions and submitted experimental projects,

- methodical analyses based on both scientific knowledge and ethical issues,

- the independence and impartiality necessary to justify and freely arrive at recommendations; this requires that its members are voluntary and that they may not receive remuneration specifically for this function.

III - FUNCTIONNING

The institutions to which the animal experimentation establishments are associated will give the committees the means necessary to fulfil their role.

An ethical committee must respect time delays for responses, compatible with the requirements of the research activity. The operating procedures guaranteeing this rapidity of response are the responsibility of each committee.

a) Ethical assessment

The ethical assessment of projects aims to guarantee that the studies are carried out in the best conditions possible for the animals, on the basis of current knowledge.

The **experimenter** contacts the ethical committee, submitting a dossier which contains the necessary and sufficient elements for rigorous evaluation of the project.

A project must be comprised of, at least, a scientific aim, an animal model, one or more experimental protocols and for each protocol methods describing how results will be obtained.

For ethical **assessment** of a project, the committee analyses the scientific aim to determine the ethical acceptability of the choice of model, the protocol and the methods involved. However, the committees must in no way replace the scientific committees of these establishments.

The ethical assessment is based on various aspects of the experiment:

- preparation of the animal,
- the choice and development of the animal model as well as its use,
- the experimental protocol, which must take into account the sensitivity of the animals as well as species-specific constraints and clearly describe the impact of experimental procedures on the physiological and psychological state of the animals,
- steps causing pain and human end-points are identified in the protocol and measures planned for the prevention and management, or elimination, of the pain are documented on the basis of established references, whenever possible,
- the use of appropriate statistical tools and analytical techniques, which must allow optimisation of the experimental methods used and to generate the maximum number of interpretable results.

The **recommendations** of a committee have, in principle, a maximum validity of three years; the committee should therefore be consulted every three years, even if no operational changes have been made to a continuing project. This new consultation partly involves a retrospective assessment which must be presented by the experimenter in the new dossier, and partly checking if new procedures have become available since the previous submission, which could allow the interventions carried out on the animals to be made more ethical, or even replaced by alternative methods.

The **experimenters** and **animal experimentation establishments** are responsible for monitoring the practice of these protocols.

b) Delegated ethical assessment

The ethical committee may delegate a part of the ethical assessment for which it is responsible to a local subcommittee specific to each of its animal experimentation establishments.

This delegation is only permitted in the following cases:

- when only small changes have been made to a protocol, which had already received a favourable opinion from the ethical committee,
- when the planned protocols are standardised, regulated, managed by a code of good professional conduct or when they do not cause pain to the animal (blood sampling, euthanasia using techniques recognised by the ethical committee).

This local subcommittee must have:

- scientific expertise (adequate for the areas of activity of the animal experimentation establishment concerned)
- scientific and technical skills concerning rearing, housing and caring for laboratory animals.

The local subcommittee can only act within the framework of a mission letter from the ethical committee, delegating this part of the assessment. The mission letter details the modes of function, notably concerning the fields of intervention and the activity reports that the unit must issue regularly to the ethical committee.

c) Participation in the promotion of ethical principles

The ethical committees participate in the promotion of ethical principles described in the Charter, and in particular of those laid out below:

- the ethical use of animals for experimental purposes involves optimisation of living conditions, housing and care of animals, notably in line with existing codes of good practice or recommendations and using one-off or continuous input from the expertise of animal specialists as necessary. This should be maintained for the duration of the experiment and for the lifetime of the animal,
- any experimentation involving animals must focus on developing methods aimed at reducing, or avoiding, their use and the related constraints.

The committees should share the knowledge and experience gained on the subject as widely as possible, including cases in which the results are not published.

IV - RELATIONSHIP WITH THE *COMITÉ NATIONAL DE RÉFLEXION ÉTHIQUE SUR L'EXPÉRIMENTATION ANIMALE* (THE FRENCH NATIONAL COMMITTEE FOR CONSIDERATION OF ETHICS IN ANIMAL EXPERIMENTATION)

"Any ethical committee for animal experimentation created by the initiative of a public or private organisation and responsible for giving recommendations on the conditions of use of the animals for experimental purposes, or other scientific purposes, must take into account the principles set out in the charter when issuing their recommendations..." Rural code R 214-124.

Each committee should state its commitment to applying the principles of the national Charter to the secretariat of the national Committee (Minister of higher education and research, DGRI, A4, 1 rue Descartes, 75231 Paris Cedex 5) in the form of declared membership signed by its president. This should detail the composition of the committee and the establishments attached to it, and should contain the following information:

- Name of the committee
- Name of the president and contact details
- The title of the animal experimentation establishment (s) attached to the committee (accreditation number(s))
- Number of individuals representative of each of the five categories mentioned in chapter II of the current annex
- Date that the committee was created
- Number of activities delegated to local subcommittees
- Internal rules, where necessary.

These data are strictly confidential and will be kept by the secretariat of the national Committee; they will not be given out under any circumstances.

The ethical committees will inform the *Comité national de réflexion éthique sur l'expérimentation animale*, of any progress they observe that may improve animal wellbeing or reduce, or avoid, the constraints on laboratory animals.

The ethical committees are committed to take into account the recommendations provided by the national Committee concerning subjects relating to animal experimentation.