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, and researchers and institutions on which they are dependent, ways of applying their national charter on the ethics of animal experimentation.

I – Role

The fundamental role of an ethical committee, defined by article 7 of the charter, is to issue recommendations to all researchers intending to undertake experiments requiring, according to current legislation, the use of living vertebrate animals. Article 7 also indicates that ethical committees must promote the principles set out in the charter.

All animal experimentation establishments must have 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 indispensable reliability.

To achieve this, they require:

- a multidisciplinary representation allowing expression of the diversity of views. To this end, an ethical committee must be composed of, at least:
  - A researcher,
  - An individual observing or attending 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 has a demonstrated interest in animal protection

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

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

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 methods describing how results will be obtained for each protocol.

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 should be 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 limits should be identified in the protocol and measures planned for the prevention and management, or elimination, of the discomfort should be documented on the basis, whenever possible, of established references,
- the use of appropriate statistical tools and analytical techniques, which must allow optimisation of the experimental methods used and the generation of 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 discomfort 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 competence 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 the 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 codes of good practice or existing 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 experimental procedure involving animals must make use of 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)

"All ethical committees for animal experimentation created at the initiative of a public or private organisation and responsible for giving recommendations on the conditions of animal use 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 a declaration of 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 cited in chapter II of the current annexe
- The 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 well-being 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.