5. Animals

This section refers to projects with research activities involving animals.

Animal welfare is a value of the Union (Article 13 of the TFEU). Animals have an intrinsic value which must be respected and they must be treated as sentient creatures. As a consequence, one of the main aims of Directive 2010/63 is to improve the welfare of animals used in scientific procedures, taking into account that new scientific knowledge is available in respect of factors influencing animal welfare as well as the capacity of animals to sense and express pain, suffering, distress and lasting harm.

5.1 Ethics issues checklist

Section 5: ANIMALS		YES/NO		Information to be provided in the proposal	Documents to be provided on request
Does your activity involve animals?		☐	☐	1) Details on the numbers of animals to be used, nature of the experiments, procedures and techniques to be used. 2) Details on species and rationale for their use. 3) Details on procedures to ensure animal welfare. 4) Details on implementation of the 3Rs Principle.	1) Copies of all appropriate authorisations for the supply of animals and the project experiments. 2) Copies of training certificates/ personal licences of the staff involved in animal experiments.
If **YES**:	Are they vertebrates?	☐	☐	Same information as above.	Same documents as above.
	Are they non-human primates (NHP) (e.g. monkeys, chimpanzees, gorillas, etc.)?	☐	☐	Same information as above plus: 1) Justification on why NHPs are the only research subjects suitable for achieving your scientific objectives. 2) Details on the purpose of the animal testing. 3) Details on the origin of the animals.	Same documents as above plus: 1) Personal history file of NHP *(See art. 31 of Directive 2010/63)*.
	Are they genetically modified?	☐	☐	1) Number of	1) Copies of all

				animals to be used, nature of the experiments, procedures, anticipated impact and how this will be minimised. 2) Details on species and rationale for their use. 3) Details on procedures to ensure animal welfare. 4) Details on implementation of the 3Rs Principle.	appropriate authorisations for the supply of animals and the project experiments. 2) Copies of training certificates/ personal licences of the staff involved in animal experiments.
	Are they cloned farm animals?	☐	☐	*Same information as above.*	1) Copies of all appropriate authorisations for the supply of animals and the project experiments. 2) Copies of training certificates/ personal licences of the staff involved in animal experiments. 3) Copies of authorisations for cloning (if required).
	Are they an endangered species?	☐	☐	1) Justification on why there is no alternative to using this species. 2) Details on the purpose of the research.	1) Copies of authorisations for supply of endangered animal species (including CITES) and the project experiments. 2) Copies of training certificates/ personal licences of the staff involved in animal experiments..

5.2 How do I deal with the issues?

Your research activities must comply with the ethics provisions set out in the Grant Agreement, and notably:

- highest ethical standards

– applicable international, EU and national law (in particular, EU Directive 2010/63).

This Directive is designed to limiting the use of animal testing for scientific purposes. It sets out EU-wide animal welfare standards (including authorisations, restrictions on the use of certain kinds of animals, standards for procedures, minimum requirements for personnel, recording and traceability, care and accommodation).

⚠ Some EU Member States have stricter rules.

This means that you must choose alternatives to animal use where possible and implement the principles of **replacement**, **reduction** and **refinement** ('**three Rs**').

Replacement — replacing animal use by an alternative method or testing strategy (without use of live animals).

Examples:

'Higher' animals can be replaced by 'lower' animals: microorganisms, plants, eggs, reptiles, amphibians, and invertebrates may be used in some studies to replace warm-blooded animals.

Live animals may be replaced by non-animal models, such as dummies for an introduction to dissection for teaching the structure of the animal or the human body, mechanical or computer models, audio-visual aids, or in vitro modelling.

Reduction — reducing the number of animals used.

Refinement — improving the breeding, accommodation and care of animals and the methods used to minimise pain, suffering, distress or lasting harm to animals.

Moreover, you must obtain:

– the necessary authorisations for the supply of animals and the animal experiments (and other specific authorisations, if applicable).

⚠ You must obtain all relevant national authorisations before you can start to use animals.

Specific cases

Non-human primates (NHPs) — Since non-human primates are so close to human beings, their use in experiments raises particular ethics concerns. Directive 2010/63 sets strict limits to their use: They may be used only for specific research purposes (of primary importance) and only if there is no alternative *(art. 8)*. Moreover, only offspring of non-human primates which have been bred in captivity or which are sourced from self-sustaining colonies may be used *(art. 10)*.

⚠ The use of great apes requires very exceptional justification and must be specifically authorised by the granting authority.

Endangered species — Endangered species cannot be used, except for very important research purposes and where there is no alternative non-endangered species that will meet the scientific objective *(art. 7 Directive 2010/63/EU)*.

In this case, you should follow agreed international practices (CITES).

5.3 What do you need to provide?

If your proposal raises one of the issues listed in the ethics issue checklist above, you must complete the **ethics self-assessment** in **Part A** of your proposal.

Your grant proposal must include the **information** referred to in the ethics issues checklist and any of the **documents** already available. Documents that are not submitted together with the proposal should be kept on file and may have to be provided later on, if requested by the granting authority.

Background documents & further reading

General

EU Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes (OJ L 276, 20.10.2010, p. 33).

The ARRIVE Guidelines — Animal Research: Reporting In Vivo Experiments. Festing MFW, Overend P, Gaines Das R, Cortina Borja M, Berdoy M (2002), *The design of animal experiments: reducing the number of animals in research through better experimental design*, Laboratory Animal Handbooks Series, 14. London: Royal Society of Medicine Press.

Hooijmans C. *et al*. (2010), *A gold standard publication checklist to improve the quality of animal studies, to fully integrate the Three Rs, and to make a systematic review more feasible*, ATLA 38: 167-182.

For alternatives to animal testing, refer to the following website: https://ecvam.jrc.it/

Research on animals

Research on animals

Endangered species

CITES