



Ethical Framework for Obtaining Material from Sentient Animals

User Guide

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Introduction

The Ethical Framework for Obtaining Material from Sentient Animals has been created to enable organisations to create their own benchmarked and standardised approaches to ethical assessment ahead of the acquisition of materials from sentient animals. It is intended to supplement, not replace, required ethical review defined in any relevant legislation, for example, the UK Animals (Scientific Procedures) Act (ASPA), or when obtaining a Veterinary Medicines Directorate (VMD) Animal Test Certificate. It is hoped that Animal Welfare and Ethical Review Bodies (AWERBs), Research Ethics Committees (RECs), Institutional Animal Care and Use Committees (IACUCs), governance/ethics functions, research managers, and other supporting teams, will find the Framework helpful for creating/revising policies and processes which support users of animal materials at their organisations.

Except where specified, the ethical assessment process described in each section is in reference to the acquisition of **material obtained from handling animals' bodies**, whether that is by personnel from the recipient organisation or via a third party. This material is usually composed of, or includes, animal cells.

Sentience in these documents is as described in the UK Animal Welfare (Sentience) Act 2022 and is also taken here to include animals protected under the Animals (Scientific Procedures) Act (ASPA). The combination of species from both pieces of legislation provides the definition of sentience for this Framework, to include:

any vertebrate other than *Homo sapiens*,
any cephalopod mollusc, and
any decapod crustacean.

The Framework is intended to provide guidance to any organisation which may acquire this material, including research and educational establishments, as well as commercial organisations. It is intended as a practical tool around which organisations can frame their own policies, processes and checklists, freely building on the Framework to add additional requirements suited to the individual needs of their organisation, if they wish to do so. The Framework will be regularly reviewed, and it is hoped that its development will be an iterative process drawing upon the experience and expertise of those organisations that use it.

Alignment to the Framework simply means that organisations can be assured that their ethical assessments are benchmarked against those of similar entities, fostering greater assurance and consistency in ethical decision-making.

It is not expected that by adopting this Framework, organisations' AWERBs, AWBs, IACUCs,

RECs or similar committees will take on additional tasks, as organisations remain free to determine that the ethical assessments described as 'Requirements' in this Framework can be undertaken by relevant individuals within, for example, research ethics, research governance, or other teams, however, they may decide that existing committee structures and processes will support this work.

The purpose of this Guidance document is to provide an outline to the structure of the Ethical Framework and to define the terms used.

Table: Glossary of Abbreviations

ABS	Access and Benefit Sharing
APHA	Animal and Plant Health Agency (UK)
ASPA	Animals (Scientific Procedures) Act (UK)
ASRU	Animals in Science Regulation Unit (UK, Home Office)
AWERB/AWB	Animal Welfare and Ethical Review Body/Animal Welfare Body
BIAZA	British and Irish Association of Zoos and Aquariums
CITES	Convention on International Trade in Endangered Species
DEFRA	Department for Environment, Food and Rural Affairs (UK)
IACUC	Institutional Animal Care and Use Committee
NC3Rs	National Centre for the Replacement, Reduction and Refinement of Animals in Research (UK)
OIE	World Organisation for Animal Health, formerly Office International des Epizooties
POLE	Places Other than Licensed Establishments (UK)
REC	Research Ethics Committee
RCVS	Royal College of Veterinary Surgeons (UK)
RSPCA	Royal Society for the Prevention of Cruelty to Animals (UK)
WAZA	World Association of Zoos and Aquariums

Definitions

Collaboration: The transfer of material within a partnership, which may include transfer across national boundaries, that is not commissioned/outsourced work.

Commissioning/outsourcing: Work directed/initiated by one organisation (Organisation A), where animals have been bred, kept or killed at another organisation (Organisation B) specifically for the commissioning organisation's (Organisation A's) purposes. In other words, Organisation B has been asked to carry out work involving live animals for Organisation A when that work would not have otherwise been carried out by Organisation B, i.e., services have been provided 'to order' for the organisation that has expressly commissioned it.

Directly obtained: Materials are obtained from animals by members of the organisation which will

also use the material.

Enhanced considerations: Steps in the assessment process which go beyond the required standard. Organisations may seek to incorporate any of these suggestions (in whole or part) from any section into their own policies in the future. Any measures in this category adopted by an organisation would be *in addition* to the required standard.

Establishment Licence: In the UK, organisations carrying out ASPA 'regulated procedures' on protected animals for research or education, must have a Home Office granted Establishment Licence.

Indirectly obtained: Animal material is obtained via a third party or from an *ex situ* collection and subsequently transferred to the recipient organisation who will use it.

Live-sampling: Samples were taken from an animal whilst that animal was alive, i.e., samples were not taken following death. Samples taken from an animal which was alive at the time the samples were taken, but where the animal has subsequently died, are still considered to have been 'live sampled'.

Post mortem: Samples were taken from a dead animal.

Primary materials: Materials obtained via the handling of an animal's body.

Project Licence: In the UK, 'regulated procedures' on protected animals must be carried out under a Home Office granted Project Licence specific to the programme of work to be undertaken.

Recipient organisation: The organisation receiving the material and subsequently using it.

Regulated procedure: In reference to the requirements under the UK Animals (Scientific Procedures) Act (ASPA), any procedure applied to a protected animal for experimental (or other scientific or educational) purposes that may cause an animal a level of pain, suffering, distress or lasting harm equivalent to, or higher than, that caused by the introduction of a needle in accordance with good veterinary practice.

Secondary materials: Materials which have not been obtained from the handling of animals' bodies, i.e., the animal's body has not been handled to obtain the materials, but secondary materials have been created or derived subsequently from the cellular material initially obtained from animals, e.g., DNA, RNA, cultured (*in vitro*) cells, cell lines, DNA libraries, etc.

Sentience: Sentience is as described in the UK Animal Welfare (Sentience) Act 2022 and is also taken here to include animals protected under the UK Animals (Scientific Procedures) Act (ASPA). Note that there are animals listed in the UK Animal Welfare (Sentience) Act which are *in addition* to those species protected by ASPA. The *combination* of species from both pieces of legislation provides the definition of sentience for this Framework.

Source organisation: The place where the material has been taken/sampled from animals.

How to Use the Framework

Please also see the Framework flowchart.

The Framework comprises two main sections. Section 1 relates to materials taken from sentient animals which are kept or bred for research or for educational purposes, including for ASPA regulated procedures in the UK. Section 2 relates to the acquisition of all samples that fall outside of this definition, for example, samples obtained from a supermarket, or a zoo, or a veterinary clinic.

The steps to complete a standard ethical assessment are listed in each section under 'Requirements', along with suggested 'Enhanced considerations' which are above the standard and which organisations may seek to incorporate (in whole or part) into their own policies in the future.

Each section is further sub-divided depending on the specific type and source of samples.

The Framework provides requirements for: sourcing from the UK or from overseas organisations; organisations directly or indirectly (i.e., from third parties) obtaining materials; and live-sampling or post mortem sampling requirements.

IMPORTANT NOTE: Where 'additional requirements' are listed within the text of a 'Requirements' section, all the information within the previous sections must ALSO be read, as some requirements will apply generally, regardless of source. For example, if post mortem materials are to be used the sections on live-sampling must also be read as some requirements may equally apply to some sources and types of materials.

In practice, it is for organisations to determine themselves the extent and scope of any review process which would enable that organisation to meet the standard requirements within the Framework. Where the document suggests a 'full ethical review' (rather than 'ethical assessment') it is recommended that this is carried out by a committee organised for this purpose, for example, an existing AWERB, AWB, IACUC or REC. Steps in the 'Requirements' sections do not need to be completed via a full review by a committee - this is not considered necessary and an assessment can be made against the standards by a person, or persons, as determined by the organisation receiving the material, e.g., appropriate individuals within research ethics or research governance teams, or sub-committees.

Use of the Tables within the Document: Where 'Enhanced considerations' are listed and the organisation is additionally seeking to adopt these into their own policies, the documentation is written so that the preceding 'Requirements' section for that source and type of material would ALSO need to be complied with.

Use of the Ethical Framework

The Ethical Framework is FREE to use and can be downloaded by any organisation. If used in publications, we ask that organisations acknowledge the source of the information by citing the URL link to the UKRIO webpage.

The Framework does not have to be used in its entirety and any organisation may take specific pieces of information from the Ethical Framework for its own purposes.

Contact Details

If any organisations using the Ethical Framework, in part or in full, have any comments about the Ethical Framework, these can be directed to: nagoya@sanger.ac.uk

The AMWG will be interested to hear if there are any omissions or need for further clarity in the documentation, or if there is potential for misinterpretation of the text. Please contact the AMWG at nagoya@sanger.ac.uk



The Animal Materials Working Group (AMWG) was formed to enable individuals from a variety of relevant UK establishments, such as universities, research institutes, funders, and other interested companies and organisations, to discuss, create and benchmark guidance which would be of use to others and promote the consideration of animal welfare in regards to the acquisition of materials from sentient animals.

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