Ethical Framework for Obtaining Material from Sentient Animals

Sentience 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) 1986. Note that there are animals listed in the Animal Welfare (Sentience) Act which are in addition to those described in 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.

Scope and Benefits

This Ethical Framework presents considerations for organisations obtaining material from sentient animals and describes a set of benchmarked, standard requirements which may complete an appropriate ethical assessment. Recipient organisations are encouraged to complete the assessment ahead of receiving materials, however, for archived materials already obtained and held in storage at an organisation, the ethical assessment may be carried out at removal from storage ahead of use.

The Framework does not cover the acquisition of reagents dependent on animals for their production, such as antibodies, foetal bovine serum or enzymes, neither does it cover material used as animal feed.

Where relevant, 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, and it does not provide explanations of legislative requirements as specific and updated information may be obtained via relevant government and authority websites.

The Framework is intended as a supportive document to assist organisations in the ethical assessment of materials from sentient animals, including in areas of use beyond research, such as teaching, and should not be considered a legislative instrument. It does not provide detailed information on the creation of ethical review processes within organisations as other sources of information are available, such as on the UK RSPCA's website at https://science.rspca.org.uk/sciencegroup/researchanimals/ethicalreview/uk which, although focused on Animal Welfare and Ethical Review Body (AWERB) operations relating to ASPA, provides suggestions regarding the ethical review process which could be more generally applied.

Organisations may continue to define their own processes, policies, guidelines and checklists regarding implementation, and create their own tools and resources, based on available resources. It is envisaged that Animal Welfare and Ethical Review Bodies (AWERBs), Animal Welfare Bodies (AWBs), 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, particularly those which consider potential reputational risks to organisations, and in supporting users of animal materials.

The Ethical Framework does not cover other considerations relating to the handling and processing of animal materials once acquired by organisations, as this would necessitate including many other operational areas, such as, health and safety, sample management, tracking and disposal, etc. Organisations will already have their own procedures in place to cover, for example, the safe use and handling of these materials.

Except where otherwise specified, the focus of this document is on the acquisition of materials directly obtained from the handling of animals' bodies, where those animals have been defined as sentient. However, it is recognised that the concept of sentience has been emergent over time and may develop further. **Organisations are, therefore, encouraged to consider whether to include animals not yet regarded as sentient in their policies.** The Animal Materials Working Group will regularly review this Ethical Framework, and may seek to incorporate changes which reflect future understanding related to the assessment of sentience.

Due to the wide scope of activities which could provide animal materials, this Framework does not attempt to define 'good practice' in all scenarios, but it is expected that recipients of materials will either have an understanding of what might constitute 'good practice' for their specialist areas of work, and/or organisations will attempt to identify any potentially applicable guidance.

This Framework generally references steps organisations must take when acquiring materials for the first time, although further use of the same materials from the same source at the same organisation is covered in Section 2.7.

Where the document suggests a 'full ethics committee review', it is recommended that this review is carried out by an existing ethics committee, or equivalent group responsible for research integrity and ethical standards.

The Ethical Framework does not include consideration of environmental DNA (eDNA) and this is not included.

The accompanying **User Guide** should be read to understand how the Framework has been laid out, and includes an explanation of the difference between 'Requirements' and 'Enhanced considerations', 'direct' and 'indirect' acquisition, and presents a **glossary of abbreviations and definitions**.

Overarching Principles

In all cases, when materials are to be obtained from sentient animals, the highest animal welfare and environmentally sustainable options available should be prioritised and best practice promoted, whenever possible. Recommendations concerning the most appropriate methods of collection, restraint, husbandry and killing of such animals may be defined and adopted by organisations, but all legislative requirements must be followed in all cases.

Materials must be obtained in accordance with the recipient organisation's relevant policies, including checks that the materials have not been obtained from sources or activities which the recipient organisation has deemed to be unethical. **Organisations may create their own list of materials or sources of materials that they would not accept and/or the circumstances in which these materials must not be obtained**, such as from animals kept in situations that the organisation may find unacceptable, or materials obtained from procedures or activities that would not be permitted in the organisation's own country.

Where there are alternative materials to those obtained from sentient animals available and which also meet an organisation's other standards, such as human participant and environmental protections, and sustainable sourcing, these alternatives should be considered.

Organisations are invited to use the Framework to inform and enhance their own policies but may find that their existing policies and processes already cover the requirements within this Framework and, therefore, amendments or extensions to existing ways of working are not needed. Where applicable, an organisation's policies should also emphasise the importance of good study design, reproducibility, and compliance with funders' terms regarding animal welfare standards, and may also include checks on whether there is existing, ethically sourced, data already available which would support the same outcomes.

It is expected that **all materials will be lawfully obtained and in-line with any relevant licensing requirements and permissions**, and any individual taking samples from live animals, or carrying out humane killing, will be competent to do so, particularly with regards to the relevant species.

Organisations should note that additional legal considerations may apply to the acquisition of some animal materials, but these requirements are not covered within this Framework. For example, in the

UK, these may include licences administered by the Animal and Plant Health Agency (APHA), Department for Environment, Food and Rural Affairs (DEFRA), Natural England, NatureScot, Natural Resources Wales (Cyfoeth Naturiol Cymru) and the Northern Ireland Environment Agency.

Organisations could also consider requirements related to biosecurity and environmental controls, including during collection and transport of materials, and the establishment of processes for recording and disposal of materials of animal origin.

Legal acquisition of overseas materials would include obtaining materials in accordance with any licensing requirements, such as the Convention on International Trade in Endangered Species (CITES), and as stipulated in relevant laws, including Access and Benefit Sharing (ABS) regulations in provider countries and national Nagoya Protocol regulations, as appropriate.

Organisations will likely have already defined their standard processes for record-keeping, which will probably include a description of the material and animal species, place of origin/source and the source organisation (and provider/providing organisation, if obtained from a third party). Routinely, organisations generally record the conclusions of any ethical assessment/review, such as, in minutes from meetings, on checklists, computerised systems, etc., and, unless otherwise defined in law, organisations are able to determine for how long such records may be kept.

Where material of animal origin has already been obtained and is to be used for a new project, study or purpose at the same organisation, and where an ethical assessment has already been conducted by that organisation in-line with this Ethical Framework (and subsequent further use would be in accordance with any existing contractual obligations and import authorisations), a 'light touch' assessment of any previous approval would be expected ahead of further use of the material.

Efforts must be made to utilise remaining, usable material still stored at the organisation prior to obtaining the same material from the same source again. Organisations could also ensure personnel are informed that enabling further use of material necessitates storing the material under optimal conditions with appropriate metadata.

The Framework does not currently cover the re-use of data. However, it is acknowledged that there are potential ethical issues that may arise if the data were originally collected in a manner not considered ethically acceptable. Organisations may, therefore, wish to consider completing a review against this Framework before using secondary data. If the same data, which the new purpose will also generate, already exists, the use of the materials must be strongly justified.

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IMPORTANT NOTE: In order to prevent duplication of information, 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 postmortem materials are to be used, the sections on live-sampling must also be read, as some requirements may equally apply.

Section 1:

Animal Materials from Sentient Species Kept or Bred for Research and/or Education Purposes, or Obtained as a Result of a Regulated (Licensed/Authorised) Procedure Being Applied to a Sentient Animal

In the UK, this also includes material obtained from ASPA regulated procedures in Places Other than Licensed Establishments (POLEs), but excludes training which is covered by the UK Veterinary Surgeons Act

General Additional Principles and Considerations for this Section

Although the use of relevant species may be permitted and lawful, for example, through licensing regimes, it is important that an appropriate ethical assessment is undertaken to cover the ethical aspects of obtaining these materials.

Where the death of a sentient animal is required for the primary purpose of supplying an organisation with materials from that animal, this must be robustly justified, including a harm *versus* benefit analysis, assessment of method of humane killing (in-line with the UK Animals (Scientific Procedures) Act (ASPA) or other guidance for the relevant species, as appropriate) and the decision recorded. Organisations will determine how this assessment may be carried out, and by whom.

In the UK, for any *live-sampling* of animals protected under the Animals (Scientific Procedures) Act (ASPA), where the sample has been obtained solely or primarily for ASPA regulated purposes, an ethical review will need to have been conducted by an Animal Welfare and Ethical Review Body (AWERB) in accordance with ASPA, and a favourable opinion recorded. Other countries may have an Animal Welfare Body (AWB), Institutional Animal Care and Use Committee (IACUC) or other nominated committee, who will have the expertise and experience to carry out a similar assessment in-line with their own national legislation relating to the use of animals for these purposes.

Organisations may consider whether it would be beneficial to involve their procurement, purchasing, finance, grants teams and/or other available resources as the organisation determines, in decision-making and the due diligence process regarding the suppliers of commissioned/outsourced services.

1.1 Primary materials (materials obtained via the handling of animals' bodies) supplied as part of a collaboration or from commissioned/outsourced services.	
Collaboration is defined as the transfer of material within a partnership, which may include transfer across national boundaries, but is not defined as commissioned/outsourced work. **Commissioning/outsourcing** is defined as 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.	
Requirement	**Directly or indirectly obtained by the recipient organisation, post mortem materials or live-sampling** **When sourcing from or commissioning UK organisations to provide materials** Where animals have been bred or have been kept under, or procedures to obtain materials have been regulated by, the UK Animals (Scientific Procedures) Act (ASPA): ● Confirmation should be obtained that source organisations hold a Home Office (ASRU) Establishment Licence and, where applicable, a relevant Home Office (ASRU) Project Licence. This includes any regulated procedures carried out in Places Other than Licensed Establishments (POLEs). Confirmation that applicable licences are in place will evidence that appropriate AWERB review has been undertaken in accordance with ASPA. Where materials are from sentient animals not listed as 'protected' under ASPA, for example, decapod crustaceans: ● The recipient organisation must assess: where and how the animals were captured (if applicable), how the animals were housed and cared for (if applicable), the methods used for live-sampling and humane killing (as appropriate), and compare these to accepted standards and identified best practice (where available); carry out a harm (to the animals) versus benefit (of the organisation's work) analysis; and record the outcome of the assessment. **When sourcing materials from overseas organisations** ● Confirmation should be obtained that source organisations hold the appropriate licences/authorisations as required by their national legislation or management authority, for example, the equivalent of an Establishment Licence and Project Licence (as appropriate), and that the work to be undertaken is legal. ● For any *live-sampling* of sentient animals, an ethical review may have been conducted by an Animal Welfare Body (AWB), Institutional Animal Care and Use (IACUC) or Research Ethics Committee (REC), and a favourable opinion recorded. The recipient organisation must log that this ethical review has taken place and that a favourable opinion has been granted. However, a recipient organisation may consider an existing ethical review does not meet the requirements of its policies and, therefore, determine that an additional ethical assessment will be undertaken at the recipient organisation in accordance with its own procedures. This will include an assessment that the method of live-sampling is humane in relation to the relevant species. ● When receiving *post mortem* or surplus materials, including when animals have been bred and killed for other research and/or education purposes, evidence of good practice at the providing organisation (including the housing and husbandry of animals) should be sought from any publicly-available information, such as websites, or requested directly from the source organisation, and assessed to determine that animal welfare was appropriate. Any methods of killing must be assessed as humane for the species. ● Where licences/authorisations (and associated ethical review) do not cover the sentient species required, the recipient organisation must assess: where and

how the animals were captured (if applicable), how the animals were housed and cared for, the methods used for live-sampling and humane killing (as appropriate), and compare these to accepted standards and identified best practice (where available); carry out a harm (to the animals) versus benefit (of the organisation's work) analysis; and record the outcome of the assessment.

Additional requirements when material is from commissioned/outsourced services overseas

- Completion of relevant overseas NC3Rs' checklists (or institutional equivalent) must be requested from commissioned/outsourced organisations, where appropriate, and a favourable outcome recorded following assessment. See https://nc3rs.org.uk/checklists-use-animals-overseas

- Evidence of good practice (including in the housing and husbandry of animals) must be obtained for commissioned/outsourced organisations within reasonable limits, for example, photographic evidence, website downloads, written veterinary assurance. This requirement will include when the commissioned/outsourced service is supplying materials obtained from animals specifically bred for their tissues.

1.2 Use of archived primary materials (materials obtained via the handling of animals' bodies), or secondary materials (materials which have not been obtained from handling animals' bodies, but 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.)

See Sections 2.7 and 2.8

Section 2:

Sourcing of Materials from Sentient Animals Obtained through Other Activities
e.g., from the food chain, veterinary clinics, farms, abattoirs, zoos, the wild, etc.

Materials from activities/practices of concern

Materials from the following activities/practices must not be obtained unless the work utilising these materials directly relates to the welfare of the animals or animal populations:

- Materials derived from populations of sheep subject to the practice of mulesing https://kb.rspca.org.au/knowledge-base/what-is-the-rspcas-view-on-mulesing-and-flystrike-prevention-in-sheep/
- Unethical production of foie gras https://kb.rspca.org.au/knowledge-base/is-eating-foie-gras-an-animal-welfare-issue/
- Whaling (except with appropriate justification (see section 2.7) where these are historical artefacts) https://uk.whales.org/our-goals/stop-whaling/
- Obtaining blood from horseshoe crabs https://www.pcrm.org/news/news-releases/years-advocacy-pay-policy-change-improves-science-and-protects-horseshoe-crabs
- Semen produced from animals by the electroejaculation method https://www.sciencedirect.com/topics/agricultural-and-biological-sciences/electroejaculation
- Live-plucking of animals for hair, such as for angora wool from rabbits
- Commercial octopus farming https://www.rspca.org.uk/-/news-rspca-calls-for-halt-to-plans-for-worlds-first-octopus-farm

Organisations may add other practices or sources of materials to this list, in-line with their own policies.

2.1 Materials from husbanded animals, including in agriculture and aquaculture, or animals kept for their wool or other skin coverings, or from the food chain process, but not directly obtained from a food retail outlet (e.g., this section does not cover materials obtained from a supermarket).

This includes live-sampling or collection of *post mortem* tissue from abattoirs, farms and fisheries. For example, collection of seminal fluid from bulls or boars, or of surplus organs from abattoirs.

Requirement	**Directly or indirectly obtained by recipient organisation** ↪ **Sampled from live animals** ● Consideration should be given to whether the sampling falls under Section 1, for example, within the UK Animals (Scientific Procedures) Act (as amended) (ASPA) (1986). If so, please refer to Section 1. ● Any method of *live-sampling* (including restraint technique, where applicable) must be assessed specifically to determine that it is humane and in accordance with any identified best practice guidance relating to the source of the material and relevant species, for example, conforming to routine veterinary practice or, alternatively, the method is generally confirmed as humane by a qualified and registered vet. As relevant to source, consideration must be given to whether the sampling falls within the UK Veterinary Surgeons Act (1966). ● Written assurance from a named person at the source organisation or other documentary evidence must be obtained, (including for cases when *live-sampling* is to be carried out by a third party solely or primarily for the recipient organisation), which verifies that the sampling is lawful (including obtaining consent from any owner of the animals), and that the person carrying out the sampling is competent, particularly with regards to the relevant species. ● If *live-sampling* is to be carried out by the recipient organisation's personnel, that is, the organisation's staff will *take material from the animal's body*, the lawfulness of the sampling (including obtaining consent from any owner of the animals), and the individual's competence with regards to the relevant species, must be assessed and recorded via the recipient organisation's review process. All relevant documentation, including permits, licences, authorisations or permissions, required in order for the recipient organisation to carry out the live-sampling, must be evidenced. Other records must be kept as required by the recipient organisation's policies. ● For *meat, dairy, poultry and aquatic species, including farmed fish,* evidence must be provided of compliance with husbandry assurance standards equivalent to or greater than the UK RSPCA Assured welfare standards, unless the recipient organisation determines that an exception is justified. ● Where recognised industry ethical standards exist for the taking of wool or other skin coverings from animals, assurances should be sought that the source organisation adheres to these standards in relation to animal welfare considerations. For example, see https://icea.bio/en/certifications/non-food/biological-and-sustainable-textile-products/ for Responsible Wool, Mohair, Alpaca and Down Standards. Other relevant standards include the Animal Fibre Standard from the Sustainable Fibre Alliance (SFA) (see https://sustainablefibre.org/) which covers cashmere goats. Evidence must either be provided of compliance with these Standards, or that animal welfare is equivalent to or greater than the Standards, unless the recipient organisation determines that an exception is justified.

	Additional requirements for post mortem obtained materials ● Unless robustly justified and considered by the recipient organisation's full ethics committee review process, and a favourable outcome recorded, animals from which materials are required may not be killed *solely* or *primarily* for the purpose of the work to be undertaken by the recipient organisation. The ethics committee review must include a harm *versus* benefit analysis and must also consider the number of animals killed and assess the method of humane killing. ● For *meat, dairy and poultry,* confirmation must be sought that the animal from which the material has been obtained has been stun-killed, unless this is inherent within an applicable welfare standard, such as UK RSPCA Assured. ● For *meat, dairy, poultry and aquatic species, including farmed fish,* written assurance must be obtained, or the acquisition reviewed by the recipient organisation and determined, that humane killing was undertaken to appropriate assurance standards equivalent to or greater than the UK RSPCA Assured welfare standard, such as those provided by the Humane Slaughter Association or the World Organisation for Animal Health (OIE) Aquatic Code (2021) (where the source is an OIE country), unless the recipient organisation determines that an exception is justified. ● For *meat, dairy and poultry*, where the facilities exist to do so and to limit transport of live animals, animals must be killed at the source organisation and must not endure additional, onward transport to another place of slaughter solely or primarily to acquire materials for the recipient organisation. Where this is, exceptionally, not possible, then the recipient organisation must determine that an exception is justified. ● For *eggs* from domesticated/husbanded fowl and poultry, material must be free-range and organic, or a robust justification provided, and the recipient organisation determines that an exception is justified. ● Where the assessment of a method of humane killing of animals is not already covered by the requirements given above, and methods of humane killing are not described in standards, legislation or publications, recipient organisations must generally assess the method used and confirm that it conforms to identified best practice for the sector, minimising the potential for pain or distress, or determine that an exception is justified. ● When receiving *post mortem* or surplus animal materials from animals not killed specifically for the food industry, evidence of good practice at the source organisation (including the housing and husbandry of animals) should be sought from publicly-available information, such as websites, or requested directly from the source organisation, and reviewed to determine that animal welfare is appropriate, or the recipient organisation must determine that an exception is justified. **Additional requirements when sourcing from overseas organisations/suppliers** ● For UK recipient organisations, if unable to source materials from the UK supply chain, justification for sourcing material overseas and appropriate animal welfare standards must be considered and recorded in accordance with the recipient organisation's policies and procedures.
Enhanced considerations	**For all materials** ● An additional assessment should be carried out by the recipient organisation to consider evidence of any undesirable drivers in the supply chain and additional

	information regarding animal welfare standards, for example, photographs, videos, Standard Operating Procedures, published animal welfare policies and/or veterinary statements. ● Recipient organisations may set a requirement of preferentially sourcing materials from UK suppliers in specific scenarios or choose to create and regularly review a list of materials, or sources/suppliers, that they would not accept under any circumstances due to low animal welfare considerations. ● Due diligence carried out by the recipient organisation should record the source organisation as showing no recent welfare breaches, prosecutions or sanctions related to animal welfare reported in publicly available sources of information, where available. ● Records should be kept of the number of animals from which the material originates (including justification for these numbers), and may include consideration of any multiple events of live-sampling from the same animals. **Additional requirement for post mortem obtained materials** ● For *meat, dairy and poultry*, material should be recorded as 'locally sourced' - defined as the most appropriate available slaughter facility closest to the point of production or origin.
Approach if requirements cannot be met	● A full ethics committee review at the recipient organisation may consider the use of non-stun-killed material in scenarios when stun-killing is generally accepted as the humane standard, for example, the UK RSPCA Assured standard, and use of the material is permitted if the recipient organisation determines that an exception is justified. ● Use of material from sources which fall outside the required animal welfare assurance standards is permitted if the recipient organisation determines that its use can be exceptionally justified.

2.2 Materials from food retail outlets (e.g., supermarkets, food stalls, local markets and independent sellers).
This section does not include live / 'wet' markets (see Section 2.3).

Requirement	**Directly or indirectly obtained by recipient organisation** ● For *meat, dairy, poultry and aquatic species, including farmed fish,* evidence must be provided of compliance with husbandry and humane killing assurance standards equivalent to or greater than the UK RSPCA Assured welfare standards, such as those provided by the Humane Slaughter Association or the World Organisation for Animal Health (OIE) Aquatic Code (2021) (where the source is an OIE country), as applicable, unless the recipient organisation determines that an exception is justified. ● For *eggs* from domesticated/husbanded fowl and poultry, material must be free-range and organic, or a robust justification is provided, and the recipient organisation determines that an exception is justified. **Additional requirement when sourcing materials from overseas** ● For UK recipient organisations, if unable to source materials from the UK supply chain, justification for sourcing material overseas and appropriate animal welfare standards must be considered and recorded in accordance with the recipient

	organisation's policies and procedures.
Enhanced considerations	**For all materials** ● For *meat, dairy and poultry,* confirmation should be sought that the animal from which the material has been obtained has been stun-killed, unless this is inherent within the applicable welfare standard, such as UK RSPCA Assured. ● Due diligence carried out by the recipient organisation should record the producer (where known) of the animals provided to the food retail outlets as showing no recent welfare breaches, prosecutions or sanctions related to animal welfare reported in publicly available sources of information, where available.
Approach if requirements cannot be met	● A full ethics committee review at the recipient organisation may consider the use of non-stun-killed material in scenarios when stun-killing is generally accepted as the humane standard, for example, the UK RSPCA Assured standard, and use of the material is permitted if the recipient organisation determines that an exception is justified. ● Use of material from sources which fall outside the required animal welfare assurance standards is permitted if the recipient organisation determines that its use can be exceptionally justified.

2.3 Materials from live / 'wet' markets.
Markets where animals are being kept alive on the market stall before slaughter.

Requirement	**For all materials** ● Materials from live / 'wet' animal markets require robust and exceptional justification for use due to the general lack of information available concerning the welfare of the animals and will need a full ethics committee review at the recipient organisation, to include the relevant requirements indicated in this Ethical Framework, checks on the provenance of the materials, animal welfare standards and an assessment of reputational risk. ● Unless robustly justified and considered by the recipient organisation's full ethics committee review process and a favourable outcome recorded, animals from which materials are required may not be killed *solely* or *primarily* for the purpose of the work to be undertaken by the recipient organisation. ● The use of material from live / 'wet' markets may only be justified if the work will benefit the relevant species and/or animal population and/or human or environmental health, for example, research into emerging panzootic infections. ● Full details of the source of the material must be provided for the ethics committees review, to include, where possible: address of market; date of obtaining the material; name of purchaser for recipient organisation or third party purchaser's name and affiliated organisation (as appropriate); circumstances in which the animal was being kept; condition of animal (visual assessment by a lay person is appropriate as a minimum, preferably augmented by photographic/visual recording, if possible); fate of animal, i.e., whether the animal was purchased live and subsequently killed, or purchased post mortem; how the animal was killed, when and by whom.

Approach if requirements cannot be met	• If the provenance of the primary materials cannot be determined, then an alternative source of materials must be considered. Where an alternative source is not appropriate, a full ethics committee review must be undertaken as per the organisation's standard procedure and use of the material is permitted if the recipient organisation determines that it is justified.

2.4 Materials from veterinary practices, clinics and diagnostic services where animals, including stray, feral and wild animals, are the 'patients'.

For example, a sample of tissue taken from an animal during a biopsy for diagnostic or clinical purposes, but is now surplus to requirements.

Requirements	**Directly or indirectly obtained by recipient organisation** **↪ Sampled from live animals** • Consideration should be given to whether the sampling falls under Section 1, for example, within the UK Animals (Scientific Procedures) Act (as amended) (ASPA) (1986). If so, please refer to Section 1. • Assurance from an advocate for the animal, such as an RCVS registered vet in the UK, or fully qualified vet overseas, or appropriate representative from an RCVS registered veterinary practice/clinic/diagnostic service in the UK, or registered veterinary practice/clinic/diagnostic service overseas, must verify that the method of sampling was carried out in accordance with routine veterinary practice. • For recipient organisations receiving samples taken for research, clinical or diagnostic purposes from *owned animals*, written assurance, or other documentary evidence, must be obtained from the veterinary surgeon, or appropriate representative, that owner/guardian consent was given for the materials to be used for the new purpose, or that the consent obtained was broad enough to allow for this new use, or that there is a legal exemption to owner/guardian consent requirements in relation to the proposed new use of the material. • For UK recipient organisations receiving samples from *owned animals* overseas, there must be recorded justification why the samples could not be obtained from the UK and use of the material is permitted if the recipient organisation determines that it is justified. • When obtaining materials from a third party veterinary diagnostic service specifically (rather than directly from a veterinary surgeon/clinic/practice where the animal is a 'patient'), written assurance must be sought from the veterinary diagnostic service that it is lawful to use the samples for the new purpose, including consideration of any owner/guardian consent received. The veterinary diagnostic service must provide their written agreement to the non-diagnostic/non-clinical use. It is important to evidence that the veterinary diagnostic service has the legal capacity and is competent to give approval for the use of the materials for the new purpose. • For samples taken primarily for clinical or diagnostic purposes from *stray* or *feral domesticated* or *wild animal* 'patients', justification must be recorded as to why relevant samples could not be obtained from owned animals. For samples from *stray* or *feral domesticated* or *wild animal* 'patients', evidence must be provided that there is a benefit to the animal population or species, or other species, or the environment, from the work to be undertaken. Use of the

	material is permitted if the recipient organisation determines that it is justified. **Additional requirement for post mortem obtained materials** ● Written assurance, or other documentary evidence, must be obtained from an RCVS registered veterinary surgeon in the UK, or fully qualified vet overseas, or appropriate representative from an RCVS registered veterinary practice/clinic/diagnostic service in the UK, or registered veterinary practice/clinic/diagnostic service overseas, stating that samples were only taken when the animal was euthanised for its own well-being or due to population health issues. **Additional requirements when sourcing materials from overseas** ● For materials obtained overseas, a fully qualified vet or registered veterinary practice/clinic/diagnostic service must confirm that the method of sampling/killing was the most humane available in the specific situation and was carried out by a competent person, particularly with regards to the relevant species.
Enhanced considerations	**For all materials** ● For *owned animals,* evidence of owner consent (as required) for the use of the materials for the new purpose should be obtained and held by the recipient organisation (with consideration of data protection issues). ● In order to avoid repeating the same work and ensure outcomes are generally available, organisations could require that material obtained from veterinary clinical trials must only be received if the relevant clinical trial is registered on an appropriate database, such as https://veterinaryclinicaltrials.org/

2.5 Materials from zoos, managed wildlife parks, animal shelters, wildlife sanctuaries, aquaria and private collections of live animals.	
Materials from captive animals where permission from an owner may be required. Does not include wild animals living in wildlife reserves (see Section 2.6).	
Requirements	**Directly or indirectly obtained by recipient organisation** **↪ Sampled from live animals** ● Consideration should be given to whether the sampling falls under Section 1, for example, within the UK Animals (Scientific Procedures) Act (as amended) (ASPA) (1986). If so, please refer to Section 1. ● Any method of *live-sampling* (including restraint technique, where applicable) must be assessed specifically to determine that it is humane and in accordance with any identified best practice guidance relating to the relevant species, for example, conforming to routine veterinary practice or, alternatively, the method is generally confirmed as humane by an RCVS registered vet in the UK or fully qualified vet overseas. As relevant to source, consideration must be given to whether the sampling falls within the UK Veterinary Surgeons Act (1966). ● If *live-sampling* is to be carried out by the recipient organisation's personnel, that is, the organisation's staff will *take material from the animal's body*, the lawfulness of the sampling, including obtaining consent from the owner of the animals, and the individual's competence with regards to the relevant species must be assessed and recorded via the recipient organisation's review

process. All relevant documentation, including permits, licences, authorisations or permissions, required in order for the recipient organisation to carry out the live-sampling, must be evidenced. Other records must be kept as required by the recipient organisation's policies.

- Written assurance from a named person at the source organisation, or other documentary evidence must be obtained, particularly for cases when *live-sampling* is to be carried out by a third party solely or primarily for the recipient organisation, which verifies that the sampling is lawful, including obtaining consent from the owner of the animals, and that the person carrying out the sampling is competent with regards to the relevant species.

- Written assurance from a named person at the source organisation, or other documentary evidence must be obtained, which verifies that all relevant permits and licences are in place (including import/export licences, as required), and must include assurance of compliance with applicable legislation, such as the Convention on International Trade in Endangered Species (CITES) and Access and Benefit Sharing (ABS), where relevant.

- Evidence must be obtained through due diligence to confirm that appropriate standards of registration and compliance are in place, as relevant, at the organisation providing the animal material. For example, for zoos, checks are made that the source organisation is a current member of BIAZA (British and Irish Association of Zoos and Aquariums), or equivalent, and that this membership body is a member of WAZA (World Association of Zoos and Aquariums). For other UK charities, a check must be undertaken that the charity is registered with the Charity Commission.

- An evaluation must be undertaken to record the welfare and husbandry standards of the source organisation through a review of publicly available information, Codes of Practice, policies or other information provided by or about the source organisation, to provide assurance that the source organisation is reputable and maintains appropriate standards of animal welfare. Attention should be paid to information which specifically evidences that animals are being kept in-line with the UK Animal Welfare Act's 'Five Freedoms' and 'Five Welfare Needs'. Checks must evidence that animal welfare standards have been assessed against any identified best practice for the species in terms of animal husbandry, restraint and transportation, as relevant, and determined by the recipient organisation to be appropriate.

Additional requirements for post mortem obtained materials

- Written information must be obtained stating the reason for humane killing (or death from natural causes, but not caused by a lack of good welfare) and that the reason adhered to any relevant Codes of Practice or similar (for example, for zoos, as defined by BIAZA or WAZA). The reason for killing is assessed and recorded by the recipient organisation as appropriate, and animals from which materials are required have not been killed *solely* or *primarily* for the purpose of the work to be undertaken by the recipient organisation. However, in exceptional circumstances, for example, during a significant disease outbreak, animal health concern or for a conservation objective, it may be necessary to kill an animal solely or primarily for the purpose of the work to be undertaken by the recipient organisation. In this case, the killing must be robustly justified and considered by the recipient organisation's full ethics committee review process, and a favourable outcome recorded. The ethical review must include a harm versus benefit analysis, review of the number of animals killed and an assessment of the method of humane killing.

- Information about the method of killing must be obtained, and where relevant information for the species is not publicly available, written assurance must be

	sought from an appropriate professional, such as an RCVS registered vet in the UK or fully qualified vet overseas, or other trained and competent person with regards to the relevant species, that the method of killing used was humane and appropriate for the species concerned, and was carried out by a trained and competent person or was observed and assessed to have been competently carried out.
Enhanced considerations	**For all materials** • The animal welfare and husbandry standards of the source organisation should be evaluated and recorded through direct knowledge, and/or audit, and/or a review of additional evidence, such as photographs, videos, Standard Operating Procedures or veterinary statements. The animal's quality of life should be assessed, as far as reasonably possible, using the additional information and determined by the recipient organisation to be appropriate, and may include consideration of any multiple events of live-sampling from the same animals. **Additional requirement for post mortem obtained materials** • A copy of the source organisation's euthanasia policy should be obtained, along with written assurance that the policy is being complied with in relation to the specific animals of interest.
Approach if requirements cannot be met	• Any deviation from the welfare standards for the species brought about by the requirements to obtain material, must be justified and determined by the recipient organisation to be appropriate.

2.6 Material from animals living in the wild or living wild on wildlife reserves, fieldwork, any animal found dead and eggs from wild animals.	
This section includes wild animals, but not stray, feral or wild animals being treated as 'patients' at veterinary practices (see Section 2.4 regarding obtaining samples from veterinary practices, clinics and diagnostic services).	
Requirements	**Directly or indirectly obtained by recipient organisation, post mortem materials and live-sampling** • Consideration should be given to whether the sampling falls under Section 1, for example, within the UK Animals (Scientific Procedures) Act (as amended) (ASPA) (1986). If so, please refer to Section 1. • If *live-sampling* is to be carried out by the recipient organisation's personnel, that is, the organisation's staff will *take material from the animal's body*, the lawfulness of the sampling and the individual's competence with regards to the relevant species must be assessed and recorded via the recipient organisation's review process. All relevant documentation, including permits, licences, authorisations or permissions required in order for the recipient organisation to carry out the live-sampling, must be evidenced. Other records must be kept as required by the recipient organisation's policies. • Written assurance from a named person at the source organisation or other documentary evidence must be obtained, particularly for cases when *live-sampling* is to be carried out by a third party solely or primarily for the recipient organisation, which verifies that the sampling is lawful and the person carrying out the sampling is competent with regards to the relevant species.

- Written assurance from a named person at the source organisation or other documentary evidence must verify that all relevant permits and licences are in place (including import/export licences, as required), and must include assurance of compliance with legislation, such as, national wildlife and countryside legislation (for example in relation to eggs from wild birds), Convention on International Trade in Endangered Species (CITES) and Access and Benefit Sharing (ABS), where relevant.

- For UK recipient organisations when sampling will take place overseas, there must be recorded justification why the samples could not be obtained from the UK and use of the material is permitted if the recipient organisation determines that it is justified.

- Methods of live animal capture, restraint, live-sampling or killing, must be assessed by the recipient organisation to be humane and in accordance with any identified best practice guidance and/or routine veterinary practice relating to the relevant species. Where relevant information for the species is not publicly available, written assurance must be sought from an appropriate professional, such as an RCVS registered vet in the UK or fully qualified vet overseas, or other trained and competent person with regards to the relevant species, that the methods used are generally confirmed as humane and appropriate for the species concerned, and were carried out by a trained and competent person or were observed and assessed to have been competently carried out.

- The reason for the humane killing of animals must be assessed by the recipient organisation as appropriate, which may include humane killing to prevent pain, suffering, distress or lasting harm to the individual animal concerned, or population control (including where it may benefit the health of the animal populations), or research for conservation or disease control reasons.

- Unless robustly justified and considered by the recipient organisation's full ethics committee review process, and a favourable outcome recorded, animals from which materials are required may not be killed *solely* or *primarily* for the purpose of the work to be undertaken by the recipient organisation. The ethical review must include a harm *versus* benefit analysis (to also consider the number of animals killed), assessment of the method of humane killing and, where relevant, impact on animal population, species' habitat and the broader environment, and the decision recorded.

- Where samples are collected and received following animals being found dead, including road-kill or where an animal has been killed by another animal, finder's details, location, date and time of collection must be recorded. All animals found this way must be examined for signs of shotgun/projectile damage and snare/trap wounds. Where deliberate killing is suspected, an assessment of the method of killing, by whom and its original purpose must be carried out. If illegal killing is suspected, the relevant authorities should be notified and the specimen handed over to the authority in question for examination. If illegal killing is not suspected, use of the material is permitted if the recipient organisation determines that it is justified. Animals likely to be owned must not be collected or sampled without the owner's permission.

Additional requirements for fieldwork assessment

- Fieldwork must be carried out in-line with relevant legislation, accepted best practice and any appropriate professional guidelines relevant to the species, as applicable.

	• For fieldwork situations, an ethical assessment must be carried out to include: numbers of animals/specimens collected (or the number of animals from which samples are to be collected); the impact of sampling methods on target and non-target species; and any impact of fieldwork activities on habitats, breeding sites and the environment. Any method of indiscriminate sampling must be assessed and is only permitted if the recipient organisation determines that it is justified.
Enhanced considerations	**For all materials** • Organisations may create a list of materials from animals living in the wild or living wild on wildlife reserves, or material collected during fieldwork activities, that they would not accept and/or circumstances in which these materials should not be obtained. **For fieldwork assessment** • Recipient organisations may choose to apply their own animal welfare and/or ethical guidelines to the collection of materials from non-sentient animals.

2.7 Archived primary materials (materials obtained via the handling of animals' bodies), e.g., organs, tissues, bones, horns, hooves, skin, tusks and cells, and eggs from wild animals.
For example, material has been obtained for use in a different project, study or for a different purpose at the recipient organisation, and is now being stored on the recipient organisation's premises or within a national or international tissue repository or biobank, as it is surplus to requirements. The requirements below only apply once the material is to be taken out of storage ahead of being used.

Requirement	**For all materials** • From the General Principles for this Framework, where material of animal origin has already been obtained and is to be used for a new project, study or purpose at the same organisation, and where an ethical assessment has already been conducted by that organisation in-line with this Ethical Framework, and subsequent further use would be in accordance with any existing contractual obligations and import authorisations, a 'light touch' assessment of any previous approval ahead of the further use of the material would be expected. • Where an ethical assessment relating to archived materials being stored at a recipient organisation for a new project, study or purpose has not previously been conducted in-line with this Ethical Framework, organisations should assess the material ahead of its use as if it was newly acquired and, therefore, in-line with this Ethical Framework. • If the provenance of archived materials cannot be determined and/or it is not known if use would be in accordance with contractual obligations and import authorisations, then an alternative source of materials should be considered, if appropriate. Organisations may decide to use archived materials where the provenance is unknown following an ethical assessment to include potential legal and reputational risks. • Efforts must be made to utilise remaining, usable material still stored at the organisation prior to obtaining the same material from the same source again. • For historically sourced materials, where collection or the collection method would not now be permitted due to current legislation, such as the Convention

	on International Trade in Endangered Species (CITES), or where materials are obtained which were originally acquired illegally (for example, they were confiscated by the police) but have subsequently been provided to the recipient organisation under appropriate authority for their use, records kept by the recipient organisation must evidence: any change in legal status of the material; detail the authoriser and the permission granted, as appropriate; and list any conditions and restrictions ahead of use of the material. All materials should be used with appropriate security and record-keeping in place. Justification for use must be recorded, including reasons why potentially less ethically sensitive materials cannot be used. Use is permitted if the recipient organisation determines that it is justified. ● For samples from a national/international tissue repository or biobank, a check must be carried out on the tissue repository's policies to confirm that when materials are deposited following the live-sampling or killing of animals, evidence is provided to the tissue repository or biobank that procedures have been assessed as humane, for example, through confirmation of AWERB, AWB, REC or IACUC review, or that appropriate licensing with an inherent ethical review step was in place. ● Organisations must ensure that an ethical assessment is carried out prior to the use of any material which the organisation deems to be ethically or legally controversial. This assessment must include consideration of: undesirable drivers in the supply chain; reputational risk; and consideration of any risks to the welfare of existing populations of the relevant species (to guard against new collection activity). Use is permitted if the ethical assessment confers a favourable opinion.
Enhanced considerations	**For all materials** ● For historically sourced materials, where collection would not now be permitted due to current legislation, such as CITES, or where materials are obtained which were originally acquired illegally but have subsequently been provided to the recipient organisation under appropriate authority for their use, organisations may define limitations on the use of these materials at their organisation. For example, organisations may require an assessment to determine that the relevant animal population will benefit from the work; and/or the work has the potential to improve the conservation of the species; and/or the work will generate knowledge which benefits biodiversity; and/or will contribute knowledge or promote understanding of these areas through education. Recipient organisations may determine that use is permitted following this assessment. ● Organisations should ensure that systems recording archived materials, in-line with that organisation's standard sample records, are able to be appropriately queried by the organisation to find references to relevant documentation and the outcome of any previous ethical assessment. ● Organisations should consider adding materials to the Research Resource Identification Portal (https://rrid.site/) to assign a reference number to materials which may be shared and enable traceability of physical resources through publications, if appropriate.

2.8 Use of secondary materials (materials which have not been obtained from handling animals' bodies, but have been created or derived subsequently from cellular material initially obtained from animals), e.g., DNA, RNA, cultured *(in vitro)* cells, cell lines, DNA libraries.	
Requirements	**For all materials** ● Organisations must check that use would be in accordance with relevant existing contractual obligations and import authorisations. ● No further ethical assessment is required.
Enhanced considerations	**For all materials** ● Organisations should check the provenance of the materials, where possible, and any publicly-available information relating to animal welfare standards at the source organisation from where cellular materials from animals' bodies were originally obtained and carry out an ethical assessment ahead of using the material. Recipient organisations may determine that use is permitted following this assessment. ● If the provenance of secondary materials cannot be determined and/or it is not known if use would be in accordance with contractual obligations and import authorisations, then an alternative source of materials should be considered, if appropriate. Organisations may decide to use secondary materials where the provenance is unknown following an ethical assessment to include potential legal and reputational risks. ● Organisations should consider adding materials to the Research Resource Identification Portal (https://rrid.site/) to assign a reference number to materials which may be shared and enable traceability of physical resources through publications, if appropriate.