Policy on the Use of Animals

Imperial College London's mission is to achieve enduring excellence in research and education in science, engineering, medicine and business for the benefit of society. Research and education are central to the university's work but can raise ethical issues that need careful consideration. Imperial is committed to ensuring that all its research and teaching activities are carried out within a rigorous ethical framework.

From antibiotics and insulin to blood transfusions and treatments for cancer or HIV, many medical achievements in the past century have depended directly or indirectly on research using animals. Only a small percentage of medical and biological research involves the use of animals. That part remains vital, however, to further the development of treatments or cures for medical conditions that blight or destroy the lives of humans - and animals.

Research in the United Kingdom involving scientific procedures that may cause living vertebrates (other than man) and cephalopods pain, suffering, distress or lasting harm must comply with the requirements of the *European Directive 63/2010/EU* on the protection of animals used for scientific purposes, and with the provisions of the *Animals (Scientific Procedures) Act 1986 (ASPA), as amended in 2012*, and any guidance and codes of practice issued under the Act. No such work involving animals can be done at Imperial without the approval of Imperial's Animal Welfare and Ethical Review Body (AWERB) and the Home Office. The AWERB Committee - which includes members who are vets, animal care staff, scientists, lay people - some of whom are independent of the university, scrutinize proposals for their scientific and ethical justification of animal use. The Committee will also provide information and advice about ethical analysis, best practice in animal welfare and new developments in techniques that avoid animal use. The UK law which governs the use of animals is widely viewed as the most rigorous piece of legislation of its type in the world and the Home Office Inspectors who administer it maintain an audit programme of facilities where work is carried out.

It is Imperial policy that animals may only be used for scientific or educational purposes where there are no satisfactory or reasonably practical alternatives to their use. The university is committed to ensuring that all staff and students involved in animal-based work treat animals with respect and consideration and develop a culture of care in all aspects of their work. Imperial is committed to the principles of replacement, reduction and refinement (the 3Rs) in animal research and all researchers are expected to implement, wherever possible, models that replace, reduce or refine the use of animals in their research. Animals held for scientific or educational purposes must be maintained under the highest standards of care and welfare. All those working with animals are expected to take a proactive interest in the welfare of animals in their charge, and to ensure that their work complies with the highest ethical standards.

Imperial expects all its staff and students to comply with this policy whether working at the university, or otherwise with collaborators elsewhere. Work undertaken overseas must comply with relevant local legislative requirements, with funder T & Cs, and be conducted in accordance with Imperial's ethical standards. In order to ensure that all work is carried out in accordance with this policy, Imperial staff and post-graduate students whose work involves the use of protected animals (including but not limited to the use of living animals, the use of animal derived materials and animal derived data) are required to consult the Animal Use guidance notes and register their studies (and gain any necessary approvals) accordingly.

All work (as defined below)¹ involving protected animals (as specified in the *Animals (Scientific Procedures) Act 1986 (ASPA), as amended in 2012*) that has not been reviewed and approved by Imperial's AWERB process must be formally registered, by the academic lead, on the university's Annual declaration of interests return. Some classes of work will additionally require review and approval by Heads of Department/Division/School/ Institute (or their delegated

approvers), henceforth referred to as Designated Approvers. Designated Approvers will be provided with guidance regarding categories of animal work that may require appropriate and proportionate ethical review to be put in place and certain categories of study will be automatically referred to Imperial's AWERB for consideration. Following AWERB review, AWERB will provide advice to the Provost who will make the final decision whether or not to allow the Imperial employee to participate in the study.

¹ For the avoidance of doubt, work involving protected animals is defined in the broadest sense to include:

- Any work (including observational studies) involving living protected animals
- Acquisition and storage of novel/primary derived materials from protected animal species on Imperial premises
- Use of novel/primary derived materials from protected animals on Imperial premises or elsewhere
- Use of data (other than data obtained from freely accessible public databases) derived from protected animal studies
- Commissioning or subcontracting protected animal studies

Guidance notes

All work involving "protected animals" (see definition below) that is covered by Imperial College London's <u>Use of Animals policy</u> and which has not been reviewed and approved by Imperial's Animal Welfare and Ethical Review Body (AWERB) process must be formally registered on the College's Declaration of Interests Animal register. The academic lead for each project should register the study; there is no requirement for post-docs/technicians/PhD students working on a project to also register the study.

The university has agreed that the registration aspect of the policy will be implemented through an extension to the current process for the Register of External Interests and Annual Declaration. Imperial College London employees will be required annually to complete a Declaration providing details of involvement in projects falling under the scope of the policy (and to update this during the course of the year if they intend to commence new studies covered by the policy). To ensure the details held are as comprehensive as possible, members of staff who do not undertake any such activities will be required to submit a nil return. Details of the information declared, and a list of non-returners, will be shared with Heads of Departments/Division/School/Institute, in alignment with the current process for registration of External Interests.

Some categories of work will additionally require approval by Heads of Departments/ Division/School/ Institute (or their delegated approvers), henceforth referred to as Designated Approvers or via Imperial's AWERB. Designated Approvers approval will be obtained via the Declaration of Interests Animal register. Certain categories of study (see below) will require prior ethical approval to be obtained through Imperial's AWERB process.

The university expects all its staff to comply with this requirement whether working at the university, or otherwise with collaborators elsewhere.

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- Acquisition and storage of novel/primary derived materials from protected animal species on Imperial premises
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Definition of a protected animal

Imperial has adopted the definition of a "protected animal" as set out in the *Animals (Scientific Procedures) Act 1986 (ASPA), as amended in 2012* as "any living vertebrate, other than man, and any living cephalopod".

- Embryonic and foetal forms of mammals, birds and reptiles are protected animals once they have reached the last third of their gestation or incubation period.
- Larval forms of fish and amphibians are protected animals once they are capable of feeding independently. Cephalopods are protected animals from the point when they hatch.
- A procedure carried out on a foetal, larval or embryonic form at an early stage of development may also be covered by the legislation if the immature form is allowed to live until after it reaches the stage of development at which it becomes protected and at that stage the procedure may cause the animal pain, suffering distress or lasting harm.

If your work involves the use of protected animals, please refer to *Flowchart A* to check whether or not you need to register your project. If registration is required, please select the appropriate button on the Use of Animals Declaration (you can also link directly to the database here). Please use Flowchart B or Flowchart C as appropriate to check whether your project also requires approval. You may also find the FAQs helpful.

Further details regarding the AWERB approvals process can be found on the Central Biomedical Services (CBS) website. Please direct any enquiries to awerb.admin@imperial.ac.uk.

Completing your return

Please note that you need to be logged in via the college network to access the use of animals' database. If you are working off site, please connect via Unified Access or a Virtual Private Network (VPN) connection before trying to complete your return. Please follow the guidance provided by ICT for accessing services remotely.

Appendix 1 – List of countries/Institutions that have been pre-approved for one or more species for certain categories of work

Tier 1 – Applicable for all species other than NHP, cat, dogs, equidae and endangered

Australia Canada New Zealand Switzerland

Tier 2 – Applicable for restricted species as listed for each entry as follows:

Rodent work at any US University Rodent work at any NIH Institution

AAALAC accredited external institutions:
Laboratory bred rodents (including rats, mice, guinea pigs, hamsters)
Laboratory bred rabbits
Laboratory bred ferrets
Laboratory bred avian species
Laboratory bred amphibian species
Laboratory bred fish

See <u>AAALAC Accredited Organisations</u> for up-to-date list of AAALAC accredited Organisations

For projects requiring referral to Imperial's AWERB:

Initial Screening for all species other than NHP, cat, dogs, equidae and endangered.

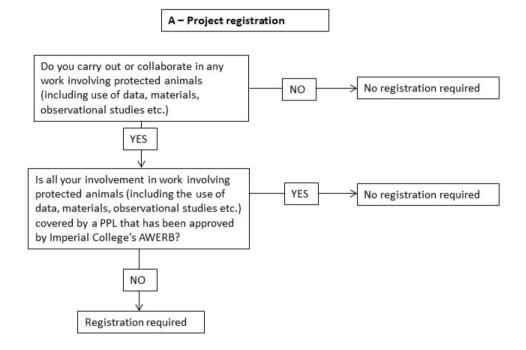
- 1. Applicants will be asked to provide a short synopsis of the proposed work.
- 2. The external organisation will be asked to complete a 3rd Party Organisation Animal Welfare Assessment Questionnaire to provide assurance regarding standards of animal welfare and ethical review processes at the external organisation. Completed forms will be reviewed by senior CBS staff. Where the questionnaire responses indicate that satisfactory standards apply, applications may be fast tracked and approved via the AWERB Chair's Action.

Applications including the use of NHP, cat, dogs, equidae and endangered species or where initial screening evaluation does not provide sufficient information for fast track approval.

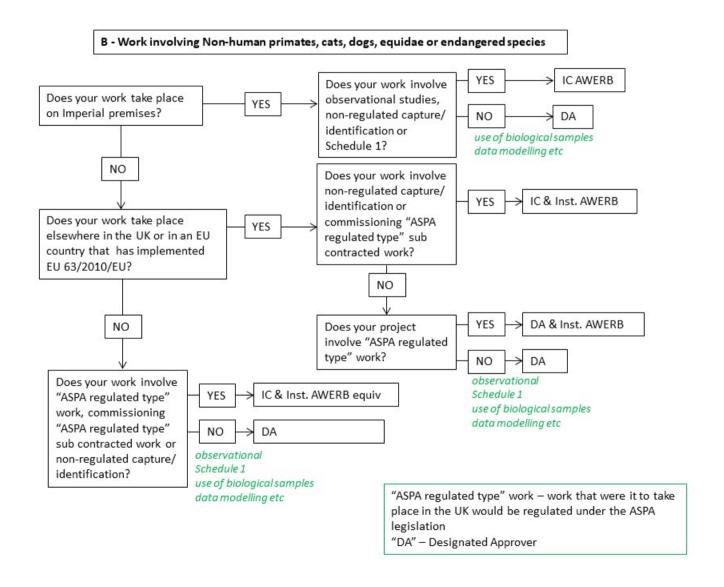
- The PI will be asked to complete an application form, and this will be reviewed by the Imperial AWERB as though the work would be taking place at Imperial. Following initial review of the proposals by the named people and peer and lay reviewers, the proposal will be referred to AWERB for full consideration.
- 2. Full details of the funding for the work, including details of ethical and peer review processes it has been through (and any additional ethical review such as NC3Rs review) will be requested.
- 3. Assurances will be sought regarding standards of animal welfare and ethical review processes at the external organisation.
- 4. The AWERB Chair may also elect to seek external guidance where appropriate (eg from NC3Rs).

Please see the CBS website for further details of the AWERB process. Completed forms should be sent to awerb.admin@imperial.ac.uk.

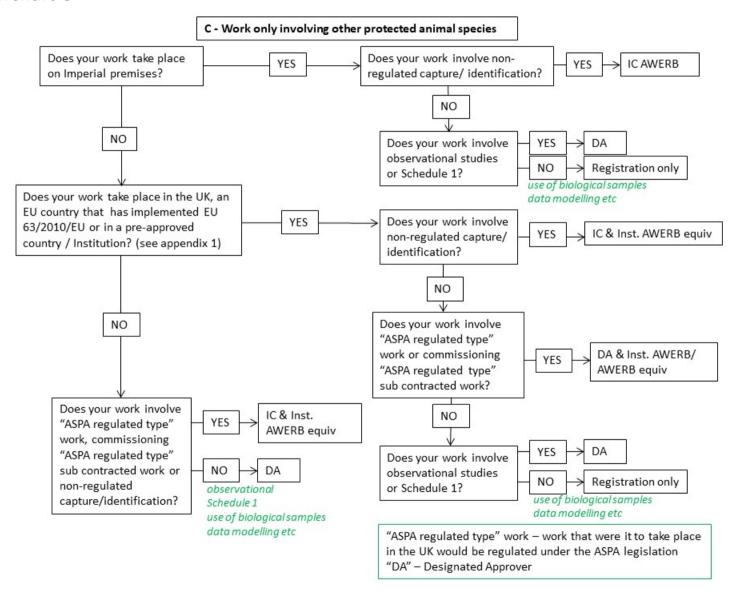
Flowchart A



Flowchart B



Flowchart C



Frequently Asked Questions

Connection / technical

- Q1. I clicked on the link in ICIS to submit my declaration but the link does not work.
- A1. Please note that you must be connected to the college network to connect to the database and should use the university's <u>Unified Access</u> system or other ICT approved mechanism if you are accessing these links from a non-university location.
- Q2. I tried to submit a nil declaration but I receive an error message telling me that there are live declarations for this year already and I am unable to create a NIL record.
- A2. The system has been designed to prevent you submitting a NIL declaration if live records, or a NIL declaration, already exist for the submission year. You can check the details currently held on the system by clicking on Declarations followed by My Records where your declaration record can be viewed and updated.
- Q3. I registered my study last year. Do I need to re-register it as part of this year's return?

 A3. If the study was/ is still ongoing for this declaration year, then yes you do need to re-register the study. In order to minimise the work involved, the database will provide you with an option to copy an existing declaration record. You can check the details currently held on the system by clicking on Declarations followed by My Records where your declaration record can be viewed and updated, and existing declarations copied.

Materials

- Q1. Receiving primate tissue from a collaborator in the USA for use at Imperial.
- A1. This involves the acquisition of protected animal materials and requires registration. As the tissue is from an animal species falling into the "special species" category, approval from the Designated Approver is also required. The Designated Approver should approve via the Annual Declaration list of projects.
- Q2. Receiving rodent tissue from a collaborator in the USA for use at Imperial.
- A2. This involves the acquisition of protected animal materials and requires registration. As the tissue is from an animal species that does not fall into the "special species" category, this requires registration only.
- Q3. Sending animals or animal materials from Imperial to Institutions elsewhere, for studies where there will be no further involvement of the Imperial investigators.
- A3. This policy does not impact on your ability to send animals/animal materials elsewhere and no registration is required. You must ensure that you follow current CBS guidance for the export of animals/animal materials from CBS facilities and ensure that such transfers are in accordance with all applicable laws (i.e. no change to current procedures). It is accepted that in some cases the recipient may acknowledge your contribution by including your name as an author on publications arising from the use of the animals / materials provided that you are not actively undertaking work at the external facility, potential inclusion as an author does not require this to be declared.
- Q4. Purchasing commercially available antibodies from a company.
- A4. This policy does not impact on your ability to purchase commercially sold antibodies. No registration is required.

Q5. Commissioning an external organisation to custom generate an antibody using animal methods for use in my work at Imperial.

A5. This involves commissioning ASPA regulated type work and requires registration and approval. The approval path will be dependent on the species used for antibody generation and the country / Institution involved in carrying out the work.

Q6. I work with a collaborator who provides mouse tissues but not live mice for my research. Do I need to declare this?

A6. Yes, you need to declare this. This involves the acquisition of protected animal materials and requires registration. As the tissue is from an animal species that does not fall into the "special species" category, this requires registration only.

Use of Data

Q1. Using publicly available gene expression data (e.g. downloaded from GEO).

A1. Use of data obtained from freely accessible public databases is exempt and you are not required to declare work of this type. No registration is required.

Q2. Using data (such as neurophysiological recordings) from non-human primates provided by a collaborator at NIH.

A2. Use of data that is publicly available (eg from public databases or through research data sets made freely available through research council data sharing policies) is not covered by the policy and use of such data need not be registered. Collaborative access to primary data not yet made publicly available is covered by the policy and should be declared. Use of data on Imperial premises from data originating on a protected species falling into the special species category requires registration and the Designated Approver should approve via Annual Declaration list of projects.

Q3. Using data (such as neurophysiological recordings) from rodents provided by a colleague at an UK university.

A3. Use of data that is publicly available (eg from public databases or through research data sets made freely available through research council data sharing policies) is not covered by the policy and use of such data need not be registered. Collaborative access to primary data that has not yet been made publicly available is covered by the policy and should be declared. Use of data on Imperial premises from data originating on a protected species that does not fall into the special species category requires registration.

Q4. I work with a collaborator who uses animals. Some of the work we do / publish together includes animal research which takes place at the collaborating institution. I do not take part in or direct the animal research, but I do make use of results / observations from their animal work to inform the areas of the collaboration that I direct. Do I need to declare this?

A4. Use of data that is publicly available (eg from public databases or through research data sets made freely available through research council data sharing policies) is not covered by the policy and use of such data need not be registered. Collaborative access to primary data that has not yet been made publicly available is covered by the policy and should be declared.

Q5. I am the administrator of a computing system being used by researchers to store and analyse data arising from animals covered by the Policy of Use of Animals in Research. Do I need to register or return for this?

A5. It is the responsibility of each project's academic lead to ensure that appropriate registration and declarations are in place for every project, including the data arising from it. Staff in facilities providing computing analysis/data management and storage are not required to register or declare this type of work themselves (unless they are the originator of the project).

Observational Studies

- Q1. Using guppy fish for observational undergraduate lab practicals. The guppies are bought from fish suppliers and are allowed to live out their natural life in the fish tanks, they are not subjected to any procedures at all.
- A1. This involves the use of a protected species on Imperial premises. This requires registration. The Designated Approver should approve via the Annual Declaration list of projects.
- Q2. Using Drosophila for observational undergraduate lab practicals. They are not subjected to any procedures at all and are just observed.
- A2. Drosophila are not a protected species under the ASPA legislation thus there is no need to register this work.

ASPA regulated research / Commissioning ASPA regulated work

- Q1. Contracting a CRO in the UK to carry out ASPA regulated pre-clinical toxicology tests on dogs for a grant funded project where I am the PI.
- A1. This involves the use of a protected species, falling into the special species category, in ASPA regulated work being commissioned by the Investigator, in the UK. This requires registration, and approval from both the Imperial AWERB and the AWERB at the CRO facility.
- Q2. Collaborating with a colleague at the University of Oxford to carry out ASPA regulated research on primates.
- A2. This involves the use of a protected species, falling into the special species category, in ASPA regulated work in the UK. This requires registration, and approval by both the Imperial Designated Approver and the AWERB at the University of Oxford.
- Q3. Contracting a CRO in the UK to carry out ASPA regulated pre-clinical toxicology tests on rats for a grant funded project where I am the PI.
- A3. This involves the use of a protected species, which does not fall into the special species category, in ASPA regulated work being commissioned by the Investigator, in the UK. This requires registration. The Designated Approver should approve via Annual Declaration list of projects. Approval from the AWERB at CRO facility will be required.
- Q4. Collaborating with a colleague at Cambridge to carry out ASPA regulated research on rats.

 A4. This involves the use of a protected species, which does not fall into the special species cat.
- A4. This involves the use of a protected species, which does not fall into the special species category, in ASPA regulated work in the UK. This requires registration, and approval by the Imperial Designated Approver, and the AWERB at the University of Cambridge.
- Q5. I carry out ASPA regulated work and all of my animal work is covered by a Project Licence with Primary (or Secondary) availability at Imperial. Do I need to register?
- A5. No, if all your work is covered by a current PPL that has been approved by Imperial's AWERB, you do not need to register this.
- Q6. I carry out ASPA regulated work and all of my animal work is covered by a Project Licence held only at Edinburgh University. Do I need to register?
- A6. Yes, if your project licence does not specify either Primary or Secondary availability at Imperial College London, you are required to register your project.
- Q7. I am having mice made by an UK commercial organisation. Do I need to declare this?
- A7. This involves commissioning "ASPA regulated" work and will require registration. The Designated Approver should approve via the Annual Declaration list of projects.

- "ASPA regulated type" work (ie work that were it to take place in the UK would be regulated under the ASPA legislation) / Commissioning "ASPA regulated type work"
- Q1. Collaborating with a colleague in a Brazilian University to carry out "ASPA regulated type" research on rats. The University is not AAALAC accredited and does not appear on the pre-approved list of Institutions in appendix 1.
- A1. This involves the use of a protected species, which does not fall into the special species category, in "ASPA regulated type" work in a country/Institution that is currently not pre-approved. This requires registration, and approval from both the Imperial College AWERB and any AWERB type equivalent at the Brazilian Institution.
- Q2. Collaborating with a colleague at NIH in the USA to carry out "ASPA regulated type" research on rats.
- A2. This involves the use of a protected species, which does not fall into the special species category, in "ASPA regulated type" work in an Institution/country that is pre-approved for this species in Appendix 1. This requires registration. The Designated Approver should approve via Annual Declaration list of projects. Approval from the AWERB equivalent at NIH will be required.
- Q3. Collaborating with a colleague at a small CRO in the USA to carry out "ASPA regulated type" research on rats. The CRO is not AAALAC accredited.
- A3. This involves the use of a protected species, which does not fall into the special species category, in "ASPA regulated type" work in an Institution/country that is not pre-approved in Appendix 1. This requires registration and approval from both the Imperial College AWERB and the AWERB equivalent at the CRO facility.
- Q4. Collaborating with a colleague in a Chinese University to carry out "ASPA regulated type" research on rats. The University appears on the pre-approved list of Institutions in appendix 1. A4. This involves the use of a protected species, which does not fall into the special species category, in "ASPA regulated type" work in an Institution that is pre-approved in Appendix 1. This requires registration, and approval by the Imperial Designated Approver, and the AWERB equivalent at the Chinese University.
- Q5. Collaborating with a colleague in a South African University to carry out "ASPA regulated type" research on primates.
- A5. This involves the use of a protected species, falling into the special species category, in "ASPA regulated type" work in a country/Institution that is currently not on the pre-approved list. This requires registration, and approval from both the Imperial College AWERB and any AWERB type equivalent at the South African Institution.
- Q6. I am having mice made by an overseas commercial organisation. Do I need to declare this? A6. This involves commissioning "ASPA regulated type" work and will require registration and approval. The approval path (Designated approver or Imperial AWERB) will be dependent on the country / Institution involved in carrying out the work.

General

- Q1. I am a technician/post-doc/PhD student working in Professor Blogs' lab. I carry out work that is covered by the policy. Do I need to register this?
- A1. No. The academic lead for the project should register this on your behalf. You do not need to register this as well. However, you may wish to liaise with Professor Blogs to ensure that s/he has registered this work in accordance with the policy. You are permitted to enter a NIL return.

Q2. I am an Independent Research Fellow running my own group and carry out work that is covered by the policy. Do I need to register this?

A2. Yes. As the academic lead for the work, you should register the project on behalf of yourself and all those working in your group.

Q3. I get paid to dog walk in my spare time, do I need to declare this?

A3. You are not required to declare work of this type, which you undertake outside of your Imperial College London employment, as part of the declaration and registration of animal work. You should however ensure that you follow any requirements for registration/approval that may be required under the existing HR external interest declaration policy and declare such work through that route where applicable.

Q4. I volunteer at an animal shelter/ petting zoo/ farm/ pet shop/ vets. Does that count?

A4. You are not required to declare voluntary work of this type, which you undertake outside of your Imperial College London employment, as part of the declaration and registration of animal work. You should however ensure that you follow any requirements for registration/approval under the existing HR external interest declaration policy and declare such work through that route if applicable.

Q5: I am a member of a research facility that provides equipment/facilities/staff assistance to many researchers across college. I may be required to carry out work covered by the policy on behalf of these researchers. Do I need to register this?

A5: No. The academic lead for the project should register this on your behalf. You do not need to register this as well. However, you may wish to liaise with the academic lead(s) to ensure that s/he has registered this work in accordance with the policy. You are permitted to enter a NIL return.