

Guidance on the ethical review requirements for research involving animals

Introduction

On 26th June 2013, Senate approved the University's [Policy on the Use of Animals in Research](#). The purpose of the Policy is to provide a clear statement about the University's position in relation to the use of animals in research and clarify the responsibilities of those whose University activities involve animals.

The policy applies to all persons, both staff and students, undertaking research that involves animals, with the intention of publishing their work under the address of the University of Manchester. This policy also applies to work carried out by external companies using University of Manchester facilities.

The purpose of this document is to supplement the Policy with guidance about which studies require ethical review and through which review process. However, it should be noted that ethical issues concerning the use of animals must always be considered by a Principal Investigator even if the research is not required to undergo formal ethical review (please refer to section 4 of the Policy).

Categories of Animal Research

The Policy divides the use of animals in research into 4 categories; A, B, C and D, and defines the ethical review requirements for each category:

Category A

The use of living vertebrates and cephalopods in scientific procedures within the University and the UK which are regulated by the Animals (Scientific Procedures) Act 1986 ([ASPA](#)) Amendment Regulations 2012 ("the Act").

Studies which fall into Category A require full ethical review and approval by the University of Manchester's Animal Welfare and Ethical Review Board (AWERB).

Category B

The use of living vertebrates and cephalopods in scientific procedures that would fall under the definitions of ASPA if conducted in the UK but are being conducted outside the UK.

Studies which fall into Category B require review and approval by AWERB.

Studies that fall into this category would require ethical review and approval by the University's AWERB or its executive committee to ensure that welfare and husbandry standards of animal care at collaborator institutions are consistent with UK legislation and standards.

Types of category B studies requiring ethical review by AWERB:

1. Where research conducted outside of the UK involves scientific procedures as defined by ASPA, and is led by a University of Manchester PI.
2. Where research conducted outside of the UK involves scientific procedures as defined by ASPA; is led by someone with a joint appointment with the University of Manchester and where the research is conducted in the PI's capacity as an employee of the University of Manchester.

Some category B studies **not** requiring ethical review by AWERB, would require local ethical review by the country where the research is being conducted. University of Manchester employees should satisfy themselves that the research complies with any local regulations in that country and is conducted in accordance with the University's ethical standards. Examples:

1. Research led by another institution for which a University of Manchester researcher is receiving tissue or similar by-products of the research. Such studies should have a Material Transfer Agreement in place. Please contact the Contracts Office for further information.
<https://www.staffnet.manchester.ac.uk/rbe/contracts/>
2. Animal experiments run outside of the UK by international collaborators who function as the PI for the entire study in question (or at least for its in-vivo component) who must comply with animal welfare/in vivo experimentation rules applicable in that country and at the researcher's institution.

Category C

The use of tissue in research harvested from living vertebrates and cephalopods killed solely for that purpose regardless of where the animals or tissue were sourced.

Studies that fall into Category C require proportionate review by AWERB.

In addition, tissue sourced outside of the University of Manchester should have a Material Transfer Agreement in place. Please contact the Contracts Office for further information.

<https://www.staffnet.manchester.ac.uk/rbe/contracts/>

Examples:

1. Analysis in the UK of tissue harvested by non-UK collaborators.
2. Analysis of materials of animal origin, i.e. antibodies, sourced outside UK and imported into UK for use in research.

Category D

The use of animals in scientific enquiry not regulated under ASPA 1986 because the animals are not vertebrates or cephalopods, or the research does not involve the animal in scientific procedures. (For example, the non-invasive use of live animals in the Manchester Museum for public education and conservation purposes and some behavioural and observation work within the University and on educational field courses).

Studies that fall into Category D require review and approval by a sub-committee of AWERB. Review and approval for studies takes between 2-3 weeks and takes place digitally.

Types of study meeting Category D research criteria:

1. The work does not require a Home Office ASPA licence (i.e. animals will not experience pain, suffering, distress or lasting harm through either a procedure or a series of procedures) but where the animals are handled, kept outside their natural environment or have their natural environment altered.
Please note: For applications where there are a series of combined procedures being carried out on vertebrates or cephalopods, or where the animals are to be re-used, such applications would then be referred to AWERB to ascertain if such use constitutes a scientific procedure.
2. The work involves any invertebrate requiring statutory permission (including but not limited to invasive species, endangered or threatened species and parasites or pathogens).

Examples:

1. The non-invasive use of live animals in the Manchester Museum for public education and conservation purposes.
2. Some behavioural and observation work within the University and on educational field courses, where the researcher may or may not interact with the animal in the environment and either remove the animal or make changes to the animal's environment.
3. Placement hosts would be asked to demonstrate their own internal review process. If a student was expected to publish their findings under the address of the University of Manchester, then in line with University policy, a full application for ethical review would be required.
4. Requirements for Defra Licence – controlled species
5. Endangered species
6. Undergraduate research projects

Application forms for all categories can be found at:

<https://app.bmh.manchester.ac.uk/facilities/research/bsf/licencing/ethics.aspx>

If you do not have access to the BSF intranet you can contact the AWERB Secretary to obtain copies of the forms: AWERB.Secretary@manchester.ac.uk