

QUEEN'S UNIVERSITY BELFAST

Regulations Governing Research Involving Animals

1. Introduction

- 1.1 Queen's University Belfast is committed to excellence in research. It requires all researchers to conduct their research with the highest integrity. Research involving the use of animals must be conducted in accordance with the law and in compliance with the necessary ethical standards. Researchers must ensure they fulfil the obligations contained within the Concordat to Support Research Integrity.
- 1.2 The University expects its researchers to strive for best practice and not to settle for legislative compliance at a basic level. It requires researchers to work to establish a 'Culture of Care' to ensure that animals are treated with compassion and respect.
- 1.3 Where animals are being studied, this must be the most appropriate method of scientific discovery that will contribute to the advancement of knowledge. In turn this may lead to the improvement of human or animal health and/or animal welfare/behaviour.
- 1.4 Many locations may be used for the study of animals; in their owner's home, a farm, zoo, within a laboratory or the animal's natural habitat. The type of research conducted will determine the legal and ethical responsibilities of the researcher. All research undertaken within in, or on behalf of the University requires the highest standards of humane care and treatment of the animals.
- 1.5 The University requires its researchers to obtain appropriate ethical approval for the proposed research **prior** to any study commencing. This is in keeping with the University's focus on research integrity and the requirement of funders. In addition, all necessary licences or regulatory approvals must also be in place at this stage.
- 1.6 The University holds and complies with its Establishment Licence, under the terms of the Animal (Scientific Procedures) Act 1986 and subsequent amendments.
- 1.7 Queen's University Belfast is a signatory to the Concordat on Openness on Animal Research, NC3Rs ARRIVE Guidelines and the Concordat to Support Research Integrity.

2. Legislation

- 2.1 All animals are protected under the Welfare of Animals Act (Northern Ireland) 1972 which makes it a crime to cause unnecessary suffering to any animal, including a wild animal. The Wildlife (Northern Ireland) Order 1985, and subsequent amendments, offers protection to birds whilst the Conservation (Natural Habitats etc) Regulations (Northern Ireland) 1995 offers protection to the natural habitats of specifically protected species e.g. otters, bats, butterflies, etc. A full list of the "European Protected species" can be found on the [Department of Agriculture, Environment and Rural Affairs website](#).

Where research involves a protected animal undergoing a regulated procedure (as defined by the Animal [Scientific Procedures] Act 1986 and subsequent amendments) then this research is subject to the provisions of the Act.

- 2.2 Researchers must hold relevant licences under the Wildlife (Northern Ireland) Order 1985 and/or Animal (Scientific Procedures) Act 1986 (ASPA), and subsequent amendments. In the event that research studies are extended beyond the boundaries of Northern Ireland it is imperative that researchers ascertain and secure the necessary licences required through equivalent legislation for England, Wales and Scotland, prior to the commencement of the research.
- 2.3 Similarly, where research is planned outside of the UK, researchers must ensure that they are aware of and comply with local laws. For example, undertaking an observational study at close quarters may be lawful within the UK but illegal in another jurisdiction.

3. **Categories of Research Involving Animals**

3.1 Schedule 1

The use of tissues harvested from animals sacrificed solely for that purpose via an approved method.

3.2 ASPA Governed

The use of vertebrates and cephalopods in scientific procedures that are governed by the Animals (Scientific Procedures) Act 1986 (and subsequent amendments).

3.3 Other Research Involving Animals

Research involving the use of live vertebrates and cephalopods undertaken as part of a behavioural, welfare, environmental, or other biological sciences study. This research could be conducted within an organised setting such as a laboratory, farm, zoo, animal rescue centre, an owner's home, or in a rural setting. This research does not involve regulated scientific procedures as defined by the Animal (Scientific Procedures) Act 1986 (and subsequent amendments).

4. **Ethical Principles and Requirements**

- 4.1 The University's Policy on the Ethical Approval of Research states that "all studies involving animals, including observational studies which are not subject to a Department of Health (DoH)/Home Office Licence, will be scrutinised by the appropriate Ethics Committee".
- 4.2 Studies should be planned with the principles of the National Centre for Replacement, Refinement and Reduction's (NC3Rs) at the forefront of the research:

Reduction	To use the minimum number of animals;
Replacement	To use alternatives wherever possible;
Refinement	To strive for the highest possible standard of animal care, use and welfare, to initiate improvements where possible and to minimise the suffering and distress caused to animals.

4.3 Schedule 1:

These studies must be reviewed by University's Animal Welfare and Ethical Review Body (AWERB). Schedule 1 applications should be made by the Principal Investigator (PI) using the form attached as Appendix 1. In the event that Schedule 1 activity is required for longer than 1 year, an applicant must make a new application annually.

The person must be trained for Schedule 1 and competency assessed. A record of training and competency must be retained by the licensed individual and the Named Competency and Training Officer informed that training has been competently completed.

4.4 ASPA Governed:

Studies governed by ASPA must be considered by AWERB. The appropriate DoH/Home Office Project Licence application form must be completed. Researchers applying for a Project Licence are required to attend the relevant AWERB meeting in person to discuss their application and have an appropriate Personal Licence. Project licence applicants must ensure that all those involved in the research have undergone the necessary training and been deemed to be competent, and this is captured in their individual training records.

4.5 Other Research Involving Animals:

The Faculty Research Ethics Committee in MHLS or EPS (Faculty REC) of the lead researcher is responsible for the review of non-ASPA animal studies. Where there is potential for doubt regarding pain, stress or lasting harm that could be experienced by an animal, the Chief Investigator/Principal Investigator must consult with the Named Information Officer in the first instance before discussing with DoH Inspector. An application form for ethical review of the research can be obtained from the [Faculty REC website](#). This must be completed and submitted along with the full study protocol to the relevant Faculty REC. A copy of the Faculty REC's approval, along with the protocol, should be sent to the Chair of the AWERB to facilitate future queries.

4.6 The Animal Welfare and Ethical Review Body (AWERB):

The AWERB is responsible for the review of project licence applications, requests for amendments and mid-term/final reports. The Committee is composed of personal and project licence holders, the Named Veterinary Surgeon, Named Animal Care and Welfare Officers. There is an open invitation to the DoH Inspector. The Committee also includes lay representatives who are external to the University. The Committee considers applications at six of their meetings per annum. Responsibilities of the AWERB are outlined in Section 9.

5. **Culture of Care**

Animal welfare and good communication, especially in relation to the sharing and innovating practices are important to further develop a 'Culture of Care' in animal research. The University has pledged to:

- (i) Put animal welfare at the heart of what we do;
- (ii) Show compassion to the animals and colleagues we work with;
- (iii) Comply with and promote a 3R's framework for designing and performing animal experiments;
- (iv) Share ideas and create an open and honest culture within which the giving and receiving of constructive feedback can take place;
- (v) Continually review our practices and training;

(vi) Communicate openly within our organisation and externally.

6. Health and Safety

- 6.1 The Health, Safety and Wellbeing of University staff and students is paramount in all forms of research. It is essential that appropriate risk assessments are undertaken, and all steps taken to mitigate against any risk of harm.
- 6.2 Where research is being undertaken within a hosting organisation, such as a farm, zoo, or animal rescue shelter, it is necessary to ensure that the host organisation's policies and procedures for Health and Safety are complied with. University Safety Services, or your School's Health and Safety representative can also provide advice, as appropriate.

7. Overseas Research

- 7.1 It may be necessary, from time to time, to undertake research overseas. It is the responsibility of researchers to ensure that they are familiar with the animal protection laws in their host country, ensuring compliance at all times.
- 7.2 Where animal research that would be governed by ASPA is to be outsourced, QUB researchers should be aware of the country's legislation governing animal research, what licensing arrangements are in place, and that the research will be ethically reviewed. In the event that a collaborating country does not have these components the researcher should question the appropriateness of the collaboration.
- 7.3 Researchers are also expected to give due consideration to the 3Rs in the design and delivery of their research.

8. Concordat on Openness

The University is a signatory to the Concordat on Openness on Animal Research in the UK. In doing so, the University is committed to being more open about the ways in which animals are used for research purposes. There are four commitments within the Concordat. These are that the University will:

- (i) Be clear about when, how and why animals are used in research;
- (ii) Enhance communications with the media and public about our research using animals;
- (iii) Be proactive in providing opportunities for the public to find out more about research using animals;
- (iv) Report on progress annually and share experiences.

9. Staff Responsibilities

- 9.1 All staff involving animals in their research must ensure they:
- (i) Do not allow an animal to experience severe pain, suffering or distress that is likely to be long-lasting and cannot be ameliorated;

- (ii) Ensure the principals of the 3Rs (Replacement, Refinement and Reduction) remain central to the research;
- (iii) Ensure accurate records of species used and the experiment severity are maintained and reported upon when requested to do so.
- (iv) Are committed to the humane care of the animals under experimentation.
- (v) Undertake to review experimental sheets.
- (vi) Maintain a written record of competencies in regulated procedures. The NTCO/BSU staff will maintain an electronic record of competencies on the tick@lab electronic data management software.
- (vii) Are knowledgeable of, and comply with, the requirements of ASPA and/or other relevant legislation.
- (viii) Maintain their individual personal licences ensuring any changes are notified as soon as possible to ensure PILs remain valid and compliant with GDPR. Where a PIL has not been used in the past five years, undertake the training required to gain their PIL.
- (ix) Comply with the research protocol and/or project licence(s).
- (x) Comply with the Concordat to Support Research Integrity and in doing so maintain research data in a manner that will ensure integrity of research results.
- (xi) Publish research outputs in accordance with the principles of the NC3Rs ARRIVE guidelines, as appropriate.

9.2 Responsibilities of the Principal Investigator (PI)/Project Licence Holder (PPLs)

The PI/PPL is responsible for the day to day running of their research. It is their responsibility to ensure that:

- (i) Where studies are being run from the Biological Services Unit (BSU), PPLs are responsible for the welfare of the animals involved in their research project.
- (ii) The appropriate licences and/or approvals are in place (when necessary) to govern the project.
- (iii) Co-Investigators have the necessary training, competence and personal licences in place prior to the research commencing.
- (iv) Their PPL is only used by their research group.
- (v) Full compliance with the PPL as granted by the DoH, including any conditions placed on that licence.
- (vi) The research has been considered and received ethical approval from the AWERB or Faculty REC.
- (vii) Statutory returns are made, when requested. Mid-term reports are submitted on time to AWERB. Annual returns are submitted accurately and on-time ensuring severity is captured in accordance with legislative definitions.
- (viii) Staff will work closely with the NACWOS and other named persons to ensure the humane and sensitive treatment of the animals in their research.

9.3 Responsibilities of Co-Investigators (Co-I)

All researchers undertaking research involving animals must ensure that they:

- (i) Have in place the necessary licences and approvals in order for the research to be conducted legally and ethically in the relevant jurisdiction(s).
- (ii) They are competent and have had their competency checked in the procedures to be performed.

9.4 The Animal Welfare Ethical Review Body (AWERB) has the following responsibilities:

- (i) The promotion of awareness of animal welfare.
- (ii) Provide a forum for discussion and development of ethical advice to the establishment licence holder on all matters related to animal welfare, care and use at your establishment.
- (iii) Consider standards of animal care and accommodation, including breeding stock, and the humane killing of animals.
- (iv) Set up and regularly review procedures and protocols, including management systems, for monitoring, reporting and following up on the acquisition, welfare and proper use of animals at QUB establishment(s).
- (v) Support named people (as defined by the legislation), and other staff dealing with animals, on animal welfare and ethical issues.
- (vi) Promote the development and uptake of the 3Rs (replacement, refinement, reduction), and advise staff how to apply them.
- (vii) Review all proposals for project licences from a local perspective, consider how the 3Rs are being applied and advise the establishment licence holder on their acceptability, bringing local knowledge and local expertise to bear.
- (viii) Throughout the lifetime of projects, follow their development and outcome, including those requiring retrospective review, so that lessons learnt can be used to further apply the 3Rs.
- (ix) Advise on re-homing animals (when appropriate) including appropriate socialisation.
- (x) Respond to enquiries and consider advice received from the national Animals in Science Committee.

9.5 The Named Animal Care and Welfare Officers (NACWO) are responsible for ensuring that the highest standards of animal husbandry are implemented and the requirements of ASPA are met. NACWOs are responsible for ensuring animals receive the necessary environmental enrichment.

9.6 The Named Training and Competency Officer (NTCO), as defined under ASPA, is responsible for ensuring that all those dealing with animals are adequately educated, trained and supervised until they are competent and that they continue to undertake appropriate further training in order to maintain their expertise.

9.7 The Named Veterinary Surgeon (NVS) is responsible for advising on the health, welfare and treatment of the animals and should help the named person responsible for compliance with the establishment licence to fulfil his/her responsibilities.

9.8 The Named Information Officer (NIO) is responsible for ensuring that those dealing with animals in the licensed establishment have access to the information they need about the species held and procedures being performed.

9.9 The Named Person Responsible for Compliance/Establishment Licence Holder is responsible for ensuring that the requirements of ASPA and the conditions of the establishment licence are complied with.

10. Publication of Research

The results of research, generated through the use of animals, should follow the ARRIVE Guidelines (Animal Research: Reporting of *In Vivo* Experiments).

APPLICATION FOR SCHEDULE 1 ACTIVITIES

The University requires that all animal research studies involving the use of vertebrates and cephalopods are reviewed and approved by an appropriate research ethics committee. In addition, the revised Animals (Scientific Procedures) Act 1986 (ASPA), now requires that records are kept for all animals that are sacrificed using schedule 1 methods. As such, all non-ASPA animal research involving both observational and schedule 1 experimentation is subject to annual ethical review by the appropriate Faculty Research Ethics Committee or QUB Animal Welfare and Ethical Review Body, respectively. The following form is for Schedule 1 activity only and should be sent to the AWERB Chair for consideration and noting.

1. Name, position and School or Research Centre/Institute of applicant:

2. Name and position of staff and students who will work on the project:

3. Outline plans for completion of personal or project licence training modules (if applicable):

4. Background and main aims of the research area for which animals will be used:

5. Detailed summary of protocols to be performed on animal tissues:

6. Justification for number of animals to be used and species involved

7. Outline why animals have to be used for these studies and whether alternative non-animal models have been considered:

8. Details of personnel who will perform schedule 1 sacrifice, methods to be used, and training undertaken (if applicable):

SIGNATURES

Applicant:

Name: _____ Signature: _____ Date: _____

Chair, AWERB:

This Committee grants approval for Schedule 1 activities for the purposes described

Name: _____ Signature: _____ Date: _____