QUEEN'S UNIVERSITY BELFAST

Regulations Governing Research Involving Animals

1. Introduction

1.1 Queen's University Belfast is committed to excellence in research and it requires all researchers to conduct their research with the highest integrity. Research that involves the use of animals must be conducted in accordance with the law and with the necessary ethical standards. Further, where animals are being studied this must be the most appropriate method of scientific discovery that will contribute to the advancement of knowledge which may lead to the improvement of human or animal health and/or animal welfare/behaviour.

1.2 There are many locations where animals may be used for research; in their owner's home, on a farm, at a zoo, within a laboratory or within their natural habitat. The type of research being conducted will determine the legal and ethical responsibilities of the researcher. Wherever the research is undertaken the University requires the highest standards of humane care and treatment of the animals.

1.3 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 both 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.

1.4 The University holds and complies with its Establishment Licence, under the terms of the Animal (Scientific Procedures) Act 1986 and subsequent amendments.

1.5 Queen's University Belfast is a signatory to the Concordat on Openness on Animal Research and the NC3Rs ARRIVE Guidelines.

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 at http://www.doeni.gov.uk/niea/wildlifeandthelawscreen.pdf. Where research involves a protected animal undergoing a regulated procedure (as defined by the Animal [Scientific Procedures] Act 1986) then this research is subject to the provisions of the Act, and its subsequent amendments.

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 clearly that "all studies involving animals, including observational studies which are not subject to a Department of Health Social Services and Public Safety (DHSSPS)/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 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 the AWERB. The appropriate DHSSPS/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 School Research Ethics Committee (SREC) of the lead researcher is responsible for the review of non-ASPA animal studies. Where there is a 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 DHSSPS Inspector. An application form that provides information on the names and positions of staff that will work on the project, the main background and aims of the research, detailed summary of protocols to be performed, including study location information, must be completed and submitted along with the full study protocol to the SREC. A copy of the SREC'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, the DHSSPS Inspector, an external lay representative and relevant University research staff. It meets 4-6 times per annum, depending on demand and will provide support and ethical advice/approval to researchers in relation to their proposed research studies. The responsibilities of the AWERB are outlined in Section 7.

5. Health and Safety

5.1 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 are taken to mitigate against any risk of harm.

5.2 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.
(http://www.qub.ac.uk/directorates/HumanResources/OccupationalHealthandSafety/SafetyService/).

6. Overseas Research

6.1 It may be necessary, from time to time, to undertake research overseas. Therefore researchers must ensure that they are familiar with the animal protection laws in their host country, ensuring compliance at all times. They are also expected to give due consideration to the 3Rs in the design and delivery of their research.

7. Staff Responsibilities

7.1 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) Are appropriately trained and that records relating to such training are maintained for review, as required.
(iv) Are knowledgeable of, and comply with, the requirements of ASPA or other relevant legislation.
(v) Comply with the research protocol and/or project licences.
(vi) Maintain research data in a manner that will ensure integrity of research results.
(vii) Publish research outputs in accordance with the principles of the NC3Rs ARRIVE guidelines, as appropriate.

7.2 Responsibilities of the Principal Investigator (PI)

The PI 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), PIs 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 licences in place prior to the research commencing.
(iv) The research has been considered and received ethical approval from the AWERB or SREC.
(v) Statutory returns are made, when requested.

7.3 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).

7.4 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.

7.5 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.

7.6 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.

7.7 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.

7.8 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.

7.9 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.

8. Publication of Research

The results of research, generated through the use of animals, should follow the ARRIVE Guidelines http://www.nc3rs.org.uk/arrive-animal-research-reporting-vivo-experiments.

Queen's University Belfast

APPLICATION FOR APPROVAL TO CONDUCT NON-LICENSED ANIMAL RESEARCH STUDIES

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 will now be subject to annual ethical review by the appropriate School Research Ethics Committee or QUB Animal Welfare and Ethical Review Body, respectively. All applicants should complete the following form and send to the Chair of the relevant committee for consideration.

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 using live animals or their tissues including study location information (research protocol must be included with the application):

6. Justification for number of animals to be used and species involved (particularly for field studies of threatened or protected animals):

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, Research Ethics Committee:
This Committee grants approval to conduct non-ASPA animal research studies as detailed.

Name: _____ Signature: _____ Date: _____