# QUEEN'S UNIVERSITY BELFAST

## Regulations Governing Research Involving Animals

### 1. Policy Statement

1.1 Queen's University Belfast is committed to excellence in research. It requires all research to be conducted with honesty, rigour, care, and respect. As open as possible, as closed as necessary and with transparency so that researchers are accountable for their work.

1.2 Research involving animals must be conducted in accordance with the law and in compliance with the necessary ethical standards. The University expects its researchers to strive for best practice and not to settle for legislative compliance at a basic level – this is particularly relevant when collaborating with overseas partners.

1.3 Researchers must engage with and work to ensure the '**Culture of Care'** (see appendix 1) is embedded in all they undertake. Ultimately the University requires researchers to ensure animals are treated humanely, with compassion and respect. Additionally, the 'Culture of Care' should encourage acceptance of responsibility and accountability and highly value all staff involved in maintaining animal welfare.

1.4 Where animals are being studied, this must be the most appropriate method of scientific discovery that will contribute to the advancement of knowledge yet do the least harm to the animals being used. The principles of the 3Rs – Replacement, Reduction and Refinement must be applied. The goal is to lead to improvements of human or animal health and/or animal welfare/behaviour.

1.5 The University recognises that many locations may be used for the study of animals, in their owner's home, a farm, zoo, natural habitat or laboratory. The type of research to be conducted determines the legal and ethical responsibilities of the researcher. Researchers are also required to ensure health and safety requirements are met if working off-site, and that appropriate authorities are given sufficient notice of the intention to undertake research activities at places other than the designated establishment facilities. Animals utilized within the Biological Services Unit (BSU) will be subject to all local rules.

1.6 The University holds and complies with its Establishment Licence, under the terms of the Animal (Scientific Procedures) Act 1986 and subsequent amendments. The University requires all researchers to obtain appropriate ethical review for the proposed research **prior** to any study commencing. This is in keeping with the University's commitment to research integrity.

1.7 Researchers involving animals in their studies must be appropriately trained and have all necessary licences or regulatory approvals in place prior to commencement. Training should be species specific when applicable.

1.8 Queen's University Belfast is a signatory to the Concordat on Openness on Animal Research. Its staff and students are expected to comply with the PREPARE guidelines for designing animal experiments, the NC3Rs ARRIVE guidelines for reporting animal studies, and the Concordat to Support Research Integrity.

## 2. Legislative and Good Practice requirements

2.1 All animals are protected under the Welfare of Animals Act (Northern Ireland) 1972, updated 2011, which makes it a crime to cause unnecessary suffering to any animal, including a wild animal.

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

(ii) 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.

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. If 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 in the chosen research jurisdiction. Researchers must also comply with local laws. For example, undertaking an observational study at close quarters may be lawful within the UK but illegal in another jurisdiction.

2.3 Studies should be planned with the principles of the 3Rs at the forefront of the research as promoted by the National Centre for Replacement, Refinement and Reduction's (NC3Rs):

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| Reduction | To use the minimum number of animals to obtain statistically robust data; |
| Replacement | To use alternatives to animals 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 pain, suffering, distress and any lasting harm caused to animals. |

2.4 Where regulated procedures are to be conducted outside of the UK, researchers must ensure welfare standards are consistent with those in the UK. Major UK research funders have adopted guidelines of good practice developed by the NC3Rs for animal research conducted overseas. Checklists have been developed for different species. It is a University requirement that the relevant checklist is completed prior to entering into a collaboration agreement/contract if research involving animals is being conducted overseas: refer to Responsibility in the Use of Animals in Bioscience Research; NC3Rs Guidelines: Primate Accommodation, Care and Use. Evidence of completion will be sought during contract review.

## 3. Categories and Ethical review requirements

3.1 Schedule 1

The use of Schedule 1 (i.e. tissues harvested from animals sacrificed solely for that purpose via an approved humane method) requires review by the University's Animal Welfare and Ethical Review Body (AWERB). Schedule 1 applications should be made by the Principal Investigator (PI) using the forms attached as Appendix 2. If Schedule 1 activity is required for longer than 1 year, an applicant must make an annual application.

3.2 ASPA Governed

Studies governed by ASPA must be considered by AWERB (Appendix 1). 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. Anyone holding a project licence must also hold a personal licence.

3.3 Other animal studies

Research not regulated by ASPA, for example behavioural, welfare, environmental, or other biological sciences study must also have an ethical review. An application must be made to the Faculty Research Ethics Committee subgroup for Animal Research. The application form 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.

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 Named Veterinary Officer/DoH Inspector.

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. Training, Competency and Responsibilities

4.1 Schedule 1

The person must be trained for Schedule 1 and competency assessed for the species being used. A record of training and competency must be retained by the individual and the Named Training and Competency Officer provided evidence that training has been competently completed. Individuals trained in schedule 1 methods will have their details added to the schedule 1 register maintained centrally at the University. Schedule 1 competencies are valid for a minimum period of two years after which the individual will need reassessed for competency.

4.2 ASPA Governed

ASPA requires all those involved in regulated procedures be licenced and trained using the species specified on their personal licence, and their competency undertaking procedures be assessed. Licence holders are required to continuously review their skills and competencies and undertake regular training updates as provision of Continuing Professional Development (CPD) to enable high quality science, protect the animals, and underpin the integrity of the research.

It is expected members of staff and students intending to undertake animal research under ASPA will hold a personal licence. The grant holder and/or research group leader is required to hold the project licence. Research undertaken on a project licence must tightly adhere to the specified scientific objectives detailed in the project licence. It is against the University ethos to use another principal investigator's project licence when obtaining a project licence would be more ethically appropriate. It is against University ethos to use another's PPL when obtaining one ensures transparency and responsibility by the relevant researcher.

### 4.2.1 Personal Individual Licence Holders (PILh)

i. Persons conducting and/or overseeing the use of regulated procedures on animals must hold a personal licence to work with the species of interest and undertake species-specific training.
ii. PILh must demonstrate to a NTCO and the project licence holder they are deemed competent following assessment (as evidenced by sign-off) before independently undertaking a regulated procedure.
iii. Comprehensive training records are the responsibility of the PILh and must be maintained by the individual.
iv. The PILh must maintain their licence by evidenced use, ensuring any changes are notified as soon as possible to ensure PILs remain valid and compliant with GDPR. Where a PILh cannot demonstrate continued use over a 5 year period to the NTCO, they must undertake the recommended retraining (required to ensure currency of knowledge) to reobtain their PIL, and will require supervision until deemed competent.
v. PILh must comply with all conditions identified under ASPA (see Appendix 3) and provide evidence of how these conditions are being met.
vi. Reports to the Department of Health, NI, must be timely and in accordance with annual reporting and/or reporting requirements detailed in any additional conditions placed on the licence.
vii. PILh are expected to attend professional development days, held locally or elsewhere within the UK, to facilitate communication of latest developments and the ongoing provision of training. Evidence of lack of engagement in required professional development events (PIL holder Town Hall sessions) may result in sanctions. Where PILh are deemed not to have engaged in these sessions (i.e. having attended 2 out of 3 per annum) their access to the BSU will be restricted and/or they may be required to attend additional training courses.
viii. PILh are required to inform the Named Information Officer in advance if they are leaving the University to facilitate timely revocation of their personal licence.

### 4.2.2 Project Licence Holders (PPLh)

i. A project licence is required for a programme of animal work. The PPLh will have completed the PPL module and is responsible for:
    a. The development and accuracy of the project licence and ensuring adherence by all those working under their licence for the duration of the research.
    b. Ensuring those working under their project licence are trained, competent and able to execute the functions of the licence.
    c. Maintaining their own PIL and competency in the procedures to be undertaken and the species to be handled.
    d. Nominating a deputy who has also completed the PPL module to ensure that a suitably trained person is available to direct activities under the project licence balancing the scientific objectives with animal welfare when the PPLh is unavailable to undertake their statutory duties.
    e. Maintaining accurate contemporaneous records of all animals on which procedures have been carried out under the authority of the project licence. This record will show the procedures used and the names of the personal licensees who have carried out the procedures, the cumulative severity of the procedures, and any animals re-used, or re-homed.
    f. Complying with all conditions under ASPA (Appendix 3), in particular, ensuring timely reporting of annual statistical returns and/or compliance with any special conditions placed on the licence.

g. PPLh will be required to review the PILh working under their PPL on an annual basis and provide a list of active PILh to the Named Information Officer on request.
h. Attending professional development days and training events such as Project Licence Holder's Town Hall events hosted within Queen's or elsewhere as reasonably requested

ii. PPL holders who are on leave or away on University business, or working less than 0.8FTE must pass responsibility to their deputy to undertake the legal responsibilities of the PPL holder during their absence.

iii. Ensuring they have a project licence in place to govern the work of your research group, unless a formal collaboration is being undertaken with another group.

### 4.2.3 BSU Staff

Biological Services Unit staff are there to protect the welfare of the animals and to ensure that the establishment complies with the standard conditions applied to the Establishment licence. BSU staff are responsible for maintaining a high standard of all support functions, including animal husbandry, care and facility maintenance, at all appropriate times. They completed daily health checks and afternoon checks to ensure provision of food and water. They play a vital role in ensuring animals are cared for, have enrichment, and are treated humanely. BSU staff should be familiar with the main provisions of ASPA, and champion improvements to the overall 'Culture of Care' within the facility in order to promote adherence to ASPA legislation. All BSU staff must be respected, and their instructions relating to animal welfare complied with. In particular, if a PIL holder is requested to attend the BSU for reasons of animal welfare, the PIL must comply in a timely manner, or make alternative provisions within their research group.

### 4.2.4 Named Animal Care and Welfare Officer (NACWO)

Some members of BSU staff are designated as Named Animal Care and Welfare Officers (NACWOs), as they carry a legal responsibility for animal welfare. NACWOs should:

a. Be familiar with the main provisions of ASPA,
b. Have a thorough knowledge of the husbandry and welfare needs of the species kept at the establishment,
c. Be aware of the standards of care, accommodation, husbandry and welfare as set out in the Home Office Code of Practice, and take appropriate steps to develop and maintain high standards of care and husbandry appropriate to the species,
d. Be aware of and competent in relevant methods of humane killing listed in ASPA Schedule 1
e. Be able to recognize signs of pain, suffering, distress or lasting harm and ensure there is available expertise to monitor all animals to identify deviations from normal health and behaviour,
f. Ensure a competent person sees and checks every animal kept in an approved holding area at least once daily,
g. Promote implementation of refinements in animal care, husbandry, and use.

### 4.2.5 Named Training and Competency Officer (NTCO)

The NTCO, in conjunction with the PPL holder, is responsible for identifying (and where appropriate aiding facilitation of) training needs and ensuring that all those dealing with animals are adequately educated, trained, and supervised until they are competent. Additionally, the NTCO will ensure that

individuals working with animals under ASPA participate in appropriate continuous training and development to maintain their expertise in regulated procedures.

#### 4.2.6 Named Veterinary Surgeon (NVS)

QUB have a Team of NVS who provide advice on the health, welfare, and treatment of the animals. The NVS is a member of the Royal College of Veterinary Surgeons and has expertise in the species being used at the establishment. They are responsible for establishing a programme of veterinary care and health monitoring and advise on biosecurity and quarantine requirements. They provide advice on the impact of procedures on animals, recognizing signs of pain, suffering, distress or lasting harm, and advice on general and experimental surgical techniques, and post-operative care. The NVS is instrumental in advising on strategies for minimizing the severity on experimental protocols, including recognizing and implementing suitable humane endpoints or other refinements. The NVS should be contacted if animals exceed or approach the severity limit on the experimental protocol and when animals die unexpectedly.

#### 4.2.7 Named Information Officer (NIO)

The NIO ensures that those dealing with animals have access to the information they need about the species held and procedures being formed. The NIO also provides information relating to local rules and processes, animal welfare and implementation of the 3Rs, provision of appropriate animal husbandry and promotion of best practices. In addition, the NIO acts as the central contact for the Establishment and liaison officer with the Department of Health Inspectors.

#### 4.2.8 Named Person Responsible for Compliance (Establishment Licence holder, ELh)

The Establishment licence holder will take ultimate responsibility for all ASPA-related research conducted in their establishment. He/she will ensure the governance requirements are met, supported by the other Named persons roles and the Research Governance, Ethics and Integrity Manager. In the event the ELh has concerns regarding compliance by a PIL or PPL, they have the authority to introduce local penalties against individuals and request suspension or cancellation of the appropriate licences if necessary.

## 5. Spin-Out Companies/Commercial Partnerships

5.1 The University recognizes that innovation programmes play an increasingly important role in accelerating the translation of research into commercial and societal and clinical impact. Those academics who choose to link their research to commercialisation have an additional responsibility to offer complete transparency of relationships with external stakeholders and clearly delineate between their academic and commercial activities.

5.2 For QUB spin-outs and spin-ins using animals in their research there needs to be clarity about the funding source and where responsibility for the experimental procedures lie. This is especially important in instances where an academic is also a stakeholder in a spinout.

5.3 It is expected that each individual company will hold and subsequently manage a company project licence separate from any academic project licence.

5.4 In recognition that it would be cost prohibitive to establish an appropriate governance structure to deliver the requirements under ASPA, the University is in agreement this can be managed through its existing systems. Where required, non-disclosure agreements can be implemented to protect intellectual property. Costs incurred in the use of the NVS, NTCO, NIO, and AWERB review of licence applications and/or amendments will be re-charged.

5.5 Animals utilized through company research will be charged at the additional levy and will be subject to the appropriate VAT rates. The PPL holder/ company will be required to sign separate agreements with recognized commercial suppliers of animals for laboratory research for the supply of animals to the establishment.

5.6 The lead academic/PPL holder will commit to protecting the University's Establishment Licence and will deliver on the requirements, in particular, any conditions placed on their project licences and their reporting requirements in a timely manner.

## 6. Sanctions

6.1 The protection of the University's Establishment Licence, its ability to seek research funding and the continued advancement of its reputation is dependent on the integrity of all those involved in research in either the University's name or on its premises.

6.2 Where researchers fail to comply with these Regulations sanctions will be imposed, the severity of which will be dependent upon the level of failure. This will include, but is not limited to, requirement to undertake and/or repeat training, exclusion from the BSU, rescinding of PIL, PPL, invoking the Regulations Governing an Allegation of Misconduct in Research and/or Financial Responsibilities of Staff. Members of the Establishment Licence Governance and Strategy Group will determine the level of sanction to be applied, utilising a pre-defined framework to support this decision process.

6.3 In the event of an internal and/or external investigation researchers are required to cooperate fully until the matter is concluded.

## 7. References/Further reading

Guidance for Training and Continuous Professional Development Under the Animals (Scientific Procedures) Act 1986

## Definitions

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.

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:

(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.

# Application for Schedule 1 Activities: RESEARCH

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 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 (awerbchair@qub.ac.uk) for consideration.

Please use a separate form for each project.

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. Level of student(s) undertaking research (e.g. UG, MSc, MPHIL, PhD) (if applicable):

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

5. Summary of protocols to be performed on animal tissues:

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

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

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8. Have you looked at the possibility of sharing organs/tissues with other researchers?

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

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**SIGNATURES**

**Applicant:**

Name: Signature: Date:

| **Section B:**<br>For AWERB Admin use only: | | |
|---|---|---|
| NACWO comments: | | |
| NACWO Name | | |
| NACWO Signature | | Date: |
| Any other advice (name and status) | | |
| AWERB comments/advice: | | |
| AWERB Chair approval to proceed: | YES ☐ | |
| | NO ☐ | |
| AWERB Chair Name | | |
| AWERB Chair Signature: | | Date: |

# Application for Schedule 1 Activities: EDUCATION

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 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. Module code and level of students involved:

3. Number of students involved in the class/module:

4. Background and learning outcomes for the class/module 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

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

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

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**SIGNATURES**

**Applicant:**

Name: Signature: Date:

Name: Signature: Date:

**Chair, AWERB:**
This Committee grants approval for Schedule 1 activities for the purposes described.

Name: _ _____ Signature: _____ Date: __

**Condition 1**
The licence holder is responsible for the overall implementation of the programme of work specified in this licence and for ensuring that the programme of work is carried out in compliance with the conditions of the licence.

**Condition 2**
The licence holder shall ensure that the specified programme of work does not involve the application of any regulated procedure to which there is a scientifically satisfactory alternative method or testing strategy not entailing the use of a protected animal.

**Condition 3**
The licence holder shall ensure that regulated procedures are not applied to an animal as part of the specified programme of work if the data to be obtained from the application of those procedures is already available in a member state and has been obtained there by procedures which satisfy any relevant regulatory requirements of the EU.

**Condition 4**
The licence holder shall ensure that the regulated procedures applied as part of the programme of work specified in this licence are those which to the greatest extent use the minimum number of animals, involve animals with the lowest capacity to experience pain, suffering, distress or lasting harm, cause the least pain, suffering, distress or lasting harm and are most likely to provide satisfactory results.

**Condition 5**
The licence holder shall ensure that the regulated procedures applied as part of the programme of work specified in this licence are designed so as to result in the death of as few protected animals as possible and to reduce to the minimum possible the duration and intensity of suffering caused to those animals that die and, as far as possible, ensure a painless death.

**Condition 6**
The licence holder shall ensure that the appropriate level of supervision is provided for all personal licensees carrying out regulated procedures under the authority of this licence.

**Condition 7**
The licence holder shall ensure that a regulated procedure is not applied to an animal as part of the programme of work specified in this licence if the procedure may cause the animal severe pain, suffering or distress that is likely to be long-lasting and cannot be ameliorated.

**Condition 8**
The licence holder shall ensure that where a regulated procedure is being applied to an animal as part of the programme of work specified in this licence, any unnecessary pain, suffering, distress or lasting harm that is being caused to the animal shall be stopped.

**Condition 9**
The licence holder shall ensure that where a regulated procedure is applied to an animal as part of the specified programme of work, death as the end point of the procedure is avoided as far as possible and is replaced by an early and humane end point; and as soon as the purpose of the procedure has been achieved, the procedure is stopped and appropriate action is taken to minimise the suffering of the animal.

**Condition 10**

The licence holder shall ensure that where a regulated procedure has been applied to an animal as part of the programme of work specified in this licence, a suitably qualified person classifies the severity of the procedure as “non-recovery”, “mild”, “moderate” or “severe” using the criteria in Annex 8 of the Animals Directive. For the purposes of this condition, a series of regulated procedures applied to an animal for a particular purpose is to be treated as constituting a single regulated procedure.

**Condition 11**
Where a series of regulated procedures are applied to an animal for a particular purpose the licence holder shall ensure that the animal is killed at the end of the series unless a veterinary surgeon or other competent person has determined that the animal is not suffering and is not likely to suffer adverse effects, as a result of the regulated procedures.

**Condition 12**
Regulated procedures shall not be carried out on any stray animal of a domestic species as part of the programme of work specified in this licence.

**Condition 13**
Except with the authorisation of the Secretary of State, regulated procedures shall not be carried out as part of the programme of work specified in this licence on any of the following type of animal:
a) any feral animal of a domestic species
b) any animal taken from the wild
c) a marmoset unless it is the offspring of marmosets bred in captivity or has been obtained from a self-sustaining colony of marmosets
d) any animal of a description specified in Schedule 2 to the Act unless it has been bred for use in procedures.

**Condition 14**
If the application of regulated procedures to animals taken from the wild is authorised in this licence the holder shall ensure:
a) that animals taken from the wild are captured by a competent person using a method which does not cause the animal avoidable pain, suffering, distress or lasting harm
and
b) that an animal taken from the wild which is found to be injured or in poor health is not subjected to a regulated procedure unless and until it has been examined by a veterinary surgeon or other competent person and, unless the Secretary of State has agreed otherwise, action has been taken to minimise the suffering of the animal.

**Condition 15**
The licence holder must give any necessary assistance to inspectors carrying out visits by virtue of section 18(2A)(b) and to experts of the European Commission carrying out duties under Article 35 of the Animals Directive.

**Condition 16**
If the licence holder becomes aware of a failure to comply with any conditions of the licence the holder must take appropriate steps to rectify the failure (if it is capable of being rectified) and keep a record of the steps taken.

**Condition 17**
All authorised procedures shall be carried out under general or local anaesthesia unless:
a) anaesthesia would be more traumatic to the animal concerned than the procedures themselves
or
b) anaesthesia would be incompatible with the purposes of the procedures.

**Condition 18**
The licence holder shall ensure adherence to the severity limits as specified in the project licence and observance of any other controls described in the licence. If these constraints appear to have been, or are likely to be, breached, the holder shall ensure that the Secretary of State is notified as soon as possible.

**Condition 19**
The licence holder shall maintain a contemporaneous record of all animals on which procedures have been carried out under the authority of the project licence. This record shall show the procedures used and the names of personal licensees who have carried out the procedures. The record shall, on request, be submitted to the Secretary of State or made available to an Inspector.

**Condition 20**
The licence holder shall send to the Secretary of State, before 31 January each year (and within 28 days of the licence having expired or been revoked), a report in a form specified by the Secretary of State, giving details of the number of procedures and animals used, and the nature and purpose of the procedures performed under the authority of the project licence during the calendar year.

**Condition 21**
The licence holder shall maintain a list of publications resulting from the licensed programme of work and a copy of any such publication shall be made available to the Secretary of State on request. The list shall, on request, be submitted to the Secretary of State or made available to an Inspector, and it shall be submitted to the Secretary of State when the licence is returned to him on expiry or for revocation.

**Condition 22**
The project licence holder shall submit such other reports as the Secretary of State may from time to time require.

**Condition 23**
The project licence holder shall ensure that details of the programme of work and regulated procedures specified in the licence, and any additional conditions imposed on those procedures, are known to:

a) all personal licensees performing those procedures
b) the named person responsible for compliance
c) the named animal care and welfare officers responsible for the day-to-day care of the animals
d) the named veterinary surgeon, on request
and
e) the named information officer and named training and competency officer, on request.

**Condition 24**
The licence holder must obtain the permission of the Secretary of State before:

a) any animal undergoing regulated procedures is moved from a place specified in one section 2C licence to a place specified in another section 2C licence

or

b) any animal is released for slaughter, unless this is already explicitly authorised by the project licence.

**Condition 25**
The licence remains the property of the Secretary of State and shall be surrendered to them on request.