#### **University of Dundee**

# Welfare and Ethical Use of Animals Committee University Policy for the Use of Animals in Teaching and Research March 2024

# 1. Introduction

The Animals (Scientific Procedures) Act 1986 regulates almost all experimental and scientific procedures using vertebrate animals and cephalopods (all octopus, squid, cuttlefish, and nautilus species). All persons involved in any capacity with such procedures should have copies of the Act, and of the associated Guidance on its operation (available from the Home Office website, <a href="https://www.gov.uk/research-and-testing-using-animals">https://www.gov.uk/research-and-testing-using-animals</a>).

This Policy is issued under the authority of the University Court. It sets out the division and chain of responsibility in the University and details specific requirements for persons working with animals, under the following headings:

- The use of animals in non-regulated procedures in teaching and research
- Responsibilities
- Security
- Introduction of animals or biological materials
- Genetically altered animals
- Animal handling
- Euthanasia
- Record keeping
- Licences
- Regulated procedures and study plans
- Training
- Research collaborations and contracts with other institutions (including overseas)
- Scientific publications
- Glossary of important terms
- Declaration

The University Policy reflects and complements the law and associated Home Office Guidance. The Home Office, through its Inspector, will scrutinise all regulated procedures relating to the use of animals. The Secretary of State has the powers to close an animal facility, to revoke a personal or project licence and to initiate criminal proceedings against any person suspected of having broken the law.

Before beginning work in a university facility, you must agree to abide by this Policy, and any local rules that may exist. Sign the declaration as evidence of reading this policy, ask your supervisor (Group leader or project licence holder, as most appropriate), for counter

signature, and return by email in its entirety to biolserv-director@dundee.ac.uk. Failure to ensure compliance with this Policy may be regarded as a disciplinary offence. Initial investigations will be carried out under the authority of the University Secretary.

# 2. The use of animals in teaching and research

The Animals (Scientific Procedures) Act 1986 applies to only those species listed in the Act and to regulated procedures carried out for the purposes of research. Other species and/or procedures are not covered by that Act, though of course they may be by other pieces of legislation.

While most of this Policy is concerned with regulated procedures carried out under the Animals (Scientific Procedures) Act 1986, please note the following additional points:

**Ethical review**. The use of *any* animal, dead or alive by members of the University in teaching or research is subject to its local ethical review processes. Information on animal use will be collected by the Director of Biological Services, who will bring it to the attention of the Welfare and Ethical Use of Animals Committee.

**Animal housing**. All animals will be housed and maintained at all times in the University facility designated for this purpose, unless specific written permission has been granted from the Director of Biological Services and the University Veterinary Surgeon.

**Involvement of undergraduates in regulated procedures**. At the time of writing, there are no project licences in the University that permit the use of regulated procedures in *teaching*. However, undergraduate students may participate in *research projects* which, at some stage at least, will involve such procedures. Please refer to Section11 and 12 for further information.

# 3. Responsibilities

# The Welfare and Ethical Use of Animals Committee (WEC)

The WEC is constituted as a committee of the University Court, to which it reports on a regular basis.

Its remit covers the oversight of *all* uses of *all* animals, living or dead (a very wide category of materials), by the University, on its premises or elsewhere (refer to Section 13 for work at other establishments). All such use must be approved by the WEC before it can begin.

Within its remit, the WEC fulfils the requirements of an Animal Welfare and Ethical Review Body (AWERB), as required in relation to procedures regulated under the Animals (Scientific Procedures) Act 1986.

All proposed work involving animals, whether or not this requires licensing under the

Animals (Scientific Procedures) Act 1986, is examined by the WEC, on the basis of the likely welfare costs to the animals, the expected benefits of the work proposed and how these considerations balance. The ethical review process is also intended to ensure that sufficient attention is being paid to the development and uptake of reduction, replacement, and refinement in the use of animals (the ``3 Rs''). Members of staff may not commission the use of animals outside the University to pursue a research programme for which a project licence application has been rejected within the University's ethical review process.

The WEC scrutinises applications for Home Office licences (including applications for secondary availability at Dundee for licences held by members of other institutions) and the progress of work it has previously authorised. It also supervises the provision of training and assessment of competence for those working with animals, the use of Schedule 1 procedures (refer to Section 9 for more information), the application of the "three Rs" and general welfare issues brought to its attention by any of its members.

#### The Establishment Licence-Holder

The Home Office has issued an Establishment Licence to the University, which authorises it to breed and use animals in specified facilities. A senior member of the University holds the Establishment Licence and is thereby legally responsible for the activities of all animal users in the University. As an officer acting in the University's name, the Establishment Licence-Holder is ultimately accountable to the University Court. Any member of the University who believes they have discovered malpractice or impropriety in the use of animals which in any way involves the University or its staff, should disclose their concerns to the Establishment Licence-Holder or to anyone else listed on the posters displayed in all the resource units for this purpose. They may also invoke the University's policy on public interest disclosure (``whistle-blowing''), <a href="https://www.dundee.ac.uk/corporate-information/whistleblowing-policy/">http://www.dundee.ac.uk/corporate-information/whistleblowing-policy/</a>.

# The Director of Biological Services (DBS)

The DBS is responsible for the management of the University's animal facilities and for acting on behalf of the Establishment Licence-Holder in ensuring compliance with the law and that adequate records are kept. The DBS also shares the legal responsibilities of the Named Training and Competence Officer (NTCO) and Named Information Officer (NIO) as required by the terms of the Establishment Licence. The DBS is required to notify the Establishment Licence-Holder of infringements of the law or of this Policy and of any problems with animal welfare or the environment, structure or staffing of facilities. Any user aggrieved by a decision of the DBS may appeal informally to the Establishment Licence-Holder. The DBS may recommend, or the Establishment Licence-Holder may decide that disciplinary proceedings against a member of the University should be initiated, (via the University Secretary's office).

# The Named Animal Care and Welfare Officers (NACWOs)

As a condition of the Establishment Licence, each animal facility must have at least one Named Animal Care and Welfare Officer, who takes legal responsibility for the animals under their care. The NACWO will normally be the manager of the facility. Local decisions relating

to the introduction of animals and biological material will be taken by the NACWO, in consultation with the DBS and the University Veterinary Surgeon. The NACWO will inform the DBS if they suspect that an infringement of the law has occurred (or is likely to occur) or that the conditions of this Policy are not being met.

# The University Veterinary Surgeon (UVS)

It is a condition of the Establishment Licence that the University retain the services of a Named Veterinary Surgeon (NVS), whose primary role is to promote the welfare of all animals used or bred in the University. The University Veterinary Surgeon fulfils this role and reports directly to the University Executive Group. Animals may only be introduced into the University with the permission of the UVS, who will need to be assured that they will pose no significant health risk to animals already present and that adequate facilities exist for their care and upkeep. The UVS should be consulted if anyanimal deviates from the expected health status. The UVS is a Named Training and Competence Officer (NTCO) and Named Information Officer (NIO). The UVS may bring any matter of animal welfare to the attention of the Establishment Licence-Holder, the convener of the Welfare and Ethical Use of Animals Committee or the University's Executive Management Group.

# The Named Training and Competency Officer (NTCO)

As a condition of the Establishment Licence, each animal facility must have at least one Named Training and Competency Officer, who takes legal responsibility 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 to maintain their expertise.

The role of NTCO is primarily fulfilled by the Training Coordinator (TC). Local decisions relating to training requirements will be taken by the TC, in consultation with the DBS and the UVS. The TC will informthe DBS if they suspect that an infringement of the law has occurred (or is likely to occur) or that the conditions of this Policy are not being met.

# The Named Information Officer (NIO)

As a condition of the Establishment Licence, each animal facility must have at least one Named Information Officer who is responsible for ensuring that those dealing with animals in the licenced establishment have access to the information they need about the species held and procedures being performed.

# The Home Office Inspector

The department in the Home Office that is responsible for the regulation of animal research is the Animals in Science Unit (ASRU). ASRU may send a Home Office Inspector, or teams of inspectors, to visit and audit facilities and processes at any time. These visits may be announced or unannounced. Inspectors can demand to see records, including those related to the use and breeding of animals, the environmental conditions in which they are kept and the regulated procedures that have been performed. They can also ask for records relating to the training, supervision, and assessment as competent of licence holders. You must ensure that your personal and project licence records are up to date. The University requires

that the Inspector is given all reasonable assistance.

# 4. Security

The University strives for the greatest possible openness in relation to its use of animals. Nevertheless, it must be recognised that there are potential risks, however small, to personal safety, that could arise from the activities of animal rights extremists.

To safeguard against these risks, it is important the following information is disseminated on a strictly 'need-to-know' basis:

- The physical locations of the resource units
- The means by which entry into the resource units is effected
- The identities of those who work within the resource units, both staff and scientists.

# 5. Introduction of animals or biological materials

The University has adopted a policy of health screening based on guidelines for health monitoring in scientific establishments, published by the Federation of European Laboratory Animal Science Associations (FELASA). The aim is to ensure that the animals are of a suitable health status for the scientific purpose for which they are intended.

The University's aim is also to maintain the best practicable health status in all its animal facilities. Its guidelines for the introduction of animals and biological materials must therefore be very strict.

#### **Introduction of animals**

The University will not allow the introduction of animals or embryos that could compromise the health status of those already in the University, nor of those which represent an unacceptable hazard to human health. The preferred source of animals for introduction into the University is a commercial supplier that can produce adequate documentation of health status. It is therefore a requirement that all vertebrate animals from any source are ordered through the NACWOs. They have the authority to order from a list of specific suppliers agreed in advance with the NVS. The health status of suppliers is checked in an ongoing manner and introduction of animals may be refused where health status changes. Introduction of animals from another source, e.g., another university or research facility, requires provision of information on the microbiological status of these animals to the NVS to and acceptance of an import will be dependent on the health status meeting or exceeding that of the relevant unit.

# **Biological materials**

These are defined as human or animal product including any materials that have passed

through animals, or animal tissues, or cell lines. They might be contaminated with infectious agents and therefore must not be introduced into animals within the University without the prior consent of the NVS and the NACWO. Appropriate microbiological checks may be required on such materials. Potentially infective material being used in laboratories must be handled and disposed of using appropriate hygiene precautions. Some infectious agents are used (under project licence authority and with the necessary biological risk assessments having been agreed) in the resource units. In all other cases, a quarantine period, usually 48 hours, must be allowed to elapse after handling potentially infective materials in the laboratory, before entering any animal facility in the University. Please discuss with the DBS and/or the NVS.

#### **Risk of contamination**

There is a potential risk of microbiological contamination being introduced into an animal facility by its human visitors. An individual must not enter the experimental facility in the University of Dundee if they have visited another animal facility within the previous 48 hours (or longer depending on the health status of the establishment). Please discuss with the NVS prior to entering the facility.

Individual facilities have local rules governing further precautions against contamination and users must understand and abide by them. These may include more prolonged quarantine periods. Users who have contact with pets, wild rodents or rabbits should inform the NVS or facility manager before entering any University animal facility. This will allow the potential risks to be considered and mitigated.

# Work in laboratories

To reduce the risk of a person carrying microbiological contamination from a laboratory into an animal facility, any materials that might harbor animal pathogens must be properly contained and segregated from 'clean' work. Examples include:

- Cell cultures deliberately infected with viruses (e.g. Sendai) or bacteria
- Cell cultures of unknown microbiological status
- Cells or tissues derived from animal carcasses obtained from other animal facilities.

A dedicated microbiological safety cabinet and cell culture incubator should be used when working with such materials. Operators should observe the standard 48-hour rule before entering an animal facility.

# 6. Genetically altered animals

The Home Office uses this generic term to cover both animals carrying mutations which have potential adverse effects on welfare (e.g., nude or SCID mice) and those in which specific genetic modifications (e.g., knockouts, transgenics) have been introduced. Use of these is subject to special regulation. Almost without exception, even the simple keeping or breeding

of genetically altered animals will be regarded as regulated procedures, requiring the authority of a Home Office project licence and management of each colony by a personal licence holder. Work with genetically modified animals must also have been approved by the appropriate Biological Agents Committee, and advice should be sought from the Divisional Biological Safety Officer, the DBS and/or the University Safety Services. Special arrangements may have to be made for the disposal of genetically modified waste, over and above the normal house-keeping routines of the animal facility.

# 7. Training

All members of staff using animals for research purposes must follow a process in the following order prior to starting work:

Read, sign and return this Policy document;

Complete the registration process;

Attend occupational health if physical access to the facility is required;

Complete the mandatory training modules (Local and legally required by the Home Office); Attend a facility induction;

Complete handling and humane killing requirements.

This information is recorded in a central database (Labtracks) as a training record for each registered individual and updated following attendance at additional training and or continual professional development sessions (in house mandatory sessions held annually for all licence holders. Refer to Section 11). Local decisions relating to training requirements will be taken by the NTCO, in consultation with the DBS and the University Veterinary Surgeon depending on advances or developments in best practice.

In addition to the central training register, which includes records of competence assessments, all people working with animals must keep their own training records. Examples of how to keep these can be found here: <a href="https://www.lasa.co.uk/wp-content/uploads/2018/05/Record-Keeping.pdf">https://www.lasa.co.uk/wp-content/uploads/2018/05/Record-Keeping.pdf</a> . If you are unsure what is required you should consult the TC, NVS or DBS.

# 8. Animal handling

The initial capture of animals from their "home-cage" can be particularly stressful to the animal as well as impacting on the data collection. Methods that might be perceived as similar to the actions of prey species, which animals might be genetically hard-wired to avoid at all costs, should therefore be avoided.

Rats and mice must therefore **not** be picked up by their tails, though they may be gently restrained by the tail once they have been captured and placed on a table, cage-top or other horizontal surface.

Rats should be captured by gently cupping them between the hands or, particularly for smaller animals, by gently scooping them up into the palm of the hand. Mice may be captured by similar methods, but a good alternative is to use a tube. Once they have become accustomed to presence of this in their cage, mice will readily run into the tube, which can then be picked up, loosely barring both ends with the hands.

These are the only rodent capture methods that will be taught in the University. Anyone who has previously been trained to capture these species by the tail will be expected to retrain in these more refined and less stressful methods.

#### 9. Euthanasia

The University attaches great importance to the need for scientific and ethical justification for killing animals, however humanely this is done and even where the law provides for this to be carried out without a Home Office licence (see below). Before starting work, users must discuss the justification, together with the scientific reasons for the choice of killing method(s), with their Principal Investigator or equivalent.

In circumstances where **all** the following conditions are met, project and personal licences may not be required for the humane killing of animals:

- 1. The provisions of Schedule 1 to the Animals (Scientific Procedures) Act 1986 are met in full.
- 2. Individuals carrying out the methods of humane killing described in Schedule 1 have been appropriately trained and assessed as being competent.
- 3. The names of such individuals have been entered in a central register held by the DBS.
- 4. Records are kept of the numbers of animals killed and for what purpose. These data may be considered by the WEC and users may be called to account for them.

Those providing the training and assessment must themselves have been assessed as competent to do so. They will normally be NACWOs, or senior members of the animal care staff.

Unless the DBS has agreed to the contrary, Schedule 1 killing must be carried out within the animal facility. Where animals are removed from an animal facility to be killed elsewhere, the NACWO and the NVS remain legally responsible for their welfare until the moment of death. Schedule 1 killing must only be carried out in a room listed in the Establishment Licence and with due consideration for other people working nearby. This room must be made available for inspection on request by the NACWO, the NVS and the Home Office Inspector.

# 10. Record keeping

To fulfil the requirements of the Act and to maintain the efficient administration of animal facilities, the University must keep a number of records. Local rules governing the completion of records in the formats required must be followed. Home Office licence-holders will have additional personal legal responsibility to keep certain records.

As for all other University premises, persons injured in an animal facility should report it immediately to the unit manager and must fill out the online incident report form (https://www.dundee.ac.uk/safety).

Biological Services keeps data about personnel (e.g., licence-holders, registered users of animal facilities) for operational purposes. The keeping of these files is regulated by the Data Protection Act 1998.

#### 11. Licences

With the notable exception of humane killing under the provisions of Schedule 1, the use of protected animals for experimental procedures requires the authority of project and personal licences issued by the Home Office. Once mandatory training for the licence application process is complete (detailed below), an account will be generated on the Animals Scientific Procedures eLicencing system (ASPeL).

# **Project licences**

ASPA states that "A project licence must not be granted except to a person who undertakes responsibility for the overall implementation of the programme of work to be specified in the licence". It is therefore University policy for Principal Investigators leading a programme of work to be the project licence holder. Any exceptions to this will require School and WEC approval. All new project licence applicants must attend and pass an accredited project licence training course. Enquiries regarding these courses should be made to the DBS who will guide you through the process.

Applications for renewal of a programme of work or research new to the University should be discussed in outline at least seven months prior to expiry of the current project licence. Once a detailed draft application is complete in ASPeL, it will then be submitted to the WEC. When agreement has been obtained on its final form, the application will be submitted by the DBS electronically to the Home Office for formal consideration.

The Home Office will return an approved licence via ASPeL. The DBS will save a copy and file electronically in a secure location for the use of the NACWO(s). The project licence holder must check the licence carefully and must also ensure that personal licence-holders have access to the active version before the commencement of work under the licence. Study plans (see below) must list the personal licence holders specifically involved in each experiment and detail the procedures that they will undertake and be responsible for.

Project licence-holders are responsible for ensuring the competence of personal licence-

holders working under their authority. They should keep a written record of the training and assessment that personal licence-holders have received and should review this provision on a regular basis. The TC, DBS, NVS and NACWOs can be consulted as to the best means by which training, and assessment should be delivered (in many cases

this will be arranged in-house, but in others a visit to a specialist centre may be more appropriate).

Project licence-holders are required by law to compile annual statistics on the use of animals under the authority of their licence and to submit these "Returns of Procedures" to the Home Office, normally by the end of January. A copy of the submission must be lodged with the DBS, who will derive amalgamated statistics on the use of animals in the University for consideration by the WEC.

Project licence-holders must also keep a number of mandatory records, including the contemporaneous record of animals used on all protocols. They must be aware of what these records are and have a system in place to ensure that the information is recorded.

Twelve months prior to the expiry of the project licence, holders must submit a Retrospective Review to WEC via the DBS. If timings harmonise, the DBS may invite the licence holder to present their review in person at the next calendar meeting.

#### **Leaving the University - project licence holder requirements**

The University requires that a licence must normally be surrendered to the Home Office (via the office of the DBS on ASPeL) at or before the time at which the holder ceases to be an employee, whether because they are moving to a new place of work or retiring. A Return of Procedures will have to be completed for that part of the current calendar year in which the licence was in force.

Anyone who wishes to make a claim for an exception to this rule must inform the DBS well in advance of the expected date of departure. The case will be considered by the School of which the person is or was a member and by the WEC.

#### Personal licences

All new personal licence applicants must attend and pass an accredited personal licence training course appropriate for the species with which they wish to work.

Personal licences stay in force indefinitely until they are revoked, though they are reviewed at five-yearly intervals. Each one attracts a fee for every fiscal year (April–March) or part thereof, for which the licence is valid. The annual fees are collected in advance from research group leaders. Failure to pay the fees will result in the University recommending the immediate revocation of the licence by the Home Office.

Except with the special permission of the WEC, undergraduate students shall not be permitted to hold personal licences, nor to perform Schedule 1 procedures. Undergraduate students may however be present when procedures licensed under the Act, or within the scope of Schedule 1 of the Act, are carried out, subject to the prior approval of the relevant head of undergraduate teaching and the DBS.

Personal licences are not, in themselves, evidence of competence in any procedure. Personal licence-holders must ensure that they are trained and competent before starting any regulated procedure. Competence must also be reviewed on a regular basis. Licence-holders are strongly advised to take the advice of the NVS and NACWOs in devising the necessary training and assessment programmes. If at any time a personal licence-holder does not feel confident in undertaking a procedure, then they should not attempt it.

#### Personal licence holders must:

- 1. Have read the relevant project licence(s) before starting work.
- 2. Be familiar with the protocols, the severity limits, and the endpoints of the licence.
- 3. Know the scientific aims of the project, and how the proposed experiment(s) will fit in with the plan of work.
- 4. Be aware of any relevant special conditions on the project licence (e.g., a requirement for a report to be submitted after a certain time or a certain number of animals have been used).
- 5. Check that their personal licence authorises them to carry out the procedures detailed in the project licence for the stated purpose.

Be aware of any additional conditions that may have been placed on their personal licence. Work can only begin once the facility manager has received confirmation from Biological Services Training Coordinator (TC) that the personal licence-holder is competent and authorised to carry out the necessary procedures (or that they are performing them under supervision), and all mandatory training requirements have been completed (Refer to Section 7).

To ensure that all personal licence-holders need their licences and are actively participating in these programmes, the Welfare and Ethical Use of Animals Committee (WEC) hasdeveloped the following procedures:

- On an annual basis, all personal licence-holders will be required to attend at least one Biological Services organised or endorsed CPD event. Multiple opportunities will be provided.
- From 31st October 2023, all new personal licence-holders will be given *one year* from the date on which their licence was granted, in which to attain this minimum standard of training. The current expectation is to complete online training in Experimental Design and Severity Assessment.
- The WEC may also mandate new training modules, or similar depending on developments and advances in best practice.
- If a personal licence-holder fails to maintain this standard, then the Director of Biological Services will inform them that their licence will be revoked.
- A 28-day period, during which an appeal may be lodged with the convener of the Welfare and Ethical Use of Animals Committee, will be allowed to elapse before this action is taken.

- Personal Licence Holders are responsible for maintaining records of their own training which may be requested for scrutiny at any time, and during audit.
- Biological Services will keep a record of assessed competences on LabTracks.
   This is accessible to every individual registered user.

#### Leaving the University - personal licence holder requirements

Personal licence holders MUST inform the DBS that they are leaving the University. Personal licences are valid at any Establishment in the UK, but the Establishment identified in their address remains responsible for paying the fees and for ensuring that the licence-holders are adequately trained and competent.

As soon as a personal licence-holder leaves the University or retires, the DBS will seek the revocation of their licence. There is a procedure for transferring a personal licence to another UK Establishment, but this should be engaged *before* the licence holder leaves the University.

As with project licences, there may be justifiable exceptions to this rule. Please notify the DBS well in advance if you wish to claim an exception. Claims will be considered by the most relevant School and WEC.

# 12. Regulated procedures and study plans

It is essential that everyone involved in the use of a particular animal knows *exactly* what has happened to it, what has still to happen to it, what deviations from normal welfare would it be reasonable to expect, and what should be done if they, or any other issues, are observed. At the very least, the information must be shared between the project licence holder, the personal licence holder(s) performing the experiment, the animal care staff, and the veterinary surgeon. The Home Office inspector also expects this information to be made available to her/him when she/he visits the unit.

The University has therefore established a system of *study plans*, in which each plan provides all the necessary detail for one experiment. A study plan *will* usually be prescriptive, though there may be occasions on which it makes sense to amend the plan for an experiment that has already started (see below). A study plan is also a logical place in which to record the *outcome* of the experiment, in terms of the severity experienced by the animals that were enrolled in it and the occurrence of any unexpected adverse events.

# Types of regulated procedure

Regulated procedures carried out in the University fall into three main categories:

- 1. Breeding and maintenance of genetically altered (GA) mouse lines under a "mild" severity limit.
- 2. Breeding and maintenance of GA mouse lines under a "moderate" severity limit.

3. "Interventional procedures" carried out on living animals, which may be wild-type or GA.

The way in which study plans are deployed differs according to which of the three categories of regulated procedures the experiment falls into:

#### Breeding and maintenance under a mild severity limit

A study plan is *not* required where the regulated procedure involves the breeding and maintenance of GA mice where no significant deviation from normal welfare is expected, where no further experimental intervention takes place and where the animals are killed at a young enough age that welfare problems and even mortality associated with advanced age are not going to be observed. In most cases, animals older than six months will not be used for further breeding. Scientists wishing to use older animals will normally be expected to do so in a project licence with a moderate severity limit, and with a study plan in place. They should contact the NACWO and NVS for advice before proceeding. The licence-holders and the resource unit staff must be constantly vigilant for any signs that the genetic alteration might in fact be affecting welfare, at any stage of development. Should any be observed, the NVS must be informed immediately.

#### Breeding and maintenance under a moderate severity limit

In a minority of cases, a particular genetic alteration may be known or suspected to be associated with a deviation from normal welfare. This will be described in the project licence, or a list of GA lines attached to the licence, together with the steps to be taken to ensure the severity is never any greater than "moderate". Because there is an expected welfare cost associated with the activity, it cannot be permitted to continue indefinitely and/or in the absence of a scientific benefit that outweighs this cost.

A study plan for such a breeding programme must therefore be completed. It should indicate the approximate total number of animals that will be required, and the anticipated end-date.

When animals are deliberately being kept until older age (i.e., significantly older than six months), then a study plan for this must be provided. Depending on current Home Office policy, the relevant project licence protocol may have to have a 'moderate' severity limit, as some age-related problems may be expected, even in wild-type animals. It is therefore necessary that the purpose of keeping these animals and the applicable humane endpoints to any suffering they may experience, are made entirely explicit. These endpoints may be defined in terms of age limits and/or the observation of specific welfare events.

# Interventional procedures and non-Schedule 1 methods of humane killing

Experiments involving such procedures, even when very short and/or conducted under terminal anaesthesia, will require study plans. These will normally be entirely explicit as to the number of animals involved and the start and finish dates for the studies. It may of course be necessary to recruit successive batches of animals to a study, to manage the breeding stock most efficiently. In this instance, there is no need to submit a new study plan simply to record the recruitment of another batch of animals to the same experiment, unless the numbers exceed those originally planned and agreed.

# Submission of study plans

A study plan must be completed and approved before any of the planned regulated procedures begin. The current template form should be used for this purpose. The completed study plan must be emailed to the email address biolserv-study-plans@dundee.ac.uk no less than seven days before the planned start of the experiment. It is the legal responsibility of the project-licence holder and personal licence-holder(s) concerned to ensure that the study lies completely within the authority of the project licence and that the techniques and species to be used are authorised in the personal licence(s). Submission of a study plan will be taken as implicit evidence that such checks have been carried out. Disciplinary procedures may be invoked should the UVS or DBS discover that a study plan is not legally compliant.

# Approval of study plans

Once a study plan has been approved, the UVS, or an experienced delegate will notify the submitter and will forward the approved plan to the staff of the relevant resource unit, where it will be made available to the Home Office inspector on request. It may also be posted on the wall of the animal room for easy reference.

# Cage cards

Cage cards *must* be labelled with the relevant study plan number so that immediate reference to the plan can be made at the cage-side. For cages of genetically altered animals being bred under project licence authority and a "mild" severity limit, a study plan may not be necessary. In this case, the card itself must be labelled with the project licence number, the protocol number, and the name of the responsible personal licence holder.

# **Surgical procedures**

An experimental study may involve a surgical intervention at some point, maybe some days or even weeks after the study has begun. In this case, the UVS and NACWO *must* be notified no less than one week before the surgical intervention is due to start and the relevant "surgery plan" sheet(s) submitted.

# **Completion reports**

After a study has finished, a completion report must be sent to the UVS. Note, however, that any *unexpected* welfare events must have been reported to her as soon as they were observed, whether they involved a breach of the severity limit set on the licence protocol or not. The completion reports should be retained by the project licence-holder as they are likely to be very useful in completing the annual statistical return required by the Home Office.

# 13. Research collaborations and contracts with other institutions (including overseas)

The University must exercise oversight of all research work done in its name that involves the use of animals, not just of those projects that are carried out on its premises or at other UK establishments that are equally subject to the requirements of the Animals (Scientific Procedures) Act 1986.

Most other nations have exacting legal and/or ethical standards in this field. For example, all member states of the European Union are required to have enacted national legislation to implement Directive 2010/63/EU. In the USA, all bodies receiving federal funding (e.g., from the National Institutes of Health) are required to comply with the *PHS Policy on Humane Care and Use of Laboratory Animals* and to follow the OLAW Guide for the Care and Use of Laboratory Animals. Furthermore, they are required to operate Animal Care & Use Committees, with very similar roles to the University's WEC. Other countries, such as Australia, New Zealand, Japan and Canada, are known to have rigorous ethical review procedures as well.

Even in countries where there may be no over-arching laws or regulations, it would be reasonable to expect research using animals to adhere to common principles. The Council for International Organizations of Medical Sciences (CIOMS) has issued International Guiding Principles for Biomedical Research Involving Animals (revised 2012). These enshrine very similar principles to those that underpin the European Directive.

Members of the University who participate in collaborative research projects or who enter into contracts involving the use of animals in other institutions, which have not otherwise been subjected to the University's ethical review process, must notify the DBS, who will ensure that appropriate ethical review measures are complied with and will keep the WEC informed. For the avoidance of doubt, the guiding principle is that notification should always be made where the results of the research work concerned are likely to be published and the researcher concerned, or the University itself, may be identified in that publication.

Funding bodies may require *all* work carried out in a funded project to comply with a single set of guidelines. For example, the Wellcome Trust and other major UK funders require compliance with the policy document entitled Responsibility in the use of animals in bioscience research: Expectations of the major research council and charitable funding bodies.

# 14. Scientific publications

Experiments involving animals should be published in sufficient detail that their validity (statistical power, treatment of environmental variables etc.) can be assessed adequately. Authors and reviewers of manuscripts should therefore abide by the Animal Research: Reporting of In Vivo Experiments (ARRIVE) Guidelines). Applicants for project licences will be expected to declare that they have read the ARRIVE guidelines before the Welfare and Ethical Use of Animals Committee will review their applications.

# 15. Glossary of important terms

# **Body Condition Score (BCS)**

The body condition of an animal describes whether it is thin, fat or "normal". A BCS is used in addition to body weight (see definition of weighing below) to help decide whether changes in weight might be causing welfare issues for the animal. The BCS gives an estimate of how much fat and muscle the animal has. If you are weighing animals, you should also be checking their BCS. If you have not been trained in assessing BCS and are weighing animals, you should seek training (please contact the Training Coordinator under these circumstances).

# Cage-mate

The general term "cage-mate" is used to describe an animal sharing a cage with one or more others. On LabTracks, the term cage mate is used to describe an animal kept in the same cage as experimental animal(s) to prevent an experimental animal being on its own or to prevent changes in the group structure, for example leaving the fifth male from a group of five in the cage when the experimental procedure will only take place on the other four, to avoid fighting.

# **Culling**

This is a general term used for humanely killing animals. "Euthanasia" or "sacrifice" have similar meanings. Usually, people use the term when the killing is of "spare" animals (so animals that have a genotype that can't be used for further breeding or for experiments) or for "wasted" animals (those that could have been used for experiments, but circumstances meant that it wasn't possible to do so for some reason).

#### Litter-mate

Pups (see definition below) that are born to the same mother at the same time make up a group of brothers and sisters known as a litter. Animals within a litter are known are littermates.

#### **Neonate**

This refers to an animal that is only a few days old. For rats and mice, a pup (see definition below) is neonatal until around roughly 5 to 7 days as a rule. Neonatal animals are entirely dependent on their mothers for nutrition. As their nervous systems are not yet fully developed, they may be less able than older animals of feeling pain or unpleasant sensation. However, this must never be assumed, and expert advice should be sought when assessing the severity of an experience in a neonate.

# Pup

This refers to a young rat or mouse from the time it is born until the time it is weaned (see below for a definition). LabTracks automatically changes the "status" of an animal record from "Pup" to "Animal" when it is weaned.

# Ear Biopsy (notches)

A small piece of tissue is removed from the ear in the process of notching it to identify the animal. There are other even more refined biopsy methods that can be applied, particularly to animals whose ears have already been notched for identification, such as hair plucking or saliva sampling. Do **not** biopsy the tail, even if this was the normal routine in your previous place of work.

# Weaning

This is the process of removing pups from their mothers, because they should now be able to eat and drink for themselves and to build nests sufficient to maintain their body heat. In mice, it is normally carried out about 21 days after birth, though there are sometimes circumstances when it is better to delay it by up to another 7 days.

# Weighing

A loss in weight, or a failure to gain weight, is usually a sign of ill-health. Weighing animals regularly can be a good idea, to make sure they gain weight at the expected rate in the period in which they should be growing and that they then maintain their adult weight. It is very important to compare the weight of one animal with the proper control. For example, a young animal in altered health may still be gaining weight, but not at the rate of a truly healthy one of the same age. Weight loss is often expressed as a percentage, but make sure again that you use the correct control value. If in doubt as to what weight you should use to compare with your experimental animal or to track its progress, please contact the University Veterinary Surgeon.

# 16. Declaration

#### Policy on the Use of Animals in Teaching and Research

Please complete this declaration and pass it to your supervisor (group leader or project licence-holder, as most appropriate) for counter-signature. The signed document in its entirety should then be returned by email to DBS at biolserv-director@dundee.ac.uk.

Name (block caps.):
Title:
Division:
I confirm that I have read and understood the University Policy for the Use of Animals in Teaching and Research;*
I undertake to observe the provisions of the Animals (Scientific Procedures) Act 1986, the Home Office Guidance on the operation of the Act and of this Policy.*
Signed:
Date:
Declaration by group leader or project licence holder:
I confirm that I have read this Policy and that this person is working under my supervision.
Name of group leader or project licence holder:
Signed:
Date: