University of Aberdeen

Code of Practice for Research Involving the Use of Animals

For Animal Research governed by the Animals (Scientific Procedures) Act 1986 Amendment Regulations 2012 to include the changes that were effected by those Regulations on 1st January 2013

Includes information on ASPA, Licensing, the Animal Welfare and Ethical Review Body, the Ethical Review Committee, the Advisory Group to the Establishment Licence Holder, and the Ethical Review Process

VERSION HISTORY		
No	**Date**	**Reason For Change**
CoP20/0001	February 2020	Annual Update
CoP20/0002	December 2020	Updated throughout to reflect appointment of Scientific Advisor and Deputy
CoP21/0001	February 2021	Annual Update Addition of Expectations of PPL section
CoP21/0002	September 2021	Removal of reference to EU Directive throughout Updating of internal approval forms appendices Addition of table at the end of document to indicate which signatures are required for which forms Addition to 6.10 Security to include working remotely

GLOSSARY

AGELH	This refers to the Advisory Group to the Establishment Licence Holder
ASPA	The Animals (Scientific Procedures) Act 1986. ASPA in this document means the consolidated amended version of the Act on the protection of animals used for scientific purposes
ASPeL	Animals Scientific Procedures e- Licensing
AWERB	University Animal Welfare and Ethical Review Body
BSU	Biological Services Unit
EL	Establishment Licence (this replaces what was formerly the Certificate of Designation)
ELH	Establishment Licence Holder (this replaces the Certificate Holder)
ERC	Ethical Review Committee
ERP	Ethical Review Process
HOLC	Home Office Liaison Contact
NACWO	Named Animal Care and Welfare Officer - under the terms of the Act, a person must be appointed in each facility who has responsibility for the day-to-day care of the animals, and who is included on the establishment licence as a Named Animal Care & Welfare Officer (NACWO); this will normally be a senior animal technician
NCO	Named Compliance Officer – has responsibility for ensuring that the conditions of the establishment licence comply with the requirements of ASPA; this role is carried out by the Establishment Licence Holder
NIO	Named Information Officer – ensures that all staff dealing with animals in the establishment has access to the information they need about the species concerned as well as about the 3Rs; this position is filled at the University by the Named Veterinary Surgeons (NVS)
NTCO	Named Training and Competency Officer – has responsibility for ensuring that all staff dealing with animals are adequately educated and trained, and that they are supervised to ensure that competency is demonstrated and maintained; this position is filled by the NVS and NACWO
NVS	Named Veterinary Surgeon
PIL	Personal Licence
PPL	Project Licence
Regulated Procedure	This is a procedure carried out on a protected animal which is regulated under ASPA.

1. UNIVERSITY STATEMENT ON THE USE OF ANIMALS IN RESEARCH

The following outlines the University's position on research involving the use of animals, as defined by the Animals (Scientific Procedures) Act 1986 (ASPA) Amendment Regulations 2012 to include the changes that were effected by those Regulations on 1st January 2013 on the protection of animals used for scientific purposes.

1. Research involving the use of animals has made, and continues to make, a vital contribution to the understanding, treatment and cure of major human and animal health problems; including cancer, heart disease, polio, diabetes and neurological diseases and disorders. Animal research has also contributed to developing methods for preventing and treating diseases of domestic and farm animals, and for improving their welfare. While new methods have enabled scientists and medical researchers to reduce studies involving the use of animals, some work must continue for further fundamental advances to be made.

2. The University of Aberdeen recognises that the use of animals in research is a privilege carrying with its unique ethical responsibilities. The University only uses animals in research programmes of the highest quality, when their use is justified on scientific, ethical and legal grounds, and when no alternatives are available. In the UK, research activity involving animals, and the acquisition of animals for use in research, is largely controlled by ASPA. Compliance with ASPA is monitored and controlled by the University and the Home Office. All researchers conducting studies involving animals must by law have prior training, relevant experience, and authority from the Home Office. Animals are housed and cared for by dedicated and trained staff under professional supervision in a manner designed to ensure the best health and wellbeing of the animal, with provisions for environmental enrichment. Veterinary Surgeons are available at all times for consultation, care and attendance.

3. All projects affecting animals are subject to the University's ethical review process, via its Animal Welfare and Ethical Review Body (AWERB), in accordance with the University Code of Practice for Research Involving the Use of Animals. This process ensures that:

    - Research on animals is conducted only when it will contribute to the advancement of knowledge that is likely to lead to improvement of the health and welfare of animals or human beings, or provide a better understanding of the animals themselves; and

    - Projects involving animals are based on well-defined scientific objectives, giving due consideration to the welfare of the animals, minimising the number of animals employed in each test, and avoiding unnecessary duplication.

    The Code of Practice also provides advice on standards of animal care, welfare, and accommodation.

4. The University of Aberdeen is committed to the implementation of the 3Rs: the **R**eplacement of animals in research with other experimental models; the **R**eduction in the number of animals used; and the **R**efinement of procedures to prevent suffering. It actively supports the development, validation and adoption of appropriate alternatives to the use of animals, in order to eliminate the need for animals in research.

5. In relation to this, the University fully endorses and supports the ARRIVE Guidelines, developed by the National Centre for the Replacement, Refinement and Reduction in Animals in Research (NC3Rs) to improve standards of reporting and ensure that the data from animal experiments can be fully evaluated and utilised. The guidelines are primarily aimed at scientists writing up their research for publication and for those who are involved in peer review. They are endorsed by over 300 journals, funders, universities and learned societies. This includes major funders of bioscience research (e.g. Wellcome Trust, MRC and BBSRC) meaning compliance with guidelines is a condition of grant funding. It is the University's expectation that all Aberdeen researchers (where applicable) should publish in line with the ARRIVE Guidelines (subject to editorial policies). This has been publicised to all relevant staff. The University has also introduced the ARRIVE Guidelines as part of training sessions held for licence holders and the formal BSU induction process.

6. The University is also committed to greater openness in its approach to animal research, and making its research in this area more accessible to the public. To this end, it is now a signatory to the UK initiative Concordat on Openness on Animal Research facilitated by Understanding Animal Research (UAR). Reflecting the ethos of the Concordat, the University is committed to enhanced clarity, transparency and openness in its communications in relation to animal research, and also to more proactive public engagement in this area. The Concordat is included in the formal training and induction process for new BSU users.

2. INTRODUCTION and LEGAL CONTEXT

The University Animal Welfare and Ethical Review Body (AWERB) encompassing the Ethical Review Process and Ethical Review Committee

This document sets out the processes and structures in place within the University of Aberdeen for ensuring compliance with the Animals (Scientific Procedures) Act 1986 which concerns research involving the use of regulated procedures on protected animals in the UK, as defined by the Act. The information given below in this introduction provides details of the legal framework to which the University is required to comply.

The Home Office requires an Establishment Licence Holder to establish, and maintain, an animal welfare and ethical review body.

The animal welfare body is required, as a minimum, to carry out the following tasks:

1. Advise the staff dealing with animals on matters related to the welfare of animals, in relation to their acquisition, accommodation, care and use;
2. Advise the staff on the application of the requirement of replacement, reduction and refinement, and keep it informed of technical and scientific developments concerning the application of that requirement;
3. Establish and review internal operational processes as regards monitoring, reporting and follow-up in relation to the welfare of animals housed or used in the establishment;
4. Follow the development and outcome of projects, taking into account the effect on the animals used, and identify and advise as regards elements that further contribute to replacement, reduction and refinement; and
5. Advise on rehoming schemes, including the appropriate socialisation of the animals to be rehomed.

At the University of Aberdeen, these requirements are met and managed by its Animal Welfare and Ethical Review Body (AWERB), by its Ethical Review Committee (ERC), its Biological Services Units (BSU) Team, its Advisory Group to the Establishment Licence Holder (AGELH), and by designated members and key staff affiliated to these groups.

Further information on the legislative and regulatory environment applicable to this area of research is available via the Home Office website at the link given below, and it is recommended that all staff take time to read over it:

https://www.gov.uk/research-and-testing-using-animals

1. ASPA LICENCES

Including Information on the Establishment Licence, Named Individuals, and Project and Personal Licences

The following section provides information on the licences required to conduct research involving the use of animals, as defined by the Act, and also information on named officers, also required as a condition of an Establishment Licence.

3.1 ASPA Licences - Overview

The Act requires that three licences must be in place before research involving the use of animals, as defined by the Act, can be undertaken:

- Establishment Licence – for the facility at which the research is carried out
- Project Licence – for the programme of research
- Personal Licence – for each person working under a project licence responsible for carrying out regulated procedures on animals

These licences provide direct lines of accountability to the Home Office. **Licences under the Act are issued to named individuals**. It is therefore the individual (not the organisation) who is responsible and accountable to the Home Office for ensuring compliance with the terms and conditions of the licence.

Failure to comply with these terms and conditions may result in the variation, suspension, or revocation of the licence or certificate, and could result in prosecution. Failures by project licence holders could expose the Establishment Licence Holder to censure and thereby, potentially affect the work of other researchers in the University. Failures by personal licensees could reflect on both the project licence holder and the Establishment Licence Holder.

Information about applying for a project or personal licence is available on the Home Office website at the following link: https://www.gov.uk/guidance/research-and-testing-using-animals. Advice can also be sought from the Named Training & Information Officers, the Named Animal Care and Welfare Officers (NACWOs); or the Named Veterinary Surgeons (NVSs).

3.2 The Establishment Licence

The Act requires that any research involving regulated procedures under a project or personal licence, or where animals are bred for use in these procedures, must have a Section 2C Licence. The Section 2C Licence replaced the former Certificate of Designation, and is generally known as an **Establishment Licence,** issued by the Home Office. This is a single licence for the whole institution.

The Establishment Licence authorises the carrying out of the following activities:

- Performing procedures – these are called scientific procedure establishments;
- Breeding protected animals listed in Schedule 2 of ASPA – these are called breeding establishments; and
- Keeping and supplying protected animals listed in Schedule 2 of ASPA – these are called supplying establishments.

The Establishment Licence is required to include the following information:

- Details of the holder of the licence (see section 3.3);
- Details of the 'named persons' required by ASPA section 2C(5) specific persons who have been given the responsibility to carry out specific roles (see section 3.4);
- A schedule of premises; this should provide detail on the areas to be used for the accommodation, care and use of animals for experimental or other scientific purposes. It provides summary details of the type of use to be made of each area. Currently, rooms within the following facilities at the University are premises where regulated procedures may be carried out under the Establishment Licence:

    - The Medical Research Facility (MRF)
    - The Institute of Medical Sciences Aquarium Research Unit (IMSARU)
    - The Biomedical Physics Building
    - The Zoology BSU, School of Biological Sciences
    - The School of Biological Sciences Aquarium

These facilities are referred to as Biological Services Units (BSU) by the University and within this Code of Practice.

3.3 The Establishment Licence Holder (ELh)

Establishment Licences are issued to legal persons occupying positions of authority at designated establishments. The University's Establishment Licence Holder is a member of the senior management and is directly responsible on behalf of the University to the Home Office under the Act.

The Establishment Licence Holder is required to maintain management systems that make all reasonable efforts to prevent the performance of unauthorised procedures. The Establishment Licence Holder is accountable to the Home Office for the performance and conduct of the Named Persons, and is responsible for the operation of the local ethical review process and for the appointment of people to implement its procedures.

All project licence applications are endorsed on behalf by the Establishment Licence Holder before submission to the Home Office.

3.4 Named Persons under the Establishment Licence

Establishment licences are required to name specific individuals who are responsible for the following:

- Ensuring that the requirements of ASPA and conditions of the licence are complied with – *the Named Compliance Officer* (NCO). At the University of Aberdeen, this is the holder of the establishment licence;

- Overseeing the welfare and care of the animals – the *Named Animal Care and Welfare Officer* (NACWO). This role is carried out at the University of Aberdeen by four Named Animal Care & Welfare Officers;

- Ensuring that those dealing with animals have access to any information they need about the species they are using – the *Named Information Officer* (NIO). This role is carried out at the University of Aberdeen by one of the Named Veterinary Surgeons;

- Ensuring that those dealing with animals are adequately educated, trained and supervised until they are competent, and that appropriate further training continues – the *Named Training and Competence Officer* (NTCO). At the University of Aberdeen, this position is held by a NVS and a NACWO; and

- Advising on health, welfare and treatment of animals – this role is carried out by two *Named Veterinary Surgeons* (NVS) with expertise in laboratory animal medicine.

3.5 The Scientific Advisor to the ERC

The University also has in place a Scientific Advisor to the Ethical Review Committee.

3.6 The Roles of Heads of School and the Scientific Advisor and Deputy Scientific Advisor

Heads of School: out with its responsibilities explicitly outlined under ASPA, the University requires relevant Heads of School to provide written assurance that the resource will be available by the proposed project start date to undertake the work described in any project licence application to the Home Office. Approval is usually granted via the internal approval form (further information available in Section 6 of this document). The Head of School may, in consultation with the Scientific Advisor (or Deputy), one of the NVSs and NACWOs, initiate proposals for the addition of premises under the Act, and forward proposals to the Establishment Licence Holder for approval.

Scientific Advisor and Deputy Scientific Advisor: out with its responsibilities explicitly outlined under ASPA, the University requires the Scientific Advisor and Deputy Scientific Advisor to provide academic leadership to ensure that the facilities and services provided in the BSUs underpins and supports research projects. Approval is usually granted via the internal approval form (further information available in Section 6 of this document).

3.7 Project Licences

Under ASPA, an individual cannot apply a regulated procedure to an animal unless the procedure is applied as part of a programme of work authorised in a project licence, within the facility or geographical location specified in that licence.

A project licence is granted by the Secretary of State, which specifies a programme of work and authorises the application, as part of that programme, of specified regulated procedures to animals of specified descriptions at a specified facility or specified facilities.

Each project licence is granted to a single, named individual and not to organisations or research groups. A new project licence holder must have completed the relevant training for project licence holders before applying for a project licence. The NVS can provide advice to those preparing new project licence applications. Details are also provided on the Home Office website.

Expectations of Project Licence (PPL) Holders

PPL holders must be the most appropriate person within the scientific group/department to hold the PPL covering the work undertaken by that unit. A PPL holder must have sufficient experience and expertise to (i) direct the research undertaken under the license and (ii) to take overall responsibility for tasks including study design, analysis, response to results and problem solving as well as (iii) having an in depth knowledge of species and the experimental techniques involved to undertake the work set out in the license. PPL holders must hold a suitable position – above the level of PhD student/ postdoctoral researcher - within the University commensurate with having responsibility for the behaviour of all current and future members of their research group involved directly and/or indirectly in animal research.

In addition, PPL holders are required to have the knowledge, ability and commitment to work within the ethical and legal framework set out in the Animals Scientific Procedures Act 1986 at all times and to abide by local regulations. They must be excellent communicators capable of dealing effectively with other members of their research group, the wider scientific community within the institution and elsewhere, the animal care staff, the Establishment Licence Holder, and Home Office Inspectors etc. With the possible exceptions of newly arrived researchers who may have internal “start-up” funding and PPL holders based within commercial companies whose animal research takes place under the auspices of the institution, potential PPL holders are expected to have a successful track record of securing funding to support their programme of research.

PPL holders must remain scrupulously independent and be aware of potential inappropriate external influence being exerted by , for example, senior members of staff holding positions of authority within the institution, line managers, CEO’s of e.g. spin out companies and other academics within and beyond UoA who hold externally funded grants.

PPL applicants must display levels of maturity and responsibility commensurate with leading a scientific research team and holding a position whereby they could be held accountable for their own actions and the actions of the personal licence holders working under their project licence.

i. Applying for Project Licence

For further information on Project Licences, including information on how to apply, please go to the Home Office website at the following link: https://www.gov.uk/research-and-testing-using-animals. It should also be noted that applications for new and amended project licences are subject to the University’s ethical review process through the Ethical Review Committee, further details on which are given below in Section 6 of this document. Applicants must be of a suitable level of seniority within the University/corporate spin off companies and must be appropriately qualified; the Ethical Review Committee will not accept applications from applicants who have not completed the appropriate Home Office accredited training programmes.

ASPeL

Project licence applications are made online using the Home Office Animals Scientific Procedures Licensing system (ASPeL). In order to apply via the ASPeL system, applicants must first have an account created. This is done through the Named Training and Competency Officers.

3.8 Personal Licences

Any person intending to carry out regulated procedures under the authority of a project licence must hold a Personal Licence. Personal Licence Holders are subject to the direction of the Holder of the Project Licence under which the procedures are being carried out. A personal licence is granted indefinitely, though will likely be subject to Home Office review at least every five years.

The Personal Licence demonstrates that a person is suitably qualified to carry out specified regulated procedures, initially under supervision. To become a personal licence holder an individual must be at least 18 years old; have satisfactorily completed the appropriate Home Office accredited training modules; and should have appropriate experience of handling protected animals and looking after their welfare.

Staff new to the University of Aberdeen who hold/have held a personal licence at another facility are required to provide appropriate training records and undergo reverification of relevant procedures prior to commencing any regulated work at the University.

Under ASPA, an individual cannot apply a regulated procedure to an animal unless all three of the following requirements are met:

- the individual holds a *personal licence* giving authorisation to apply a procedure of that category to an animal of that type;
- the procedure is applied as part of a programme of work authorised in a project licence; and
- the place where the procedure is carried out is specified in that project licence.

In order to obtain a Personal licence, an individual must complete the relevant formal modular training to qualify for the specific categories of procedure required. An individual may be exempt from these requirements (with the exception of modules E1 and L) if he/she can supply evidence of equivalent relevant education, training and experience.

A new personal licence holder will have to undertake further practical training and be supervised until satisfactorily competent. Training and supervision needs should be periodically reviewed with the one of the NTCOs.

Personal licence holders who do not carry out any regulated procedures within a period of 3 years after completing an accredited training course are required to re-attend an appropriately accredited training course prior to carrying out regulated procedures.

For further information on the responsibilities and requirements relevant to the Personal Licence, including information on how to apply, please go to the Home Office website at the following link: https://www.gov.uk/guidance/research-and-testing-using-animal.

All applications for a personal licence must be approved by the relevant project licence holder; the Head of School and the Establishment Licence Holder. This is done via signatures on the Personal Licence Internal Approval Form (Appendix 5a to this document) Applicants should consult the Named Training and Competency Officers in the first instance.

ASPeL

Personal licence applications are made online using the Home Office e-licencing system, ASPeL. In order to apply via the ASPeL system, applicants must first have an account created. This is done through the Named Training and Competency Officers who can also advise on the form completion.

3.9 Training

In order to ensure that the University complies with Home Office requirements it is essential that proper arrangements are in place for those who require it, to undergo appropriate accredited training at the appropriate time, and that training records are maintained. The Home Office guidelines require:

- Training courses to be formally accredited by a Home Office approved accrediting body;
- New applicants for personal and project licences to have undertaken accredited training;
- Other staff and some students to have attended certain modules within accredited training courses/internal courses; and
- The Establishment Licence Holder has stipulated at all licence holders are required to attend at least one Licence Holder Refresher Training Seminar every 2 years. Refresher training seminars are held on a regular basis

Project licence writing seminars are also available.

All queries on training should be made to the Named Training & Competency Officer.

3.10 Study Plans

Study plans are strongly endorsed by the Home Office and by the Establishment Licence Holder and are part of the University Business Continuity risk management system.

All studies involving regulated procedures and Schedule 1 work necessitating the ordering in of animals and/or removal of live animals from the MRF to IMS and carried out in the MRF, IMSARU and Zoology require an approved study plan to be in place prior to commencement. Study plans are also required for regulated procedure studies carried out in Places Other Than Licenced Establishments (POLES).

Study plans from all BSUs should be submitted to the MRF study plan group.

The purpose of the study plan is to ensure:

- The relevant 3Rs are applied to all studies;
- Those carrying out the study have received the appropriate training, are deemed as being competent and have the required paperwork in place;
- Shared space, equipment and technical support are available as and when required throughout the course of the study;
- All required Home Office project licence, personal licence and establishment licence authorities are in place;
- Animals can be ordered, arrive and be acclimatised over an appropriate period prior to study commencement.

Study plans identify any practical, legal or welfare issues relating to reduction, replacement and refinement and are reviewed by the study plan team consisting of specific NAWCOs, NVS and NTCOs. Additional input is provided by the Health & Safety Coordinator and the MRF deputy manager. This review forms part of the responsibilities of the Named People, PPL, PIL holder and the encompassing AWERB - working proactively together to strive towards consistency of the 3Rs.

Study plans must be submitted at least 7 days prior to the proposed study date in order to ensure the appropriate individuals have sufficient time to review the plans.

The study plan template forms are updated in response to the requirements of those involved following appropriate consultation. The latest version of the study plan form and guidance on the completion of the study plan forms can be found on SharePoint.

4. THE ANIMAL WELFARE AND ETHICAL REVIEW BODY (AWERB)

As stated above, the ASPA requires that the University has in place an animal welfare body (AWERB). By way of compliance, as part of the AWERB, the University has in place an Ethical Review Committee (ERC) which undertakes ethical review of Home Office project licence applications and amendments. The other responsibilities are met by BSU Team and other named individuals.

4.1 Role of the AWERB

The role of the AWERB, as required under the Act, is given below (also summarised in Appendix 2 to this document). It should be noted that each specific responsibility is carried out by the ERC, BSU Team and/or named individuals.

- Promotes awareness of animal welfare;
- Provides 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;
- Sets up and regularly reviews procedures and protocols, including relevant management systems, for monitoring, reporting and following up on the acquisition, welfare and proper use of animals;
- Supports named people, and other staff dealing with animals, on animal welfare and ethical issues;
- Promotes the development and uptake of the 3Rs and advise staff how to apply them;
- Reviews all applications for new project licences and amendments to existing licences from a local perspective, considering how the 3Rs are being applied and advising the applicant and ultimately the Establishment Licence Holder on the acceptability of proposals, bringing local knowledge and expertise to bear;
- Follows the development of projects throughout their lifecycle by carrying out retrospective reviews (in-term reviews), so that lessons learnt can be used to further apply the 3Rs;
- Advises on re-homing animals including appropriate socialisation;
- Responds to enquiries and considers advice received from the national Animals in Science Committee;
- Reports and makes recommendations to the Advisory Group to the Establishment Licence Holder, as appropriate; and
- Has ethical oversight, and provides ethical approval to some level, on proposed animal research which will involve using animals which are not covered by the Animals (Scientific Procedures) Act (Amended 2012).

The Ethical Review Committee (ERC) carries out detailed ethical review on all project licence applications (including applications for amendments to existing licences), but does not make decisions regarding individual projects, rather it advises the Establishment Licence Holder. It reviews projects to seek to ensure that they are informed by ethical as well as scientific considerations and to ensure that the highest standards of animal care and welfare are observed at all times. Together the ERC, BSU Team and named individuals promote active consideration of the 3Rs in respect of all projects reviewed and for animal care and welfare across the University generally.

The Ethical Review Committee (ERC) will also consider any research proposal which involves the use of animals (as defined by ASPA) even where the research proposed is not governed by ASPA. In such cases there would be no legal requirement for the ERC to carry out ethical review. However, by way of good practice and according to its own expectations and standards of governance, the University is committed to ensuring that all research (and teaching) involving animal use is subject to some level of ethical scrutiny and justification. Section 6.9 of this document provides further information.

The BSU Team comprises of the two NVSs, NIO, NACWOs (on a rotational basis), the MRF project licence holder, the MRF facility and deputy manager, a lay member and at least three scientific representatives. Additionally, animal care staff and researchers involved in particular initiatives are invited/encouraged to participate. The primary AWERB responsibility of the BSU Team relates to the consideration and promotion of the 3Rs focussing mainly on reduction and refinement strategies and a Culture of Care. This is in the form of reactive 3Rs responses to be considered arising from professional bodies such as the Home office/Animals in Science Committee/NC3Rs/IAT/LASA and other associations and proactive 3Rs initiatives to be considered arising from the animal care staff/named persons/researchers.

It is University practice to circulate information about best practice and relevant legislation to all project and personal licence holders. The AWERB will ensure that relevant ethical advice is also distributed. In addition, the NIO, NVS, the Clerk and the Convener of the ERC will act as points of contact for members of staff throughout the institution who wish to seek more detailed guidance on ethical concerns.

4.2 ERC Composition and Process

The composition of the ERC is as follows:

- A pool of lay members (non-scientists) of the University community (one of whom convenes the Committee, and one of whom is Deputy Convener)
- The Scientific Advisor to the ERC
- Scientific Advisor
- Deputy Scientific Advisor
- Named Animal Care and Welfare Officers
- Experienced members of the animal care staff (including but not limited to those who have previously held the position of NACWO)
- Named Veterinary Surgeons
- Named Training and Competency Officers
- Named Information Officer
- Scientific members/project licence holders (including but not limited to all existing University project licence holders)

The Establishment Licence Holder or representative and the Home Office Inspector are also invited to attend each meeting.

Guidance notes for the lay members; scientific members; vets and NACWOs are detailed in Appendix 4b.

The **quorum** for review panels is **four** members

- the Lay-Convener (or Deputy Convener, or substitute)
- 1 scientific member (usually a project licence holder)
- 1 Named Veterinary Surgeon
- 1 Named Animal Care and Welfare Officers

Usually the panel consists of the Convener/Deputy convener, 2 lay members, both NVSs, 1-2 NACWOs and at least one scientific representative.

New project licence applications and amendments are dealt with by focused panels drawn from the wider membership of the ERC, which meet on a scheduled basis every two months. Where required, an additional ERC panel meeting may be convened out with the set schedule, but only in exceptional circumstances.

Any advice given by the ERC, and decisions taken as a result, must be properly documented and made available to inspectors as and when requested. These records are kept for at least three years, as required under the Act.

The Establishment Licence Holder, or someone designated by the Establishment Licence Holder, must countersign each request for a project licence or amendment involving work at the University, confirming that an application has completed local ethical review at the home institution.

Guidance for research staff on the ethical review process and submitting applications to the ERC is given in section 6 of this document.

4.3 Training

As part of its educational role, the ERC, via the Named Training and Competency Officers, arrange seminars for the discussion of relevant issues and offer guidance to animal care officers and to licence holders about welfare and ethical matters. The RSPCA hold annual lay members' forums and occasional workshops. The ongoing process of review of project licences also provides an opportunity to discuss such issues with individual licence applicants and holders.

All licence holders are required to attend a Home Office refresher training seminar at least once every 2 years. Internal training seminars are provided on a regular basis.

ERC members should also, where appropriate, undertake training in ethical review processes and should be fully acquainted, through appropriate training (e.g. ScotPIL and routine refresher events), with the legal administrative requirements of the Home Office Inspectorate.

4.4 ERC Reporting Requirements

The ERC and the BSU Team provide annual reports to the Advisory Group to the Establishment Licence Holder (AGELH) meetings (details on AGELH given in next section). These reports include details of all applications considered by the ERC, and any other significant issues.

5. ROLE OF THE ADVISORY GROUP TO THE ESTABLISHMENT LICENCE HOLDER

As part of the governance arrangements the University has in place to meet the requirements of ASPA, it has an Advisory Group to the Establishment Licence Holder (AGELH). The AGELH is to advise the Establishment Licence Holder on all aspects of the implementation of ASPA and other Home Office matters relating to animals, and to make recommendations to University management on current issues and policy relating to the use of animals in teaching and research. The AGELH meets three times per year.

5.1 AGELH Business

At each meeting, the AGELH will consider any business directly relevant to the implementation of ASPA by the institution, but will also consider standard reports, as outlined below:

- **BSU Report**: the AGELH receives detailed reports, coordinated by the BSU Manager with input from appropriate NACWOs, from each of the University's Biological Services Units at each meeting, including information on:

    - Animal Usage (annual)
    - Occupancy Rates (annual)
    - Incidents
    - Staffing
    - Facilities and Plant (Estates related issues)

- **NVS Report**: the AGELH also receives a report from the NVS at each meeting. The NVS report usually covers issues relating to the following:

    - A health status for each BSU facility, including information on animal screening, the results of all animal screening tests, and subsequent actions taken
    - A general update on any significant issues relating to the Home Office
    - Welfare issues

- **ERC Report:** the AGELH also receives a report from the AWERB at each meeting, which includes an update on its membership, its workload, any variation in its processes, and any other significant issues it has to report

- **BSU Team Report:** the AGELH also receives an annual report from the BSU Team, which details the group's activities including the promotion of the 3Rs

- **Training Report:** The AGELH will seek advice from the NTCO regarding the appropriate training of day care staff and researchers. Such staff will also be encouraged to attend relevant seminars and conferences. It will use the wide range of expertise of its membership to identify training opportunities to ensure competency in all staff involved in animal care. In particular, through its membership the AGELH maintains a close association with the local and national ScotPIL committees and other accredited training bodies, which arrange training for project and personal licence applicants.

- In addition to the above, the AGELH also receives reports from its Directorate of Estates & Facilities and Health, Safety and Wellbeing section.

5.2 AGELH Composition

The AGELH composition is as follows:

- Establishment Licence Holder
- Named Training and Competency Officers
- The Scientific Advisor to the ERC
- Convener of the Ethical Review Committee
- BSU Manager/ Deputy Manager
- Appropriate NACWOs
- Director of Estates & Facilities or representative
- Head of Health, Safety & Wellbeing
- Named Veterinary Surgeons

- BSU User representative
- Named information Officer
- Convener of the BSU team

6. THE ETHICAL REVIEW PROCESS

Guidance for Research Staff on Submitting Items to the Ethical Review Committee (ERC)

The following section provides guidance for research staff on submitting items to the ERC, and of the ethical review process which the AWERB has responsibility for managing and delivering. Flowcharts showing the ethical review process for new project licence applications, and amendments to existing project licences, are included in Appendix 3a and 3b.

6.1 Review of Project Licence Applications

The ERC aims to review all applications for new and amended project licences promptly, while ensuring that all applications are subject to rigorous ethical scrutiny. Each application is reviewed by a panel drawn from the full ERC membership.

The **quorum** for review panels is **four** members

- the Lay-Convener (or Deputy Convener, or substitute)
- 1 scientific member (usually a project licence holder)
- 1 Named Veterinary Surgeon
- 1 Named Animal Care and Welfare Officer

Usually the panel consists of the Convener/Deputy convener, 2 lay members, both NVSs, 1-2 NACWOs and at least one scientific representative.

Meetings of the ERC are set at the start of each academic year. Applicants are required to submit project licence applications, with accompanying paperwork, to the University's ERC Clerk **by** a deadline of **four weeks** before the date of the meeting at which they wish the application to be considered. The applications will then be reviewed in advance by the NVSs and NACWOs (on a rotational basis) who may submit feedback and suggest changes to the applicant, following which amendments may be made and changes re-submitted to the ERC Clerk no later than **two weeks** before the date of the meeting. Late applications will not be considered. Applicants are expected to attend the meeting at which their application is being considered, or as an alternative, they may be permitted to send a nominated senior researcher in their place. However, if an applicant is submitting their first project licence application, they will be required to attend in person.

6.2 The Project Licence Application

All researchers submitting an application to the University's ERC must have completed the appropriate Home Office accredited programmes – i.e. Modules E1/L, PILA, PIL B (+/- PILC), 2, 9, 10 and 11. Applications will not be considered from staff who do not have the appropriate training unless they have held a project licence prior to the introduction of modular training courses

Before beginning work on an application for project licence renewal, or amendment to an existing licence, applicants must seek appropriate advice from the BSU Manager, NVS and relevant NACWO(s). Entirely new project licences will require additional approval from the relevant Head of School and Scientific Advisor (or Deputy) to the ERC.

Application forms, annotated forms and guidance notes for new/amendments to project and personal licences are available on the Home Office website at the following link: https://www.gov.uk/research-and-testing-using-animals.

Both when drafting the licence application and in preparation for the ethical review meetings, applicants should bear in mind the purpose of the ERC. The ERC is a key component within the local framework acting to ensure that all use of animals in the establishment is carefully considered and justified; that proper account is taken of all possibilities for reduction, refinement and replacement (the 3Rs); and that high standards of accommodation and care are achieved. The ERC will want to examine the expected benefits of the research and the likely costs to the animals; and how these considerations balance – the harm benefit analysis. Applicants should be able to explain clearly, in non-scientific terms, the likely costs to the animals and the likely benefits of the research, to allow the panel to make an informed judgement.

In the application, notably in the internal Lay-Summary Proforma, the applicant should: indicate what sources of references have been consulted in justifying the proposal and in designing the study; and clearly explain the overall scientific objectives and the experimental design - providing a rationale for the proposed numbers of animals to be used, the species selected and the experimental approach. Applicants should make it clear that they have considered all likely adverse effects, and clarify how they propose to minimise these.

The panel will require evidence, via its internal Lay-Summary Proforma (see Appendix 4a) that the number of animals to be used for each protocol has been determined on sound statistical principles. Applicants should refer to the methodology used, the advice taken, experience gained from any previous studies, peer reviewed grant applications, and peer reviewed publications.

6.3 Submission of the Application and Additional Information Required

As noted above, all researchers submitting an application to the University's ERC must have completed the appropriate Home Office accredited programmes – i.e. module E1/L,2, 9,10, 11, PIL A, PIL B and where appropriate PIL C. Applications will not be considered from staff who do not have the appropriate training unless they have held a project licence prior to the introduction of modular training courses.

Applicants should submit applications to the panel for ethical review by the ERC at least four months in advance of when the licence is required in order to ensure that the Home Office have adequate time to review and return.

Although applicants may contact the Home Office to discuss general principles, it is recommended that any queries are directed to the NVSs in the first instance.

The NVSs will be able to advice on these circumstances and should be contacted in the first instance.

Together with the application, the applicant should submit to the ERC Clerk (by email) the following internal documentation:

- A completed Lay-Summary Proforma (see Appendix 4a). This is an internal document for the ERC only (it will not be submitted to the Home Office), and it should describe the research programme and its aims in terms that the lay members of the panel will understand. It should also specify how their application addresses the 3Rs
- The Internal Approval Form, signed by one of the NVSs and NTCOs, the Scientific Advisor (or Deputy) of the appropriate BSU Facilities, and appropriate Head of School (see Appendix 5b)

6.4 Project Licence Non-Technical Summary (NTS)

In early 2013 the Home Office Project Licence Application was amended to replace the Abstract Section with a new Non-Technical Summary (NTS) section. This is an extremely important part of the application; it will be made available on the Home Office website.

Because the NTS is for publication, the ERC will review it particularly carefully, and might also seek the advice of the University's Research & Innovation Department on its content, to ensure that publication does not impact on intellectual property issues. Although the NTS, like the lay summary described above, should be written in lay terms, applicants should note that the two documents are written for different audiences: the lay summary for members of the ERC only, and the NTS for Home Office website publication.

6.5 Submission and Review of Applications for Amendments to Project Licences

When submitting an application for an amendment to a project licence, applicants should submit one copy of the full project licence showing all the changes requested e.g. by background highlighting the altered text and striking through text to be removed. Prior to amendment, existing paper licences must be converted to the Home Office electronic format (ASPeL) as the Home Office will no longer accept hard copy licence amendments. The NTCOs/HOLCs should be consulted in the first instance to set up an ASPeL account.

Major amendments

Normally, major amendments are those which impact on the number of animals used and/or the severity of procedures. The process for reviewing applications for major amendments to project licences is similar to that for new project licence applications (see above). A lay summary of the changes is required, together with a lay summary proforma and an Internal Approval Form (see Appendix 5b).

Minor amendments

Applications for minor amendments must be made by submitting a completed Minor Amendment Fast Track Approval Form (see Appendix 6a). An application for an amendment will usually be accepted as a "minor amendment" if it:

- Does not involve an increase in the number of animals used

- Does not result in an increase in the severity of procedures
- Does not involve any additional procedures
- Involves a refinement

If an application for an amendment does not meet this criteria, then it will likely be subject to full ethical review by the ERC. A decision on this will be made at the discretion of the NVSs, the Scientific Advisor (or Deputy) and the ERC Convenor, who may be deem that the proposed amendment does not warrant full ethical review by an ERC panel - even if it does not meet all criteria for fast-tracking. For example, they may agree that a minor and relatively harmless increase in the number of procedures carried out is not a significant enough change to warrant full ethical review by the ERC.

Applications will be considered by the Convener of the ERC, one of the NVSs and the Scientific Advisor (or Deputy), by circulation.

If an applicant has any doubt if an amendment is minor or major, advice should initially be sought from the NVS

Amendments to Genetically Altered (GA) Records

When an amendment is being made to a GA Record/Passport of sub-threshold or mild severity, full ERC consideration may not be required although will be subject to the University internal approval system. The advice of the NVS should be sought in the first instance.

An up-to-date appendix must be lodged with the all copies of the project licence.

6.6 Applications for secondary availability

All applications where the University of Aberdeen is to be a secondary availability establishment on a project licence must undergo ethical review by the University. The ERC is presented with evidence that will satisfy it that the project has undergone and met the requirements of the Ethical Review Process at the primary establishment; and that a lay summary of the application is provided, together with a clear statement regarding which parts of the proposed research are to take place at the University of Aberdeen. Applicants are required to attend an ERC meeting to discuss the work to be carried out at the University of Aberdeen only.

6.7 Retrospective Reviews of Project Licences

Under the Animals (Scientific Procedures) Act 1986, the University's ethical review process must allow for retrospective reviews. Retrospective reviews are described by the Home Office as reviews "looking back on the animal welfare costs encountered and benefits realised". The objectives of such reviews are to; determine whether the actual costs and benefits are in line with those anticipated; the objectives have been achieved and identify, build on, enhance and promulgate good practice and improvements in the 3Rs during the course of a project (the **R**eplacement of animals in research with other experimental models; the **R**eduction in the number of animals used; and the **R**efinement of procedures that cause suffering).

The ERC carries out three forms of retrospective review:

- In-term Review: formal ERC review applied to all project licences carried out in the 4th year of a Project Licence

- Retrospective Assessment: formal ERC and Home Office review applied to specific project licences identified by the Home Office carried out towards the conclusion of a Project Licence

- Additional reviews specified by the ERC e.g. after 1 year may be carried out

Additional annual reporting conditions may be imposed by the Home Office.

As part of the in-term review process, project licence holders will be required to deliver a short presentation to the ERC and to complete a short final report (2-3 pages), which reflects the objectives of in-term review set out above, particularly focussing on the implementation of the 3Rs. This is to allow Licence Holders to reflect on the project as a whole, and to capture any examples of lessons learned or best practice to share with others. In addition, if the Licence Holder is intending to apply for a further project licence, the report can be used to provide the basis for the new application.

Details on exactly what licence holders should present will be given in advance of any review session. A copy of the in-term review form and guidance is attached to this document as Appendix 6b and 6c.

A copy of the ERC/Home Office Retrospective Assessment form is attached to this document as 6d.

6.8 The ERC Panel Meeting

Prior to a meeting of the ERC panel at which his/her application or in-term review is being considered, the applicant will be sent a communication inviting them to attend the meeting and setting out the areas which the panel will address. The applicant will also receive a presentation template focussing on the main points of the application the panel wish to consider.

The applicant will be invited to attend the panel meeting, and to discuss the project licence with the panel. If the applicant is applying for a project licence for the first time, they will be required to attend the panel meeting. An application will not normally be considered in their absence. Any applicant who has previously applied for a project licence will be expected to attend the panel meeting. Senior researchers are also encouraged to attend, though this is optional. The applicant should be aware that some members will have a non-scientific background, and therefore at the meeting, should be prepared to explain the proposed work in non-technical language.

The panel will inform the applicant of any recommendations that it intends to make to the Establishment Licence Holder on acceptance of the minutes. If the panel wishes the applicant to make changes to a project licence application, a follow-up email will be sent to the applicant summarising the changes required. The changes are checked and confirmed by one of the NVSs.

6.9 Animal Research Not Covered by ASPA

It is recognised that there may be circumstances where a research or teaching proposal involves the use of animals which are listed as protected under ASPA (meaning all living vertebrates other than man and cephalopods), but **does not** involve undertaking regulated procedures as defined by the Act. In such cases, there would be no requirement to have in place a Home Office licence. However, researchers seeking to undertake any such research are still required to submit a proforma to the ERC for consideration before the work has commenced.

A copy of the proforma is attached to this document as Appendix 7. The proforma asks the applicant to give details on the number, source and capture of animals proposed for use, an overview of husbandry and welfare arrangements, and an outline of the procedures proposed. The applicant will only be required to attend the meeting in person if the programme of work proposed is deemed to warrant enhanced scrutiny. This requirement will not apply in cases where a non-regulated procedure in a BSU has already undergone review by one of the NACWOS and NVSs as part of the internal study plan process.

This process is designed to ensure the following: that the institution has oversight and knowledge of all research and teaching undertaken which uses animals (as defined by ASPA), regardless of whether the research is governed by ASPA; that all ethical and welfare standards expected of Aberdeen researchers conducting research in this area are adhered to; and to mitigate against the risk of reputational damage. Researchers should contact one of the NVSs in the first instance with any queries.

6.10 Security

Project licence applications must be handled in strict confidence. Those working under the controls of the 1986 Act are currently required not to disclose information that they gain as a consequence of such involvement and all participants in the ethical review process are required to agree to such an undertaking. All members of the ERC should return to the Clerk all documents circulated to them as part of the ethical review process in order that those documents can be disposed of securely. Should members of the ERC be joining remotely, all documents should be deleted securely.

6.11 Appeals

If an applicant wishes to raise an appeal against the advice given to the Establishment Licence Holder by the ERC, they may ask the Establishment Licence Holder to arrange for the application to be reviewed a second time with the requirement that the composition of the second panel includes the range of expertise appropriate to the proposed licensed procedures. The Establishment Licence Holder will then decide whether the project should be allowed to go forward to the Home Office or be returned to the applicant.

6.12 Animal Research Carried Out Abroad

This process is currently under review.

7. RAISING CONCERNS ON ANIMAL WELFARE AND REPORTING ALLEGATIONS OF UNACCEPTABLE RESEARCH CONDUCT

The University has in place formal procedures for reporting allegations of unacceptable research conduct. This includes research involving the use of animals (which includes stock animals). These procedures are outlined in detail in Section 4 of the University's Handbook for Research Governance and apply to all staff involved in animal research, including academic staff, technicians and support staff.

However, if a member of staff involved in animal research would like to raise initial concerns in relation to animal welfare on an informal basis, they should contact any of the following: an NVS; a NACWO; the applicable project licence holder; the applicable personal licence holder or the facilities manager. If they do not feel comfortable raising concerns with any of these parties, they should, alternatively, discuss with their Line Manager; the Scientific Advisor (or Deputy) or the Establishment Licence Holder. It should be noted that any *bona fide* concerns raised in good faith will be dealt with in strict confidence, without any prospect of the complainant suffering detriment. Equally, it should also be noted that there are disciplinary procedures in place for dealing with malicious complaints.

APPENDICES

- Appendix 1: Contact Details for Key and Named Individuals
- Appendix 2: Role of the Animal Welfare and Ethical Review Body
- Appendix 3a: Project Licence Application Process
- Appendix 3b: Project Licence Full Amendment Process
- Appendix 4a: Lay Summary Proforma
- Appendix 4b: ERC Meeting Guidance Notes
- Appendix 5a: Personal Licence Application: Internal Approval Forms
- Appendix 5b: Project Licence New and Major Amendment: Internal Approval Form
- Appendix 6a: Fast Track Approval Form (for minor amendments)
- Appendix 6b: In-Term Review of Project Licences Proforma
- Appendix 6c: In-Term/Retrospective Review Guidance Notes
- Appendix 6d: ERC/Home Office Retrospection Assessment Form
- Appendix 7: Animal Research not covered by ASPA
- Appendix 8: Signatures required for internal approval forms

Appendix 1

Contact Details for Key Individuals Referred to in this Code of Practice

To contact any of the key individuals holding the roles below, please e-mail holc@abdn.ac.uk

Clerk to the Ethical Review Committee (ERC)
Clerk to the Advisory Group to the Establishment Licence Holder (AGELH)
Convenor of the Advisory Group to the Establishment Licence Holder (AGELH)
Deputy Lay-Convenor of the Ethical Review Committee (ERC)
Deputy Scientific Advisor
Establishment Licence Holder
Lay-Convenor of the Ethical Review Committee (ERC)
Named Animal Care and Welfare Officer (NACWO)
Named Information Officer (NIO)
Named Training and Competency Officer (NTCO)
Scientific Advisor
Named Veterinary Surgeon (NVS)
Convener of the BSU team
MRF manager
Depute to the MRF manager

24-hour emergency cover is provided by:

Donview Veterinary Centre, Inverurie
Tel: 01467 621429

Appendix 2

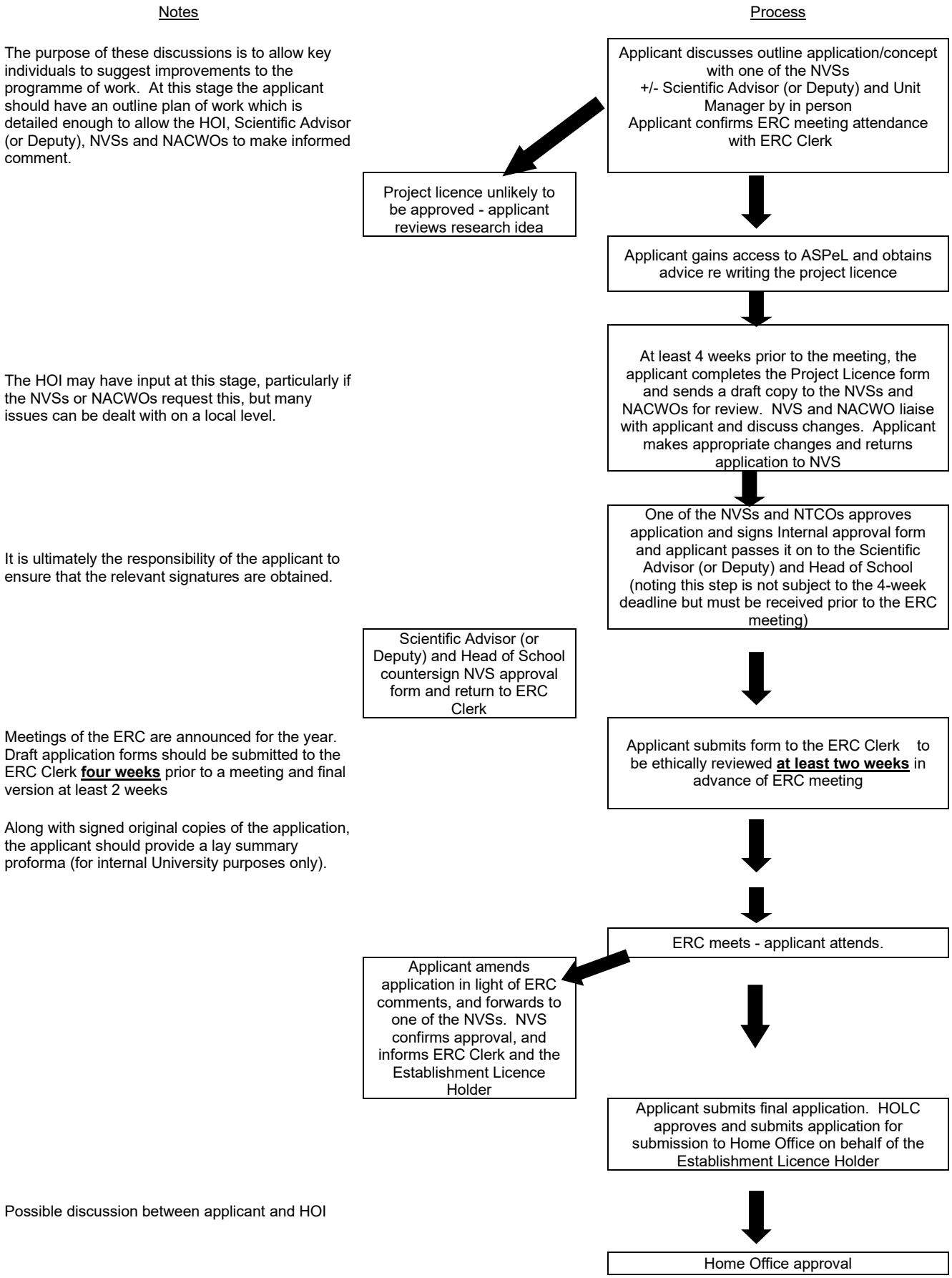
Role of the Animal Welfare and Ethical Review Body

The role of the Animal Welfare and Ethical Review Body is as follows:

- Promotes awareness of animal welfare;
- Provides 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 the University;
- Sets up and regularly reviews procedures and protocols, including relevant management systems, for monitoring, reporting and following up on the acquisition, welfare and proper use of animals;
- Supports named people, and other staff dealing with animals, on animal welfare and ethical issues;
- Promotes the development and uptake of the 3Rs and advises staff how to apply them;
- Reviews all applications for new project licences and amendments to existing licences from a local perspective, considering how the 3Rs are being applied and advising the applicant and ultimately the Establishment Licence Holder on the acceptability of proposals, bringing local knowledge and local expertise to bear;
- Follows the development of projects throughout their lifecycle by carrying out retrospective reviews (in-term reviews), so that lessons learnt can be used to further apply the 3Rs;
- Advises on re-homing animals including appropriate socialisation;
- Responds to enquiries and considers advice received from the national Animals in Science Committee;
- Reports and makes recommendations to the Advisory Group to the Establishment Licence Holder, as appropriate; and
- Has ethical oversight, and provides ethical approval to some level, on proposed animal research which will involve using animals which are not covered by the Animals (Scientific Procedures) Act (Amended 2012).

Appendix 3a

Project Licence Application Process



Appendix 3b

Project Licence Full Amendments Process

Notes

At this stage the applicant should have enough information about the proposed changes to allow the Scientific Advisor (or Deputy), NVS, NACWOs and HOI to make informed comment.

Changes which will require an application for an amendment include changes to: objectives, protocols, severity limits, number of animals, licence holder and deputies.

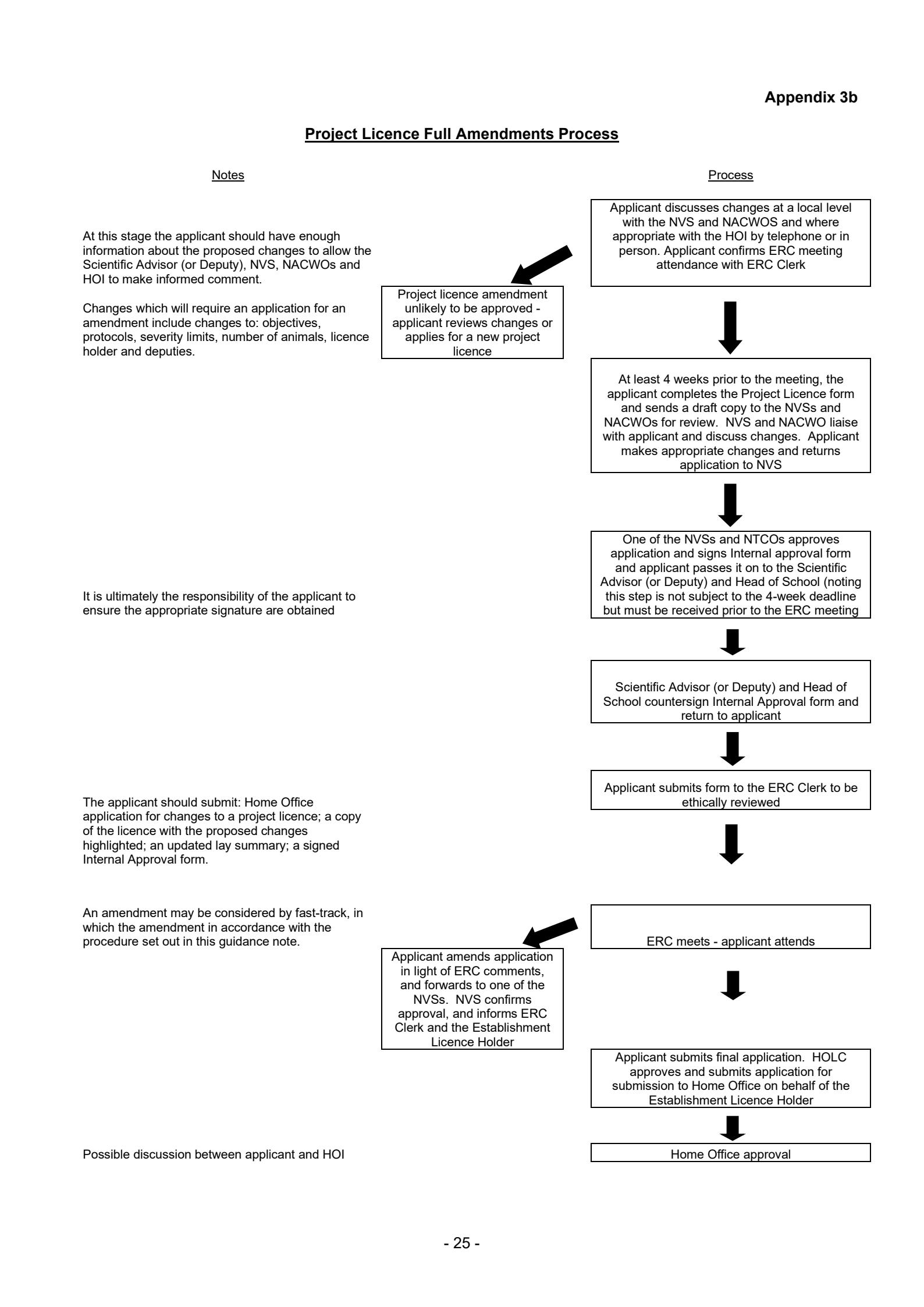
It is ultimately the responsibility of the applicant to ensure the appropriate signature are obtained

The applicant should submit: Home Office application for changes to a project licence; a copy of the licence with the proposed changes highlighted; an updated lay summary; a signed Internal Approval form.

An amendment may be considered by fast-track, in which the amendment in accordance with the procedure set out in this guidance note.

Possible discussion between applicant and HOI

Process



Appendix 4a

UNIVERSITY OF ABERDEEN
PROJECT LICENCE APPLICATION / APPLICATION FOR AMENDMENT
LAY SUMMARY PROFORMA

To note:

This document asks you to provide key information designed to give an overview of the proposed research to the Ethical Review Committee (ERC), including its lay-members. This is an internal document to be written specifically for the ERC only.

In the lay summary section, please provide a lay summary of your project licence application or / application for a major amendment to your existing project licence. Content may vary from that included in a project licence application form (such as in the Non-Technical Summary (NTS) section). The NTS in the project licence application form requires a higher level of scientific detail than requested here, and the information provided in the NTS should be tailored for a wider audience, noting that it will be made publically available via the Home Office website.

As noted above, this lay summary form is strictly for internal use, to make the proposed research more accessible to the ERC, most notably its lay members. It should describe the research programme and its aims using non-technical terminology that the lay members of the ERC, who do not have a scientific background, will understand. It should not exceed one side of A4 in length.

Project Title:	
Date of Ethical Review:	
Lay Summary (include objectives and overview of the scientific questions/clinical needs to be addressed and expected benefits):	

Application of the 3Rs: note, the Non-Technical Summary section of the Home Office Project Licence Application requires information specific to the application of the 3Rs and therefore applicants are not asked to replicate information here. However, the following question relating to reducing the number of animals used should be answered:	
Have Efforts Been Made to Reduce the Number of Live Animals, and if so, what are they?	
If yes, please provide evidence of statistical power calculations used to determine the number of animals proposed for use:	
If no, please provide clear justification of why this has not been done:	
Funding Sources (please provide details of the research funder):	
Does the funding body have any ethical requirements, and if so have they been satisfied?	
Please provide any other relevant information:	

Appendix 4b

Animal Welfare and Ethical Review Body
Ethical Review Committee
Guidance for lay members

The role of the lay member on the Ethical Review Committee is to ask questions on behalf of the animals undergoing experimentation, in order to ascertain whether the benefits of the research outweigh the proposed harms to the animals.

As a lay-member, you will receive a copy of the Project Licence Application. While it is important to read the document in full, the most pertinent information for lay members appears in the lay summary, the section on the 3Rs, the non-technical summary and the benefits sections. The form includes detailed information on the procedures the animals will undergo, the effects of these procedures on the animals including potentially harmful outcomes, and the procedures in place to monitor and alleviate these effects, in the Protocols section.

Lay members should feel free to ask any question that helps them understand and assess the benefits of the research and the harms to the animals. For example, lay members may wish to ask the applicant to clarify and explain:

- the specific benefits of the research
- what justifies the number of animals used on a protocol or the whole project
- what any one animal will undergo during their lifetime
- why specific procedures are, or are not, being used
- what justifies the use of a particular species
- whether there are any ways of **reducing** the number of animals used
- whether it is possible to **replace** *in vivo* (live) experiments with other kinds of research (e.g. *in vitro* cell cultures, computer models)
- whether any **refinements** to improve animal welfare could be introduced
- how the researchers will monitor suffering and distress.

The applications can be difficult for lay members to understand due to their scientific content. Bear in mind that you are not expected to be an expert: other members of the committee (scientific members, the NVS and NACWOs) have expertise in assessing the scientific, veterinary, and practical elements of the application. Your role is to ask the questions that occur to a member of the general public concerned about animal welfare, and to contribute your perspective to the committee's discussion.

If you have questions or concerns outside of the meeting, the best person to contact is the NVS who can help you to understand the contents of the application. Further literature and support on the role of the lay member is available from the RSPCA.

Animal Welfare and Ethical Review Body
Ethical Review Committee
Guidance for Scientific members

Scientific members of the Ethical Review Committee bring their expertise to bear on the scientific justification for proposed studies, the appropriateness of methods and models, and technical aspects of the study, including the design of experiments. Ultimately, scientific members have the same duty as all members, namely to ask questions on behalf of the animals undergoing experimentation, in order to ascertain whether the benefits of the research outweigh the proposed harms to the animals.

As a scientific-member, you will be a member of a pool of researchers who may be invited to ERC meetings on an ad hoc basis depending on the scientific specialisms of project licence applications under consideration at the relevant meeting. You will receive a copy of the Project Licence Application/s in advance of the meeting at which the project licence application/s are to be reviewed. Scientific members are asked in particular to review sections C (the aims of the project in relation to the scientific background and benefits) and D (The Programme of Work). Scientific members will also be asked to comment on Protocols (section E), particularly where members have knowledge and expertise in the relevant technique. It is also important to review the consistency of the science background, aims and objectives with the information in the lay summary, the section on the 3Rs, the non-technical summary and the benefits sections.

At the ERC meeting, members of the ERC will then discuss the project with the applicant. Scientific members may wish to ask the applicant to clarify and explain:

- The scientific background, relevant previous work, and the aims and objectives
- the specific benefits of the research
- the justification for the number of animals used on a protocol or the whole project
- why specific procedures are, or are not, being used
- what justifies the use of a particular species
- the principles of experimental design to be used and whether there are any ways of **reducing** the number of animals used
- whether it is possible to **replace** *in vivo* (live) experiments with other kinds of research (e.g. *in vitro* cell cultures, computer models)

At the end of the meeting, members of the Committee summarise their view on the project enabling there to be a recommendation on the basis of a harm-benefit analysis. Such recommendations may include endorsement of the project, minor or substantial revisions to the project licence proposal and its component protocols, or a rejection on ethical grounds.

If you have questions or concerns outside of the meeting, the best person to contact is the NVS who can help you to understand the contents of the application. Further literature and support on the role of the lay member is available from the RSPCA.

Animal Welfare and Ethical Review Body
Ethical Review Committee
Guidance for Named Veterinary Surgeons (NVSs)

The role of the Named Veterinary Surgeons (NVSs) on the Ethical Review Committee is to bring their expertise to bear in terms of the scientific justification for proposed studies, practicalities of the proposed studies and the appropriateness of methods and models in terms of refinement of the study including the procedures the animals will undergo. Ultimately, the NVSs have the same duty as all members, namely to ask questions on behalf of the animals undergoing experimentation, in order to ascertain whether the benefits of the research outweigh the proposed harms to the animals.

The NVSs are expected to assess the application in advance of submission to the ERC for scrutiny to confirm that the document complies with local and Home Office requirements in terms of standard wording, scientific justification. They will also encourage applicants to ensure that their documentation includes information sufficient and appropriate for other members of the ERC and the Home Office Inspector to carry out a cost benefit analysis. Applications failing to meet the required standard will not be approved by the NVS and will not be submitted to the ERC for ethical review.

The NVSs have an overall understanding of the scientific research involving animals being undertaken at the University and therefore and review documentation submitted to the ERC in full. The NVSs are asked in particular to consider the lay summary, the benefits section, the section on the 3Rs, adverse effects including unexpected adverse effects from the previous licence, training and sections D (The Programme of Work) and E (The Protocols).

NVSs should feel free to ask any question that helps them understand and assess the benefits of the research and the harms to the animals. For example, NVSs may wish to ask the applicant to clarify and explain:

- the severity of individual protocols
- the overall collective/accumulative suffering in terms of regulated and non-regulated studies throughout the life time of the animals
- the “worst case scenario” of individual animals
- scoring systems and humane end points
- the specific benefits of the research
- what justifies the number of animals used on a protocol or the whole project
- why specific procedures are, or are not, being used
- what justifies the use of a particular species
- whether there are any ways of **reducing** the number of animals used
- whether it is possible to **replace** *in vivo* (live) experiments with other kinds of research (e.g. *in vitro* cell cultures, computer models)
- whether any **refinements** to improve animal welfare could be introduced

At the end of the meeting, members of the Committee summarise their view on the project enabling there to be a recommendation on the basis of a harm-benefit analysis. Such recommendations may include endorsement of the project, minor or substantial revisions to the project licence proposal and its component protocols, or a rejection on ethical grounds.

Animal Welfare and Ethical Review Body
Ethical Review Committee
Guidance for Named Animal Welfare Officers (NACWOs) and Senior Animal Technicians

The role of the Named Animal Welfare Officers (NACWOs) and senior animal technicians on the Ethical Review Committee is to bring their expertise to bear in terms of the practicalities of the proposed studies and the appropriateness of methods and models in terms of refinement of the study, including the procedures the animals will undergo. Ultimately, NACWOs and senior animal technicians have the same duty as all members, namely to ask questions on behalf of the animals undergoing experimentation, in order to ascertain whether the benefits of the research outweigh the proposed harms to the animals.

As a NACWO/senior animal technician, you will receive a copy of the Project Licence Application. While it is important to read the document in full, the NACWOs/senior animal technicians are asked in particular to review the section on the 3Rs and sections D (The Programme of Work) and E (The Protocols). In addition to reviewing the costs to the animals in terms of the expected adverse effects and the amelioration of the adverse effects, it is also important to review the practicalities "on the ground" of the proposed procedures, particularly where members have knowledge and experience of those and related procedures.

NACWOs/senior animal technicians should feel free to ask any question that helps them understand and assess the benefits of the research and the harms to the animals. For example, NACWOs/senior animal technicians may wish to ask the applicant to clarify and explain:

- the severity of individual protocols
- the overall collective/accumulative suffering in terms of regulated and non-regulated studies throughout the life time of the animals
- the "worst case scenario" of individual animals
- scoring systems and humane end points
- the specific benefits of the research
- what justifies the number of animals used on a protocol or the whole project
- why specific procedures are, or are not, being used
- what justifies the use of a particular species
- whether there are any ways of **reducing** the number of animals used
- whether it is possible to **replace** *in vivo* (live) experiments with other kinds of research (e.g. *in vitro* cell cultures, computer models)
- whether any **refinements** to improve animal welfare could be introduced

At the end of the meeting, members of the Committee summarise their view on the project enabling there to be a recommendation on the basis of a harm-benefit analysis. Such recommendations may include endorsement of the project, minor or substantial revisions to the project licence proposal and its component protocols, or a rejection on ethical grounds.

If you have questions or concerns outside of the meeting, the best person to contact is the NVS who can help you to understand the contents of the application.

Appendix 5a

UNIVERSITY OF ABERDEEN

POLICY, PLANNING AND GOVERNANCE

PERSONAL LICENCE APPLICATION - INTERNAL APPROVAL FORM

To: **Susan Barr/Kay Mennie, Named Training and Competency Officers**

From:

Date:

Subject: **Home Office Personal Licence Application:**

This form is for the relevant Project Licence Holder* and the relevant Head of School to provide endorsement to the Named Training and Competency Officer, for the Home Office personal licence application cited above. This must be signed by both the Project Licence Holder* and the Head of School and will be made available to the Home Office Inspector as proof of internal approval. Once completed, it should be passed to the University's Named Training and Competency Officers (NTCOs).

Name of applicant ……..

As project licence holder* I confirm the following regarding the applicant

a. I have knowledge of the education, experience and character of the applicant**.

b. I have seen the applicant's accredited Home Office (or equivalent) training certificate.

c. I understand that I may be guilty of an offence if for the purpose of assisting another person to obtain a licence under this Act I furnish information which I know to be false or misleading in a material particular or recklessly furnish information which is false or misleading in a material particular.

d. The applicant has a command of English sufficient for him/her to understand the terms and condition under which (s)he may hold a licence under the Animals (Scientific Procedures) Act 1986, which have been explained to him/her.

* If you are not the project licence holder please confirm under what capacity you are signing (for example, Facility Manager; Senior NACWO)

** See Home Office personal guidance notes at www.gov.uk/research-and-testing-using-animals

PROJECT LICENCE HOLDER (confirmation of above and endorsement):

SIGNATURE: _____ DATE: _____

PRINT NAME: _____

POSITION: _____

HEAD OF SCHOOL (approval of application):

SIGNATURE: _____ DATE: _____

PRINT NAME: _____

POSITION: _____

ESTABLISHMENT LICENCE HOLDER (for submission to the Home Office):

SIGNATURE: _____ DATE: _____

PRINT NAME: _____

UNIVERSITY OF ABERDEEN

POLICY, PLANNING AND GOVERNANCE

PERSONAL LICENCE AMENDMENT APPLICATION - INTERNAL APPROVAL FORM

To: **Susan Barr/Kay Mennie, Named Training and Competency Officers**

From:

Date:

Subject: **Home Office Personal Licence Amendment Application:**

This form is for the relevant Project Licence Holder* to provide endorsement to the Named Training and Competency Officer, for the amendment application to the Home Office personal licence cited above. This must be signed by the Project Licence Holder* and will be made available to the Home Office Inspector as proof of internal approval.

Name of applicant ……..

As project licence holder* I confirm the following regarding the applicant

a. I have knowledge of the education, experience and character of the applicant**.

b. I have seen the applicant's accredited Home Office (or equivalent) training certificate.

c. I understand that I may be guilty of an offence if for the purpose of assisting another person to obtain a licence under this Act I furnish information which I know to be false or misleading in a material particular or recklessly furnish information which is false or misleading in a material particular.

d. The applicant has a command of English sufficient for him/her to understand the terms and condition under which (s)he may hold a licence under the Animals (Scientific Procedures) Act 1986, which have been explained to him/her.

* If you are not the project licence holder please confirm under what capacity you are signing (for example, as Facility Manager or Senior NACWO)

** See Home Office personal guidance notes at www.gov.uk/research-and-testing-using-animals

PROJECT LICENCE HOLDER (confirmation of above and endorsement):

SIGNATURE: _____ DATE: _____

PRINT NAME: _____

POSITION: _____

ESTABLISHMENT LICENCE HOLDER (for submission to the Home Office):

SIGNATURE: _____ DATE: _____

PRINT NAME: _____

POSITION: _____

Appendix 5b

UNIVERSITY OF ABERDEEN

ETHICAL REVIEW COMMITTEE (ERC)

INTERNAL APPROVAL FORM

To: **Liza Young, University Office, Old Aberdeen**
cc: **Susan Barr, Anja Petrie Named Veterinary Surgeons**

From:

Date:
Subject: **Home Office Project Licence Application/Major Amendment Application:**

This form has been passed to you on behalf of the ERC, to request your approval for a Home Office project licence application (by signature at the bottom of the form). This form provides endorsement of the application by the Named Training and Competency Officer (NTCO), the Named Veterinary Surgeon (NVS), the Scientific Advisor (or Deputy) and the relevant Head of School.

This form must be completed and signed by all parties listed below and must accompany any new or amended project licence when it is submitted for ethical consideration by the ERC. Applications submitted to the ERC without this form will not be ethically reviewed.

Name of applicant:

Position:

PPL Title and Number:

Head of School (or nominated signatory): I can confirm that the applicant has the suitable education, training and experience to proceed with this application. The proposed research also aligns with the strategic research priorities of the School.

SIGNATURE:
POSITION: DATE:

Scientific Advisor (or Deputy): I can confirm that there is sufficient research space available and suitable facilities within an appropriate BSU facility for the proposed research outlined in this application to proceed.

SIGNATURE: DATE:

Named Training & Competency Officer: I can confirm that the applicant has undergone the appropriate modular training required for carrying out the proposed research (Modules E_1L,PILA, PILB, (+/-PILC), 9,10 and 11). I have seen copies of the training certificates; they are stored in the applicant's personal and/or training folder and will be maintained as long as this licence is held at this establishment (in accordance with Home Office Guidance (www.gov.uk/research-and-testing-using-animals). NOTE: *where there has been no evidence to confirm that the appropriate training has taken place, this form should not be signed and the application cannot proceed, unless exemptions apply; limited exemptions exist for researchers who held a project licence prior to the introduction of the training module system.*
Please provide comment if required:

SIGNATURE: DATE:

Named Veterinary Surgeon: I can confirm that the application has been completed to an appropriate standard to be considered by the ERC. This application should therefore be allowed to proceed.

SIGNATURE: DATE:

Appendix 6a

UNIVERSITY OF ABERDEEN

ETHICAL REVIEW PROCESS

FAST TRACK APPROVAL FORM FOR PROJECT LICENCE MINOR AMENDMENTS

TO NOTE:

A completed copy of this form with all relevant signatories must accompany any application for a minor amendment to a project licence, for subsequent approval via the fast-track process. This form is verification of approval of the amendment and confirmation that it can be classified as "minor" (as defined in the University Code of Practice for Research Involving the Use of Animals), and therefore that it meets all requisite criteria for fast-track approval. It is not necessary to submit an accompanying Internal Approval of New or Amended Project Licences (NVS Approval) form with this document.

An amendment is classified as minor by the Ethical Review Process, and therefore eligible for fast-track approval, when it meets the following criteria:

a. The amendment involves no additional procedures, or if so, only procedures which result in improved compliance with the 3Rs

b. The amendment involves no increase in total animal numbers

c. The amendment involves no increase in the severity of procedures used

d. The amendment involves no additional adverse effects

For further information on minor and major amendments to project licences and the fast-track approval process, please see the University Code of Practice for Research Involving the Use of Animals.

Please provide the following information and submit to the relevant University Named Veterinary Surgeon.

Name of Licence Holder: .....

Title of Licence: ..... …….

.....

.....

PPL Number:

		/					

Please provide a short lay summary in the box provided, of the proposed amendments to the Project Licence. This should not exceed one paragraph:

Do the proposed amendments involve an increase in the number of animals currently used?

If yes, please give details: .....

Do the proposed amendments involve allowance for carrying out additional regulated procedures as defined under the Animals (Scientific Procedures) Act 1986?

If yes, please give details: .....

Do the proposed amendments involve an increase in the severity of the procedures currently used? .....

If yes, please give details:

Applicant Signature: .....Date: .....

Amendment approved as minor, for fast-track, by NVS (signature): .....Date:.....

Amendment approved as minor, for fast-track, by NACWO (signature): .....Date: .....

Amendment approved as minor, for fast-track, by Scientific Advisor (or Deputy) (signature): .....Date: .....

The following section should be completed once NVS and Scientific Advisor (or Deputy) sign-off has been obtained.

Approved by Convenor of the
Ethical Review Committee:

....
Signature Date

The following section should be completed once all other signatures have been obtained.

Approved by Establishment
Licence Holder:

....
Signature Date

NOTE: the completed document should be sent to the relevant Head of School for information.

Appendix 6b

UNIVERSITY OF ABERDEEN

ETHICAL REVIEW BODY

In-Term Review of Project Licences – Proforma

1 Name of project licence holder					
2 PPL number					
3 Project title					
4 Project Lay-Summary: please provide a lay summary of the work undertaken to date. This should briefly cover the background, key objectives, and an outline of progress made to date in meeting those objectives.					
4 Where is the work carried out?					
5 In the table on the right, please provide the following information: **Row 1:** state which protocols regulated procedures have been carried out under. **Row 2:** state the species and type of animals actually used to date in your project **Rows 3 – 6:** state the number of animals used and the actual severity of these animals. **Example:** if you use 100 GA mice on Protocol 4 with 55 as mild severity and 45 as moderate, the information you would provide the following in each box: **B**ox 1 - Protocol 4; Box 2 - mice (GA); Box 4 – 0; Box 5: 55 mild; Box 6: 45 moderate; Box 6: 0	1. Protocol number i.e. 1, 2, 3, etc.				
	2. Species and type of animal (i.e. WT/GA, pregnant, aged).				
	3. No. of animals used of unclassified severity.				
	4. No. of animals used of mild severity.				
	5. No. of animals used of moderate severity.				
	6. Number of animals used of severe severity.				
6 Animal Numbers: if the number of animals has changed significantly, i.e. more than 10% from that anticipated in your original licence application (refer to Section E summary and protocol numbers of project licence) please state the variance and provide an explanation.					

7 Replacement: in what way(s) have you tried to find replacements for animal use in your research?	
8 Reduction: In what way(s), in terms of replacement and experimental design, have you tried to reduce the numbers of animals used? In which studies did you: a) Consult a statistician? b) Carry out randomisation/blinding? c) Carry out power calculations?	
9. Refinement: in what way(s) have you tried to refine experimental techniques used in your research?	
10 Adverse Effects: provide a summary of any unexpected adverse effects (condition 18 reports), including prevention methods.	
11 Excess Animals: (i) How many excess animals have been produced and why e.g. if you are only using one sex; (ii) What steps have been taken to reduce the number of excess animals?	
12 Harm/Benefit Analysis: provide a short paragraph outlining why you think the outcome of research has been justified in terms of harm / benefit.	

13 Publications: provide a list of research papers published to date as a result of the research undertaken on this licence. This should include papers submitted for publication, presentations and posters resulting from the project. Please confirm whether all papers were published in accordance with the ARRIVE guidelines.	
14 New Information on 3Rs: over the course of working on this project, has any new information, which would enhance implementation of the 3Rs, which may be applicable to future projects, been identified?	
15 Do you wish to add any further explanatory comments?	

Appendix 6c

UNIVERSITY OF ABERDEEN

ETHICAL REVIEW COMMITTEE

IN-TERM/RETROSPECTIVE REVIEW GUIDANCE

FOR RESEARCH INVOLVING THE USE OF ANIMALS UNDER THE ANIMALS (SCIENTIFIC PROCEDURES) ACT (AMENDED 2012)

Summary

This guidance note provides a summary of the University of Aberdeen In-Term Review process (noting this also applies to retrospective reviews). An In-Term Review is required for all project licences under which research involving the use of animals, in accordance with the Animals (Scientific Procedures) Act (Amended 2012) (ASPA), takes place at the University of Aberdeen. The In-Term Review process forms part of the institutional ethical review process, and is carried out by the institutional Ethical Review Committee (ERC)

University Ethical Review Process: In-Term Review - Overview

In accordance with ASPA, the University's ethical review process must carry out some form of retrospective reviews for all project licences. Retrospective reviews are described by the Home Office as reviews "looking back on the animal welfare costs encountered and benefits realised". The objectives of such reviews are; to determine whether the actual costs and benefits are in line with those anticipated; and identify, build on, enhance and promulgate good practice and improvements in the 3Rs during the course of a project (the **R**eplacement of animals in research with other experimental models; the **R**eduction in the number of animals used; and the **R**efinement of procedures that cause suffering).

Sources:

- The National Centre for the 3Rs: www.nc3rs.org.uk
- Understanding Animal Research: http://www.understandinganimalresearch.org.uk/how/three-rs/
- The European Union Reference Laboratory for Alternatives to Animal Testing (EURL ECVAM): https://eurl-ecvam.jrc.ec.europa.eu
- *The Go3R semantic search engine to avoid animal experiments: www.ncbi.nlm.nih.gov/pubmed/19326030*
- *The Norwegian Reference Centre for Lab Animal Science and Alternatives: www.oslovet.norecopa.no*
- ARRIVE Guidelines: http://www.nc3rs.org.uk/arrive-guidelines
- Prepare guidelines
- Named Information Officer

Objectives of the In-Term Review

1. To determine whether the actual costs and benefits of the research are in line with those anticipated; and
2. To provide reassurances on the implementation of the 3Rs, and identify, build on, enhance and promulgate good practice and improvements in the 3Rs during the course of a project.
3. The Panel will look to learn from the licence holder's experience to assist in the review of new applications and amendments of applications.

Format of the In-Term Review Meeting

The In-Term Review will be carried out by a panel comprised by members of the ERC.

The project licence holder must attend the meeting, but, in order to promote the educative role of the ethical review process, a maximum of two personal licence holders working under a project licence are, at the discretion of the project licence holder, invited to accompany the project licence holder to an in-term review meeting.

***At the Panel meeting licence holders will be required to*:**

- ***Complete the in-term review pro-forma*** (this includes a lay-summary section, addresses the 3Rs and looks at outcomes to date. This is to be submitted by a set deadline in advance of the meeting).
- ***Deliver a 10 – 15 minute PowerPoint presentation*** - the presentation should focus primarily on implementation of the 3Rs and should include at least one slide addressing this issue. It should also provide

a short overview of progress made on the project to date, highlighting whether the actual costs and benefits of the research are in line with those anticipated. Responses to unforeseen circumstances or adverse reactions to procedures should also be described. A final slide describing the potential impact of the research should also be included. Please remember this is presentation is to the AWERB, which comprises a number of lay-members, and not a scientific panel. A copy of the slides should be submitted along with the pro-forma to allow the panel to consider the content in advance.

- ***Engage with the panel in answering any questions*** it might have, in relation to the information provided in the completed proforma, or during the presentation.

The Panel meeting will not exceed 30 minutes.

Issues for discussion

An example of issues which may form part of the discussion with the panel are given below.

General

- how is compliance with the project licence monitored

Relating primarily to costs/benefits:

- is the existing animal model still the most appropriate for answering the scientific question;
- are the results as expected, if not why not;
- is the science on track, if not why not;
- have there been other scientific developments which need to be taken into account and that might augment or diminish the value of the project;
- how do the actual effects on the animals compare with the anticipated effects;
- is the balance of the harm versus benefit still the same

Relating primarily to the 3Rs:

- have there been any particular welfare problems with this animal model, and are alternative models available which would result in less suffering;
- the experimental design, including the opportunity for refinement of procedures, adjustment of numbers being used or amelioration of adverse effects e.g. changes to anaesthetic and analgesic regimes, surgical approaches, dosing routes or vehicles, humane endpoints;
- animal supply and transport;
- animal housing and care;
- records of adverse effects
- the well being of individual animals on long term studies;
- the eventual fate of the animals – euthanasia, re-use, rehoming;
- any wastage of animals and the reasons for this;
- standard operating procedures;
- are there any specific examples of the 3Rs incorporated into your research which may be shared with and of benefit to other research groups within the establishment?

Appendix 6d

UNIVERSITY OF ABERDEEN
RETROSPECTIVE ASSESSMENT (RA) OF PROGRAMME OF WORK (ASPA 5F)

To note:

If you are required to submit a retrospective assessment of your programme of work, you MUST include the information under the headings below.

Project Title:	
Purpose of Project Licence:	

Has the programme of work been carried out?
a. For each protocol, has any work been done?
b. Which objectives have been addressed in part or completely?

Have the objectives of the programme of work been achieved?
a. For each protocol that animals have been used, show that their use has been valuable, show what results have been achieved.

The amount of harm caused to animals by the carrying out of the programme of work (including the number of animals subjected to regulated procedures as part of the programme of work, the species of animals subjected to those procedures and the severity of those procedures)

Protocol number	**Number of animals (of each species) used**	**Severity classification of protocol**	**Actual severity reported for animals (number and severity)**	**Comments regarding harms**

Discuss any reason for harms in excess of those predicted, including non-procedural harms.
Discuss any differences between observed harms and those discussed in the project licence, including incidences, and potential reasons behind such differences.

Whether any lessons can be learnt from the programme of work which may contribute to the further implementation of the principles of replacement, reduction and refinement.

Consider whether there are any alternatives pre-existing or which have been developed since the last review/application which could replace some or all of the work.

Consider for each of the experiments or types of experiments performed whether the numbers used were correct/have been revised accordingly.

For each protocol describe any refinements you have been able to carry out AND any refinements which would be possible IF resources were available. List any resources you would like.

Appendix 7

UNIVERSITY OF ABERDEEN

ETHICAL REVIEW COMMITTEE

ANIMAL RESEARCH NOT COVERED BY ASPA (2012) – PROFORMA

To note: this proforma must be completed by anyone intending to carry out research or teaching using animals (animals as defined by ASPA: https://www.gov.uk/research-and-testing-using-animals), which is **not** governed by the legislation. This would apply to animal research which does not involve the use of regulated procedures, as defined by ASPA, and therefore, does not require Home Office licensing.

The proforma must be submitted to the University's Ethical Review Committee (ERC) for consideration before the research starts. It will be considered via circulation, and the applicant will not be required to attend an ERC meeting unless the application raises significant concerns. The proforma will help to ensure that the University is aware of all animal research undertaken at the institution. It will also enable the ERC to assess the likely cost/benefit balance, and whether the proposed research gives the required consideration to issues relating to animal welfare.

1. Provide a brief lay-summary of the proposed research. This should explain why it is necessary to use live animals, and whether replacements were considered.	
2. State the species and number of animals to be used in the research and the length of time for which they will be kept. Where more than one species is to be used, provide the proposed numbers and length of time they will be kept for each.	
3. Provide a short technical description of the proposed research, to include details on how the number of animals proposed for use was determined.	
4. Provide details on how the animals will be sourced (bought or captured).	
5. Provide details of husbandry conditions, and also details of what experience and training you/your group have in handling or working with the species involved.	

Appendix 8

Required signatures for internal approval forms:

	New PPL/ Major Amendment Internal Approval Form	Minor PPL amendment (fast track) Internal Approval Form	New PIL Internal Approval Form	PIL amendment Internal Approval Form
Establishment Licence Holder	*	✓	✓	✓
ERC Chair	*	✓		
Head of School	✓		✓	
Scientific Advisor/Deputy	✓	✓		
NVS	✓	✓		
NTCO	✓			
Project licence holder	*	✓	✓	✓

*E-mail confirmation after ERC meeting changes have been carried out.