

ANIMAL WELFARE AND ETHICAL REVIEW PROCESS

Rev	Date	Purpose of Issue/Description of Change	Equality Impact Assessment Undertaken
1.	March 2009	Initial Issue	
2.	August 2011	Amendment – Change of Chair, Change of Quorate requirements for ERC	
3.	9 th November 2015	Revision and approval by the University Ethics Committee	
4.	6 th June 2023	Review and re-approval by the Animal Welfare and Ethical Review Body	

Policy Officer	Senior Responsible Officer	Approved By	Date
Senior Research Governance and Policy Officer	Chief Operating Officer	Animal Welfare and Ethical Review Body	6 th June 2023

This Process will be updated in 3 years

Bangor University

Animals (Scientific Procedures) Act 1986 Animal Welfare and Ethical Review Process

A. Background

It has been a requirement set out as a standard condition since 1999 that each establishment designated under Section 6 or 7 of the Animals (Scientific Procedures) Act 1986 (“the Act”) has an Ethical Review Process. These requirements were updated by the Animals (Scientific Procedures) Act 1986 Amendment Regulations 2012 (SI 2012/3039) and the Guidance on the Operation of the Animals (Scientific Procedures) Act 1986 issued under the terms of section 21(1) of the Act.

B. Animal Welfare and Ethical Review Process

1. In the Animal Welfare and Ethical Review Process the Establishment Licence Holder should ensure as wide an involvement of establishment staff as possible in a local framework acting to ensure that all use of animals in the establishment, as regulated by the Act 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.
2. The process adopted by the University will be informed by, and meet the requirements identified in Appendix J.
3. The Animal Welfare and Ethical Review Body (AWERB)

The AWERB will have the following membership (as required in Schedule 3, Part 2, paragraph 6 of the Act)

Core Membership

The Named Veterinary Surgeon (NVS)

The Named Animal Care and Welfare Officer(s) (NACWO)

At least one or up to two Project Licence and / or Personal Licence Holders

The following individuals will also be invited:

The Establishment Licence Holder

A senior member of Animal Care Technical Staff

Up to 3 Co-opted members who do not hold a licence under the Act

A Lay member who has an interest in animal welfare and / or ethics

A member of the University Secretary's Office responsible for compliance with the Act and the associated guidance, policy and processes.

The Establishment Licence Holder (when present) will normally chair the AWERB, in their absence the Named Animal Care and Welfare Officer will take the chair. The Home Office Inspector shall also have the right to attend any meeting of the AWERB.

The AWERB shall be quorate if the core membership are present or have been included in any decision.

Any person who is co-opted shall serve as a member of the Committee for an initial term of three years and may be re-appointed to serve one further term of 3 years.

4. The membership of the AWERB includes those with defined responsibilities and obligations specified in the Premises Establishment Licence. The co-opted members will have an interest in animal welfare and / or ethics but they will not be engaged in work under the Act.
5. The work of the AWERB will be as set out in Schedule 3, Part 2, paragraph 6(3) of the Act namely:
 - a) advise staff dealing with animals in the licensed establishment on matters related to the welfare of the animals, in relation to their acquisition, accommodation, care and use;
 - b) advise on the application of the 3Rs, and keep it informed of relevant technical and scientific developments;
 - c) establish and review management and operational processes for monitoring, reporting and follow-up in relation to the welfare of animals housed or used in the licensed establishment;
 - d) follow the development and outcome (retrospective review) of projects carried out in the establishment, taking into account the effect on the animals used; and to identify and advise on elements that could further contribute to the 3Rs; and
 - e) advise on re-homing schemes, including the appropriate socialisation of the animals to be re-homed.

These aims will be achieved by the AWERB performing the three main functions of the animal welfare and ethical review process (as set out in sections 6 – 8 below).

6. Approval of Applications for Project Licences and Amendments

- 6.1 The AWERB will consider and approve all applications for project licences before they are signed by the Establishment Licence Holder and submitted to the Home Office.
- 6.2 Applicants must comply with all requirements of the Act along with all relevant University policies. Applicants must consult and seek advice from existing experienced project licence holders, the Named Animal Care and Welfare Officer and the Named Veterinary Surgeon before submission of their applications.
- 6.3 To prevent undue delay in the consideration of applications due to scheduling of meetings of the AWERB the Senior Research Governance and Policy Officer, having consulted with the Establishment Licence Holder and the NACWO, can call an extraordinary meeting of the AWERB. It is only in exceptional circumstances that decisions will be made electronically.

- 6.4 Applications may be signed by the Establishment Licence Holder once an AWERB has been held, or favourable responses have been received from members of the AWERB.
- 6.5 Among the criteria used by the AWERB to assess applications will be the following derived from the 3Rs:
- Is it clear that there are no valid alternatives to the use of animals in the work proposed?
 - Is the number of animals which it is proposed to use appropriate – i.e., large enough to produce a statistically valid result and not larger.
 - What is the balance between the cost to the animals involved and the likely benefits to be gained by the research?
 - Irrespective of the latter, are there ways in which the procedures could be refined to reduce the cost to animals without affecting the scientific validity of the project?
- 6.6 Project licence applications approved by correspondence will be reported to the next meeting of the AWERB.
- 6.7 Amendments to current project licences must be approved by the Establishment Licence Holder before submission to the Home Office. If, after consulting the NACWO, the NVS, an experienced project licence holder and / or an experienced personal licence holder, the Establishment Licence Holder is advised that the amendments are either trivial or advantageous to the animals then he/she shall have the authority to approve them and report them to the next AWERB meeting. If issues of substance are raised then all members of the AWERB shall be consulted by correspondence, and if necessary an extraordinary meeting of the AWERB will be called. All amendments approved by the Establishment Licence Holder shall be reported to the next AWERB meeting.
- 6.8 Applications for secondary availability of project licences in the University's designated premises shall be treated as new applications.
- 6.9 Amendments to project licence applications and alternations to them made by the Home Office shall be reported to the AWERB.
7. Facilities, Management and Staff: Advice, Support and Guidance
- 7.1 The designated animal facilities are located within the College of Environmental Science and Engineering. The Establishment Licence Holder has both duties and responsibilities under the Act and delegated management responsibilities for the provision of appropriate animal facilities and for the staff using them. The AWERB will be concerned to ensure that high standards of care and accommodation are practised in the animal facilities and that appropriate managerial systems are in place to ensure compliance with the Act. The Establishment Licence Holder will also be responsible for advising the University's Campus Services on requirements of maintenance and improvements to the facilities.
- 7.2 Members of the AWERB will be invited to visit the animal facilities on a regular basis.

- 7.3 The AWERB will receive annual information about project and personal licence holders, technical staff, and others concerned with animal care, including training and staff development undertaken. The AWERB will review this information and will advise on how all staff involved with the animals can be appropriately trained and how competence can be ensured. The AWERB will also ensure that suitable resources are in place to facilitate this.
- 7.4 The AWERB will offer advice on any ethical matter relating to the use of animals under the Act within the University, and will receive and respond to expressions of concern (in confidence if necessary). In particular members of staff considering undertaking work with animals of a controversial nature will be advised to contact the AWERB at an early stage.
- 7.5 The AWERB will consider in the light of its developing experience what steps it can take to advance best practice in the use of animals and to promote reduction, replacement and refinement alternatives in animal use.

8. Review of Current Projects

- 8.1 The AWERB will receive regular project summaries. At the review stages project licence holders will be required to submit a short-written report, covering *inter alia*:
- Progress to date; are the results as anticipated; are amendments necessary;
 - Any adverse effects of procedures and corrective action;
 - Information of number of animals used and scope for reduction in numbers and refinement of techniques.

9. Records and Dissemination of Information

- 9.1 The Establishment Licence Holder shall be responsible for the keeping of adequate records of the ethical review process, including minutes of meetings which shall be circulated to members and the Home Office Inspector.
- 9.2 Record keeping: Schedule 3, Part 2, paragraph 6(4) of the Act requires the Establishment Licence Holder to ensure a record is kept of any advice given by the AWERB and any decisions taken as a result. These records will be kept for five years and will be made available to an Inspector, or to the Secretary of State, on request.
- 9.3 The Establishment Licence Holder shall be responsible for the preparation of an annual report of the work of the AWERB. This will be submitted to the AWERB for approval and then to the University Ethics Committee who will include the information submitted in its annual report to Council.

The existence and purpose of the AWERB shall be made known within the University through appropriate means and the annual report shall not be unreasonably withheld from any member of the University seeking information. Submissions relating to the work of the AWERB and to the operation of the Act from other University Committees, individual members of the University, or organisations and individuals external to the University may be made via the Senior Research Governance and Policy Officer and shall be considered by the AWERB.

- 9.4 The AWERB will also receive regular information on ethical review, the 3Rs, best practice in animal welfare and other relevant matters distributed by the Home Office, the National Centre for the Replacement, refinement and Reduction of Animals in Research and any other animal welfare and relevant organisations.
- 9.5 The NACWO shall be responsible, on behalf of the Establishment Licence Holder, for maintaining a central register of all persons within the University trained and authorised to carry out Schedule 1 procedures.
10. Reporting Issues
- 10.1 Any issues or breaches in relation to this Process should be reported immediately to the Chief Operating Officer (Establishment Licence Holder).
- 10.2 It is important to report any issues or breaches as quickly as possible so as to minimise any potential distress to either animals or to individuals, and to minimise the potential damage to the University (including reputational).
- 10.3 Under no circumstances should any person attempt to conceal a breach. Such a breach could lead to disciplinary action and the Home Office may also wish to take action.
- 10.4 The University also has a Whistle Blowing Policy. This allows individuals who have concerns over another person's actions to raise such concerns in a structured and constructive manner.

*Approved by the University Council 27th March 2009. Version 1
Updated and Approved by the Ethical Review Committee August 2011
Approved by the University Ethics Committee 9th November 2015
Updated and Approved by the Animal Welfare and Ethical Review Body January 2023
Approved by the Research Governance and Ethics Committee March 2023
Updated and Approved by the Animal Welfare and Ethical Review Body June 2023*

Excerpt from***Guidance on the Operation of the Animals (Scientific Procedures) Act 1986*****10. Animal Welfare and Ethical Review bodies (AWERBs)**

Animal Welfare and Ethical Review Bodies (AWERBs) should, in most respects, continue and develop the work of the local Ethical Review Processes (ERPs) they replaced on 1 January 2013. For further information, see the joint RSPCA/LASA report “Guiding principles on good practice for Ethical Review Processes” (2010) [<http://www.rspca.org.uk/laymembers>]

10.1 The requirement

Under Article 26 of the Directive we, the Home Office, must ensure that each breeding, supplying and user establishment sets up an animal welfare body. Article 26 also stipulates the minimum membership of the animal welfare body and Article 27 sets out its minimum tasks.

These requirements are implemented by ASPA Schedule 2C and Schedule 3.

ASPA Schedule 2C, Part 1, paragraph 6, stipulates that a section 2C establishment licence must include a condition requiring the holder to establish and maintain an ‘Animal Welfare and Ethical Review Body’. ASPA Schedule 3, Part 2, paragraph 6, sets out the relevant standard condition, including membership requirements.

10.2 Minimum membership

ASPA Schedule 3, Part 2, paragraph 6 specifies that the AWERB must have, as full members, at least one of your establishment’s Named Animal Care and Welfare Officers (NACWO) and at least one of your Named Veterinary Surgeons (NVS). If yours is a user establishment, your AWERB must also include a scientific member. Under ASPA Schedule 3, Part 2, paragraph 6(2)(b), the required credentials for this member must be acceptable to the Secretary of State. In general, we are likely to accept a nomination of an individual who is actively engaged in science using animals and who is willing to commit time to the work of the AWERB. You should also ensure that your other named persons, including NIOs and NTCOs, are actively engaged with the AWERB given the breadth of its tasks (see Section 10.4).

10.3 Additional members

Under ASPA Schedule 3, Part 2, paragraph 6(2)(c), it is also open to the Secretary of State to specify, through this Guidance, requirements for other people to be members of the AWERB. Accordingly, in order to help ensure the integrity of the process, we expect establishment licence holders to arrange for their AWERBs to actively seek a wider membership taking into account, in a transparent manner, the views of people who do not have responsibilities under ASPA, as well as one or more persons who are independent of the establishment. Inspectors may also attend meetings of the AWERB from time to time as part of their responsibilities for monitoring compliance with the legislation.

10.4 Minimum tasks of the AWERB

ASPA Schedule 3, Part 2, paragraph 6(3) stipulates that the AWERB must carry out the tasks set out in Article 27 of the Directive. These are to:

- (a) advise staff dealing with animals in the licensed establishment on matters related to the welfare of the animals, in relation to their acquisition, accommodation, care and use;
- (b) advise on the application of the 3Rs (see Section 2), and keep it informed of relevant technical and scientific developments;
- (c) establish and review management and operational processes for monitoring, reporting and follow-up in relation to the welfare of animals housed or used in the licensed establishment;
- (d) follow the development and outcome (retrospective review) of projects carried out in the establishment, taking into account the effect on the animals used; and to identify and advise on elements that could further contribute to the 3Rs; and
- (e) advise on re-homing schemes, including the appropriate socialisation of the animals to be re-homed.

10.5 Additional tasks

ASPA Schedule 3, Part 2, paragraph 6(3) also provides for AWERBs to be allocated other advisory and reviewing tasks, either through the relevant establishment licence or in guidance issued by the Secretary of State.

Accordingly, AWERBs should also:

- advise the establishment licence holder whether to support project proposals, primarily considering such proposals from a local perspective and bringing local knowledge and local expertise to bear;
- assist with the retrospective assessment of relevant projects carried out at their establishment (see Section 5.17); and
- respond to enquiries, and consider advice received, from the Animals in Science Committee (see Section 13).

More generally, AWERBs should:

- promote awareness of animal welfare and the 3Rs;
- provide a forum for discussion and development of ethical advice to the establishment licence holder on all matters related to animal welfare, care and use at their establishment;

- support named persons, and other staff dealing with animals, on animal welfare, ethical issues and provision of appropriate training;
- help to promote a 'culture of care' within the establishment and, as appropriate, in the wider community.

Whilst protecting confidentiality, it may be appropriate to share some of the outputs from the AWERB with colleagues in the establishment, and the wider community, to promote awareness of the AWERB's activities.

10.6 Record keeping

ASPA Schedule 3, Part 2, paragraph 6(4) requires the establishment licence holder to ensure a record is kept of any advice given by the AWERB and any decisions taken as a result. These records must be kept for at least three years and must be made available to an inspector, or to the Secretary of State, on request.

Home Office
March 2014