Animal Welfare and Ethical Review Body (AWERB)

Terms of Reference

1. Overview

The Terms of Reference outline the requirements of AWERB as described in the Animals (Scientific Procedures) Act 1986 (ASPA) Amendment Regulations 2012 ('the Act')[1], Guidance on the Operation of ASPA[2] and the Guiding Principles on Good Practice for Animal Welfare and Ethical Review Bodies by the RSPCA and LASA[3].

2. Membership

Secretarial support for AWERB will be from the Research Governance, Ethics and Integrity team.

The membership of AWERB includes the following:

- A Chair
- A Deputy Chair
- The Named Veterinary Surgeon (NVS), or deputy
- The Named Animal Care and Welfare Officer(s) (NACWO)
- The Named Training and Competency Officer(s) (NTCO)
- The Named Information Officer(s) (NIO)
- BSF 3Rs Manager/subgroup chair
- Current or past licence holders (expected to attend 50% of meetings)
- Director of the Biological Sciences Facility and Establishment Licence Holder's delegate
- Academic Lead of the Biological Sciences Facility (BSF)
- Lay members (expected to attend 50% of meetings)
- An expert statistician

By invitation:

- The Establishment Licence Holder
- Home Office Inspectors – HOI can attend the AWERB at their discretion without formal invitation and are not members of it, but observers.

A quorum shall be 50% members which must include the Chair (or deputy), NVS (or deputy), a NACWO, a Project Licence holder (or deputy) and a lay member.

[1] Animals (Scientific Procedures) Act 1986 Amendment Regulations 2012, https://www.gov.uk/guidance/research-and-testing-using-animals

[2] https://www.gov.uk/guidance/guidance-on-the-operation-of-the-animals-scientific-procedures-act-1986

[3] RSPCA and LASA, 2015, Guiding Principles on Good Practice for Animal Welfare and Ethical Review Bodies. A report by the RSPCA Research Animals Department and LASA Education, Training and Ethics Section. (M. Jennings ed.)

The Establishment Licence Holder is responsible under ASPA Schedule 2C and Schedule 3 for the establishment and maintenance of an AWERB. The Establishment Licence Holder, or designate, will appoint people to implement its procedures, ensuring wide involvement of establishment staff and including laypersons. Training/Continued Professional Development will be provided for members of the AWERB appropriate to their role and active consideration will be given by the Establishment Licence Holder, or designate, to succession planning to ensure the continued long-term efficiency and effectiveness of the AWERB.

3. Objectives

The AWERB is a committee with accountability for leading and driving the local activities. It addresses welfare, 3R's and facilities, communication and engagement strategy, reporting & measurement, plus risk management & security issues. With regard to its role as the strategic and management committee for ethical review it reports to the Establishment Licence Holder or delegate (Chair) and acts as a focal point for the development of a culture of "good science, animal welfare and legislative compliance". It meets regularly to provide a forum for discussion of issues relating to the use of animals and to consider how staff can be kept up to date with relevant ethical advice, best practice, and relevant legislation.

4. Tasks of AWERB

The minimum tasks of the AWERB or any of its subgroups are to:

1. uphold the principles set out in the University's 'Policy for the Ethical Conduct of Research Involving Animals'.
2. 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;
3. advise on the application of the 3Rs, and keep the AWERB informed of relevant technical and scientific developments;
4. 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;
5. 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
6. advise on re-homing schemes, including the appropriate socialisation of the animals to be re-homed.

In addition, AWERBs have the following advisory and reviewing tasks to:

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

5. Concordat on Openness in Animal Research

The Concordat on Openness in Animal Research was signed by Higher Education Institutions, including the University, bio-industry companies, charities and research councils in 2014. It pledges transparency and public engagement. As a response to the Concordat, the University published an award winning website, which contains case studies, governance information, and facts and figures - in infographic form - designed to inform readers, while emphasising the culture of care among staff working with animals. It also contains all project license non-technical summaries, anonymised minutes of AWERB meetings and a much-praised virtual tour of the unit. There has also been substantial media activity on our research which involves animals. The unit is also very active in terms of engagement activity. It welcomes regular tours for year 11

and year 12 school students, facilitates presentations to University staff, and hosts local political representatives, undergraduate students, patients and non-scientific university staff.

6. Operational processes

Further information on how AWERB operates including the delegation of some tasks to the 3Rs subgroup can be found in the Appendix – 'Operational Processes'

6.1. Work falling under the Act

The University's 'Policy for the Ethical Conduct of Research Involving Animals' covers four categories of research involving animals. Category A applications are those that involve the use of living vertebrates and cephalopods in scientific procedures within the University and the UK which are regulated by the Animals (Scientific Procedures) Act 1986. Research that falls into Category A requires full ethical approval by the University's AWERB.

The AWERB will conduct ethical review of each Project Licence application, including amendments, and conduct reviews during the lifetime of Project Licences and retrospectively via the 3Rs subgroup for AWERB which reports formally to the main AWERB on a quarterly basis. In carrying out this ethical review, the AWERB believe that the responsible use of animals is necessary and justified in the pursuit of scientific knowledge and the betterment of human (and animal) health and welfare. However, such use can only be justified where an appropriate balance is agreed to exist between the likelihood of scientific and medical benefits, the quality of the research and the potential suffering to animals.

In carrying out these reviews:

The AWERB and subgroups may consider the ethical impact to animals of:

- breeding, rearing and transport;
- maintenance in a laboratory environment;
- euthanasia;
- causing distress and pain - whether through breeding, rearing, maintenance or research;

And will take into consideration likely scientific and medical benefit in terms of:

- increasing health and welfare of humans and animals;
- increasing scientific knowledge, particularly in terms of originality, timeliness, effect on understanding;
- education and training;
- conservation of natural resources or decreasing of impact of humans on the environment.

In addition, the AWERB shall assure itself regarding:

- the availability of valid alternatives (3Rs);
- the numbers, type and source of supply of animals;
- the appropriateness and quality of the facilities;
- the education, training and competence of the Project Licence holder, Personal licensees and animal care staff;
- progress with, and required continued application of, the 3Rs to all projects, throughout their duration.

It is expected that the learnings from these reviews will be distributed widely and that this will contribute to improved practice both in science and welfare.

- the use of "best practice" in all areas of the work.

- whether the proposals are likely to comply with ASPA and other national or local legislation, regulations or policies;
- the appropriateness of methods of detection and control of pain, suffering and distress;
- the attitudes of the scientific community, both internally and externally
- the attitudes of the whole community both within the establishment and externally.

It is expected that a pre-AWERB team including the Project Licence Holder, NTCO, NIO, NVS, NACWO and others as required will have an active role in the drafting of any Project Licence or major amendment prior to submission for AWERB review.

AWERB will also regularly review and endorse all practices affecting animal welfare, including experimental and non-experimental procedures e.g. euthanasia, anaesthesia and humane endpoints.

6.2. Work outside the Act

The University's 'Policy for the Ethical Conduct of Research Involving Animals' includes 3 categories for research involving animals that do not fall under the definitions of ASPA however require full ethical approval by AWERB if deemed necessary by the executive committee (Category B) or appropriate and proportionate ethical review by the University (Category C and Category D).

7. Reporting

Minutes of AWERB meetings shall be recorded formally by the Secretary and retained for the period outlined in the Records Retention Schedule.

8. References:

Act 1986, Guide for the Care and Use of Laboratory Animals, 8th edition, Directive 2010/63/EU

9. Review of the ToR

These Terms of Reference will be reviewed in March 2020 and annually thereafter. Minor amendments to the Terms of Reference may be made by the Secretariat or AWERB members when required.

9.1. Revision History:

Version	Date Revised	Revised By	Reason for Revision
2.0	11/02/2019	Mary Birch Graham Morrissey	Update required following appointment of new Chair
2.1	1/11/2019	Karen Lythe	Minor revisions to those made for version 2.0
2.2	19/03/2021	Karen Lythe	Updated to include subgroups of AWERB
2.3	16/05/2022	Karen Lythe	Updated to include expectation of membership attendance.
2.4	12/10/2022	Karen Lythe	Updated with minor revisions regarding the PELh's responsibilities and attendance of HOI at meetings.
2.5	April 2024	Karen Lythe	Minor revision to include appendix and review of existing information.

Appendix – Operational Processes

Animal Welfare and Ethical Review Body (AWERB)

Operational Processes

1. Overview

This document should be read in conjunction with the Terms of Reference for AWERB, the BSF pre-AWERB Terms of Reference and the 3Rs subgroup for AWERB Terms of Reference.

2. Storage of documentation

All documentation relating to AWERB will be stored on SharePoint. The Secretary for AWERB will ensure that the most recent versions of all documents are on SharePoint.

3. Meetings

Meetings will be held approximately every 4 weeks.

Meetings will be scheduled for 2 hours where possible. AWERB members should hold 2.5 hours in their diaries in case the meeting runs over.

Membership and attendance at meetings are covered in the Terms of Reference for AWERB.

Regular 'away days' are held where regular discussions take place on 3Rs topics such as cryopreservation, replacement models or improvements to animal welfare. Minutes are taken and actions followed up and reported on at the following main AWERB meeting.

4. Circulating papers for meetings

Papers for the meeting will be provided to the AWERB Secretary by the BSF administration 11 working days before the meeting.

The AWERB Secretary will upload the papers onto SharePoint 10 working days before the meeting. Members will be emailed with the link to the papers and an agenda.

5. AWERB member comments on applications

All AWERB members should enter comments on the applications to the Excel template on SharePoint. AWERB members should enter comments by 48 hours before the meeting (e.g. by the end of Tuesday for a meeting on a Thursday). The day before the meeting the Secretary will collate the comments and circulate these to the members.

6. Review of Project Licence applications

Submissions for new Project Licences will be considered by the full committee and discussed at a formal meeting. The applicant, or a suitable delegate with an in-depth knowledge of the proposed work, will be required to attend the meeting to address issues arising from the review.

The AWERB Secretary will invite applicants to attend the AWERB meeting. Applicants will be given a 30-minute slot on the agenda. The application will be discussed by AWERB members prior to the applicant being invited into the room. After the applicant gives their presentation AWERB members may ask questions.

The applicant will be asked to present their work in 15 minutes with 6 slides to cover the following:

- Brief Background
- Aims of the PPL
- How you are going to demonstrate the application of the 3R's
- What will happen to an animal in a typical experiment
- Adverse effects and how these will be controlled, and humane end points
- A slide to summarise the various changes that you have made to your application after the pre-AWERB meeting. The committee members can then review the submitted draft to confirm that those changes have been enacted appropriately.

If you Project Licence contains any severe protocols we ask that you include a 7th slide to cover the following:

- Please consider a hypothetical situation where permission for severe suffering is denied, and explain how your ability to achieve your objectives would be affected in such a scenario.

Following the meeting the AWERB Secretary will provide feedback to the applicant to summarise any items discussed at the meeting and highlight any points requiring revision in the documentation. Revisions will be checked by the NTCO on behalf of AWERB. Once the revisions have all been accepted, the Establishment Licence Holder (or Delegate) will confirm that each Project Licence application has completed the establishment's local AWERB review and approval process by signing the AWERB application form.

Current Project Licence holders will be contacted by the AWERB Secretary 12 months before the end date of the licence. The process for applicants will be the same as that covered in point 6, however applicants will also be asked to detail any refinements made on the current licence in their first slide.

Applicants for Project Licences (both those seeking a renewal or new Project Licence holders) will be asked to begin preparation for their Project Licence submission to the Home Office 12 months before it is needed to be in place.

Applicants will be required to attend a meeting with the Named Persons before they attend an AWERB meeting. At the initial meeting with the Named Persons, they will be allocated to an AWERB meeting and various milestones and meetings will be agreed so that the project licence is submitted in a timely manner. Applicants will be told that if they do not adhere to the requirements and timelines set out by AWERB and the BSF staff then their application may not be considered at the meeting initially allocated to them and this could mean delays in the researcher receiving their Home Office Licence.

Recommendations made by the Named Persons should be made prior to circulation of the application to a full AWERB committee. If the Named Persons are not satisfied that all the recommendations have been

taken on board the applicant will be informed that the application cannot proceed for full review until it has been revised.

7. Review of Amendments

Amendments to Project Licences will be classified as either 'major' or 'minor'. The NVS (or suitable deputy) will decide the most appropriate category for an amendment.

If a project licence for which an amendment is being sought contains any severe protocols or the amendment will lead to a change of a protocol severity rating the amendment will be classed an 'major'.

'Major' amendments may also include proposals to start any new work that is of ethical concern, or significant increase in numbers, or significant increase in harm or for a significant change in the purpose of any such work.

Examples of types of work that may be considered of ethical concern include:

1. Procedures in the "severe" category.
2. Procedures in the "moderate" category that, in the opinion of the NVS (or deputy), require further ethical review.
3. Procedures where a favourable cost/benefit ratio is not immediately clear.

'Minor' amendments will not require a formal meeting of the committee but will be considered under an administrative review.

Examples of amendments that may be suitable for administrative review include:

1. Editorial changes.
2. Reduced burden/improved welfare for animals.
3. Improvement in the cost/benefit ratio.
4. The addition of a standard dosing route to a procedure.
5. The duplication of a procedure in another licence for a related purpose.

7.1. 'Major' amendments

Major amendments will be considered by the full committee and discussed at a formal meeting. The applicant, or a suitable delegate with an in-depth knowledge of the proposed work, will be required to attend the meeting to address issues arising from the review.

The AWERB Secretary will invite applicants to attend the AWERB meeting. Applicants will be given a 15-minute slot on the agenda. The application will be discussed by AWERB members prior to the applicant being invited into the room. After the applicant gives their presentation AWERB members may ask questions.

The applicant will be asked to present why they are seeking an amendment in 5 minutes with 1 slide to cover the following:

- Why are you wanting to do the amendment
- Scientific justification
- What will happen to the animals
- Adverse effects and how these will be controlled and

- Humane end points

AWERB members will be provided with the original approved Project Licence Application for 'major' amendments so that the amendment can be considered in the context of the whole project.

7.2. 'Minor' amendments

If a project licence does not fall into the criteria for it being assessed by the full AWERB committee, it will be considered via administrative review. To meet quorum, amendments via the administrative review system will be reviewed be a NACWO, an NTCO, an NVS, the Chair of AWERB or Deputy Chair, a Personal Licence Holder (PIL), and a Project Licence Holder (PPL). The administrative review committee will be made up of more people than required for quorum to allow for absences and so that the PIL and PPL chosen to review the amendment have relevant knowledge/experience in the project licence. Amendments will be uploaded to SharePoint and the BSF Administrator will email the relevant administrative review members for that amendment to let them know an amendment requires their review. Comments should be made within 5 working days. The NTCO will collate the comments and inform the applicant of the outcome.

A summary of all administrative reviews will be reported, for ratification, to the AWERB at the next formal meeting. The paperwork will be provided to members by the Secretary and the Chair will ask if AWERB members have any questions regarding the list of licences processed since the last meeting. If there are no questions then the NVS will not verbally go through the amendments approved via administrative review.

8. Review of Additional Availability for Project Licences held at other institutions

If applications for Additional Availability are submitted which contain Severe protocols the applicant will be invited to attend an AWERB meeting, and the full committee will review the application.

Applications for Additional Availability that contain mild/moderate procedures will be considered by under administrative review.

9. Mid-term and Retrospective review of Project Licences

Retrospective review of projects carried out in the establishment is a minimum task of an AWERB.

All Project Licences will undergo both mid-term and retrospective review, even if the Home Office has not stipulated a review be carried out during the period of a licence. The relevant form will be sent to the Project Licence Holder by the AWERB Secretary. Completed forms will be submitted to the AWERB Secretary.

The 3Rs subgroup will review all licences apart from those that have a 'severe' protocol on the licence or those that require a retrospective assessment to be carried out as stipulated by ASRU. The licences with a 'severe' protocol or those that require a retrospective assessment will come to the main AWERB for review.

Project Licence holders will be given a 15-minute slot on the agenda and asked to give a 5-minute presentation. The review form will be discussed by AWERB members prior to the licence holder being invited into the room. After the licence holder gives their presentation AWERB members may ask questions.

10. Retrospective Assessment of Project Licences

An additional task of an AWERB is to assist with the retrospective assessment of relevant projects carried out at their establishment. The Guidance on the Operation of ASPA states that "all projects involving procedures classified as severe, must be assessed retrospectively, however other projects may be selected on a case-by-case basis to undergo retrospective assessment".

Project Licence holders required by the Home Office to do a retrospective assessment will be contacted by the AWERB Secretary and invited to attend a main AWERB meeting. The 3Rs group will **not** carry out retrospective assessments. The relevant form will be sent to the Project Licence Holder by the AWERB Secretary. Completed forms will be submitted to the AWERB Secretary.

Project Licence holders will be given a 30-minute slot on the agenda and asked to give a 15-minute presentation. The retrospective assessment form will be discussed by AWERB members prior to the licence holder being invited into the room. After the licence holder gives their presentation AWERB members may ask questions.

The licence holder will be asked to present:

- What the objective were, and if to date what have they met or partially met?
- What has not worked and how has this informed your future experiments?
- Those animals that went to severe, have any refinements been enacted to reduce the chance of them happening again?
- How have you enacted any 3Rs related elements; refining your protocols, reducing/refining your groups sizes, any replacement strategies enacted?
- What achievements there have been including publications?

11. Review of work classified at Cat B, Cat C or Cat D

Submissions for Category B work will be reviewed by the administrative committee (i.e. Named Persons) unless the Named Persons believe that the work requires review by the full AWERB committee. AWERB will be notified for information only of any work submitted in this category.

Submissions falling under Category C will be processed by the BSF staff and Named Persons. AWERB will be notified for information only of any work submitted in this category.

Submissions falling under Category D should be made to the AWERB Secretary who will process the application in accordance with the Terms of Reference for the Committee for the ethical review of Category D Research.

12. Review of the Biological Services Facility animal care and use program

Program review and facilities inspections should occur at least annually or more often as required (e.g., by the Animal Welfare Act and PHS Policy). After review and inspection, a written report (including any minority views) should be provided to the Establishment License Holder and Delegate about the status of the Program.

13. Publishing of redacted AWERB minutes on the external facing website

Once the minutes have been approved at a subsequent meeting the Secretary will upload these onto SharePoint.

A redacted version of the minutes will be created, removing all personally identifiable details. The redacted minutes will be published on the external facing website:
https://www.manchester.ac.uk/research/environment/governance/ethics/animals/

14. Publishing of Non-Technical Summaries on the external facing website

Once a Project Licence has been granted the related Non-Technical Summary (NTS) will be uploaded to the external facing website:
https://www.manchester.ac.uk/research/environment/governance/ethics/animals/research/

15. Revision History:

Version	Date Revised	Revised By	Reason for Revision
2.1	12/04/2021	Karen Lythe	Updated to include changes to the process for mid-term and end-of-licence reviews, and retrospective assessments.
2.2	25/11/2021	Karen Lythe	Inclusion of information relating to Cat B, Cat C and Cat D applications.
2.3	05/04/2022	Karen Lythe	Information for Retrospective Assessments updated to reflect longer slot on the agenda and longer time for presentation.
2.4	16/05/2022	Karen Lythe	Update to meeting frequency and number of meetings members need to attend.
2.5	April 2024	Karen Lythe	Minor revisions and review of information.