Animal Welfare and Ethical Review Body (AWERB)

Annual Report 2023-24

1. Overview

The Department of Health (DOH) requires that each designated establishment maintains a viable ethical review process, which is open to continued assessment by the local inspector. The satisfactory operation of the ethical review process is a standard condition of the establishment licence held by QUB under the Animals (Scientific Procedures) Act (ASPA) 1986 (and subsequent amendments).

2. Animal Welfare and Ethical Review Body (AWERB)

2.1 The primary function of the AWERB is to review project licence applications, amendment requests and mid-term and final reports, and to discuss issues directly relevant to animal welfare and ethics. The specific role of the AWERB is outlined in Appendix 1. The AWERB is comprised of representatives from all relevant research areas, including Medicine, Dentistry & Biomedical Sciences, Biological Sciences, Nursing & Midwifery and Pharmacy. This ensures wide involvement of staff within the establishment, as recommended by the DOH.

2.2 At the end of the reporting period (31st August 2024), the committee composition was as follows:

i. Academic Staff: Four representatives from relevant research areas, who are typically current project licence holders. This includes a Chair who is appointed by the QUB NCO.

ii. Post-doctoral Staff: One postdoctoral contract researcher who is currently working within the above research areas and routinely involved with animal research.

iii. Postgraduate Students: One PhD student who was working within the above research areas and routinely involved with animal research.

iv. BSU Staff: The Biological Services Unit (BSU) manager and one deputy as Named Animal Care and Welfare Officers (NACWO). One BSU technician also served from October 2023 to April 2024.

v. BSU Director: Academic lead of the QUB animal facility.

vi. QUB Named Training and Competency Officer (NTCO): Two Academic leads for personal licensee management and training.

vii. QUB Named Information Officer: Point of contact for all PIL, PPL enquiries and main contact for DoH

viii. External Lay Representative: Our longstanding Lay member has commitments elsewhere which has prohibited regular meeting attendance. Two additional non-QUB lay members were recruited and appointed in conjunction with Research Governance. They have been in post since October 2023.

viii. Named Veterinary Surgeon (NVS): Two independent veterinary surgeons appointed by the NCO.

ix. DOH Inspector: Invited to be in attendance at all AWERB meetings.

Following approval for amendment to ToR from RGEIC in 2024, the committee was expanded to include:

x. QUB Technician: one representative of technical staff who holds a PIL and is involved in animal research

xi. Co-opted member: currently a QUB research assistant who holds a PIL and is involved in animal research

2.3 During the reporting period six AWERB meetings were held (18th October 2023, 13th December 2023, 21st February 2024, 17th April 2024, 19th June 2024, 21st August 2024) at which 11-19 members were present, thus satisfying the quorum of six attending members set by the terms of reference. In addition, Strategic AWERB meetings are held to deal with additional responsibilities of AWERB. They do not deal with applications or reports. Four strategic AWERB meetings were held within the reporting period (20th September 2023, 15th November 2023, 20th March 2024, 15th May 2024). Detailed minutes of discussions and decisions are prepared and are made available for review by the DOH inspector as requested.

3. Project Licences

3.1 A project licence provides authorisation from the DOH for a defined programme of work and is typically valid for 5 years. At the end of the reporting period, there were 36 project licences issued to QUB, held by 32 different staff members, which is a little lower than previous years but in line with recent trends (c.f. 40 PPLs from 35 staff members in 2021-22).

3.2 At QUB, the processes involved in project licence applications include early conversations with NVS (compulsory) and AWERB Chair, NTCO, NIO and DOH inspector (as required), AWERB reviews the application and amendments are reviewed and approved by AWERB Chair (and NVS if required) before submission to DOH.

3.3 The process for project licence application is outlined in a Standard Operating Procedure. The applicant (or appropriate designate) is required to attend the AWERB meeting at which their application is considered so that they may discuss any issues or concerns directly with the committee. They are required to satisfy the AWERB that the proposed research is fully justified in relation to realistic outcomes of the project balanced against animal use. Typically, revisions are requested by the committee and final ethical approval is only granted by the Chair upon their satisfactory completion.

3.4 During the reporting period, the AWERB approved 5 project licence applications.

3.5 A project licence provides authorisation only for a specified programme of work as defined in the original application and is normally approved for a period of 5 years. If, subsequent to issue, the project licence holder decides that they would like to modify an experimental protocol or make any other change to the licence, no matter how small, they are required to apply to the AWERB for ethical approval.

3.6 The application process is similar to that for project licence applications, with advice generally sought from and/or offered by the Chair, DOH Inspector, NVS and NACWO, prior to ethical review by AWERB.

3.7 During the reporting period, 22 project licence amendment applications were reviewed and approved. These ranged in complexity from changes in PPL holders or deputies to addition of new protocols. Minor amendments were reviewed and approved by AWERB Chair and noted at following AWERB meeting. Major amendments were reviewed by the committee prior to final review/approval by AWERB Chair.

3.8 Mid-term reviews of all active project licences are undertaken by the AWERB at two and a half years, in which the project licence holder is required to report on:

i. project progression, including details of animal usage (licensed and Schedule 1), retrospective severity, and research outputs

ii. project management, including details of meetings with the NACWO, BSU staff and NVS

iii. project refinement, including plans for reducing animal use or improving animal welfare, and details of any observed adverse effects

iv. future plans, estimating animal usage and detailing available funds for completion of the work

3.9 The mid-term review process also involves a mandatory meeting with the NVS to discuss project progression and refinement. Only when the AWERB is satisfied that acceptable progress has been achieved, the conditions of the licence have been adhered to, and that appropriate future plans have been put in place (including funding), is ethical approval granted for project continuation. During the reporting period, 8 mid-term reviews were undertaken, all of which were approved for continuation.

4. Final Reports

4.1 In order to maintain appropriate oversight of animal research conducted under QUB project licences and to assess the balance of outputs/outcomes against animal use, the AWERB routinely review and approve all final reports before they are submitted to the DOH. Upon expiry of their project licence, holders are required to report on the same categories as detailed above in relation to mid-term review. The DOH requires a retrospective assessment of relevant projects (typically those including one or more severe protocols) which involves submission of a lay summary to be published on the Home Office website alongside the original non-technical summary approved at the start of the project. Retrospective assessments were reviewed and approved by the AWERB in parallel with project licence final reports. All final reports and retrospective assessments are considered in advance of project licence expiry and typically in parallel with the relevant renewal application.

4.2 During the reporting period, the AWERB reviewed and approved 9 final reports, 3 of which included retrospective assessment and one of which was surrendered early due to end of employment:

5. Additional Conditions

The DoH Inspector may impose additional conditions on individual PPLs such as annual reports of use of specific protocols. Currently, five PPLs have additional conditions. Usually, AWERB has no requirement to be involved in this process, however, these additional conditions are becoming more frequent and two of the current five PPLs with additional conditions require AWERB/ethical review of every new study under the licence. In addition, one PPL held by a QUB spinout also requires AWERB review of every new study (13 studies reviewed and approved in the reporting period).

6. Use of Schedule 1

In 2021/22, AWERB acquired the function of reviewing applications for use of animals/animal tissue for educational purposes. In 2022/23 this was extended to requests for schedule 1 of animals for research projects not otherwise covered by a PPL. During the reporting period, AWERB reviewed 1 application for use of animals for research purposes. AWERB approved the request with the condition that only

surplus animals could be used. No animals would be permitted to be used solely for the purpose of this research.

7. The 3 R's

7.1 Part of the ToR of AWERB is to promote the 3R's (replacement, reduction and refinement). Early in 2023, a small working group consisting of AWERB and non-AWERB members of the animal research community at QUB undertook a self-assessment of the Institutions' commitment to 3Rs. From this an action plan was developed which underwent a period of consultation and feedback by the QUB animal research community at the Annual Culture of Care Day in 2024. A number of actions are underway or have been completed:

a. our seminar series is now held in person
b. a policy to rehome some animals is in the final stages of development
c. a tissue sharing board has been established
d. the use of experimental design tools and reporting standard frameworks are promoted through training, MS Teams posts and in review of PPL at all stages (application, midterm review, final reports)
e. An annual 3Rs prize is awarded at the Culture of Care Day

7.2 3Rs is now a standing item at all strategic AWERB meetings. In the reporting period items discussed in this section included the continued use of intraperitoneal injection as a delivery route, the potential of delivering radiation under sedation rather than anaesthesia and a task and finish group developed and agreed a method of standardising tumour measurement to facilitate the application of humane endpoints.

8. Culture of Care

On 6th March 2024, the third Annual Culture of Care Day was held. With over 70 internal and external delegates, invited speakers and exhibitors and an award for the most impactful 3R's initiative, the day was really well received and feedback was very positive.

9. Other Business

The following work has been undertaken by the AWERB during the reporting period:

i. AWERB Membership: Alongside the usual turnover in academic, postdoctoral and PGR representatives, approval was sought from RGEIC to amend the tenure of some categories of staff and to expand the staff categories represented on AWERB, therefore additional members were recruited as detailed in section 2.2 above.

ii. BSU Standard Operating Procedures: With a move to align Northern Ireland PPLs to the rest of the UK there has been a need to develop SOPs for all procedures. This process began in 2020/21 and involves allocating responsible users of the procedure to draft the initial SOP followed by AWERB member review and approval. As new PPL applications are reviewed, applicants provide any additional SOPs required for the proposed work. SOPs require regular review and renewal and this process is currently underway.

iii. AWERB Hub: QUB AWERB Chair is also Chair of the NI AWERB Hub which consists of all AWERB Chairs from licenced establishments in NI. A meeting of the AWERB Hub chairs was held online on 12th December 2023.

iv. The Annual NI ASPA Training Day, hosted and organised by QUB, was held on 30th April 2024 in hybrid format with delegates attending in person and online. There were 194 delegates (110 in person and 84 online) from across NI and 5 external speakers.

v. CPD: AWERB Chair attended several workshops throughout the year including the Annual Animals in Science Committee AWERB Hub workshop (online on 11th October 2023). One new lay member attended the Annual Lay Members Forum in London in December 2023.

Role of Animal Welfare Ethical Review Body

The Animal (Scientific Procedures) Act 1986 (and subsequent amendments) gives clear guidance as to the operation of the Animal Welfare Ethical Review Body. Specifically, the AWERB has a statutory duty:

i. For the ethical review of all applications for research involving animals protected under the Animal (Scientific Procedures) Act 1986.
ii. To discuss and develop ethical advice and guidance to the Establishment Licence Holder on all matters related to animal welfare, care and use within Queen's. This shall include, but is not limited to, the standards of animal care and accommodation, including breeding stock, and the humane killing of animals.
i. Examine proposed applications for new project licences and review any amendments to existing project licences to determine local impact, how the 3Rs (Replacement, Refinement and Reduction) are being applied, and to advise the Establishment Licence Holder on the acceptability of the applications/amendments.
ii. Throughout the lifetime of projects the AWERB shall review ongoing projects ensuring continued operation against the approved project licence. Projects shall be reviewed at mid-term and on completion to enable lessons to be learnt and provide greater understanding of the 3Rs.
iii. To promote awareness of animal welfare.
iv. To promote the development and uptake of the 3Rs and advise staff how to apply them.
v. To set up and regularly review procedures and protocols, including management systems, for monitoring, reporting and following up on the acquisition, welfare and proper use of animals at your establishment.
vi. To support named people, and other staff dealing with animals, on animal welfare and ethical issues.
vii. To advise on re-homing animals including appropriate socialisation.
viii. To respond to enquiries and consider advice received from the national Animals in Science Committee.
ix. To provide an annual report to the University Governance and Integrity Committee giving assurances to the University on compliance with the requirements of ASPA.