Queen's University Belfast

Animal Welfare and Ethical Review Body (AWERB)

Annual Report 2022-23

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 2023), 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. One further academic staff member was in post until July 2023.

ii. Post-doctoral Staff: Two postdoctoral contract researchers who are currently working within the above research areas and are 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 was in post from September 2022 to July 2023.

iv. BSU Staff: The Biological Services Unit (BSU) manager and one deputy as Named Animal Care and Welfare Officers (NACWO).

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: One non-QUB lay member who was appointed in conjunction with Research Governance.

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.

x. QUB Named Compliance Officer (NCO): Invited to be in attendance at all AWERB meetings.

2.3 During the reporting period six AWERB meetings were held (19th October 2022, 14th December 2022, 15th February 2023, 19th April 2023, 21st June 2023, 16th August 2023) at which 11-14 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 meeting was held within the reporting period (21st September 2022, 16th November 2022, 18th January 2023, 17th May 2022). 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 35 different staff members, which is a little lower than previous years (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 the following 9 project licence applications:

- Developing novel nanomedicines for cancer therapy and imaging
- Mechanism study of the host gut-liver circuit and microbiome in the development of metabolic diseases
- Endothelial progenitors in retinal and
- choroidal degeneration
- Evaluating metabolic and epigenetic therapeutic vulnerabilities in cancer
- Neurovascular complications of the retina and brain in cerebral malaria
- Preclinical assessment of therapeutic agents to treat retinal disease
- Production of antibodies
- Strongyloides lifecycles in rodent models
- Neurovascular remodelling in ischaemic retinopathies

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, after 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, 12 project licence amendment applications were reviewed and approved. These comprised: changes to PPL holders (2), an increase in numbers on particular protocols (2), amendments to individual protocols to include controls (1) or to remove/change wording related to volumes, doses or time points (2), addition of alternative administration routes (2) and addition of new protocols (3). 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 the NVS and 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 of 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 the following 7 final reports, 1 of which included retrospective assessment:

- Investigating the effects of squirrel pox virus in Northern Ireland
- Assessment of radiobiological responses in normal tissues
- Development of Novel Non-Viral Gene Vectors for Therapeutic and Imaging Applications
- The immune response to antigens
- Investigating the ecology of the pine marten (Martes martes)

- Epigenomics of neural
- development
- Vascular remodelling in ischaemic disease
- Production of antibodies to food contaminants
- Therapeutic evaluation of agents in thoracic associated cancer models

5. Additional Conditions

The DoH Inspector may impose additional conditions on individual PPLs such as annual reports of use of specific protocols. Currently, seven PPLs have additional conditions. Usually AWERB has no requirement to be involved in this process, however, 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.

6. Use of Schedule

6.1. In 2021-22, AWERB acquired the function of reviewing applications for use of animals/animal tissue for educational purposes. A set of principles was agreed by AWERB and these were conveyed to staff through presentations at School Board meetings in early 2022. During the reporting period, AWERB reviewed 3 applications for use of animals for educational purposes- all were approved.

6.2 During the reporting period, the use of animal tissue for UG and PGT projects not already regulated by an existing PPL was added to AWERB responsibilities. During the reporting period, AWERB reviewed no requests.

7. Other Business

7.1 Although the main role of the AWERB relates to project licence application and review, it also has other responsibilities (outlined in Appendix 1). At the main bimonthly AWERB meetings, NACWO, NVS, BSU Management and Regional AWERB Hub reports are included as standing agenda items, but time does not usually allow discussion of additional responsibilities. Therefore, shorter strategic AWERB meetings are held in the interim months specifically for additional 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, we are recruited a pool of lay members in conjunction with Faculty Research Ethics Committees and Research Governance.

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 has involved allocating responsible users of the procedure to draft the initial SOP followed by AWERB member review and approval. A number of SOPs are available for use and training with more added regularly. A period of training, embedding and review is required. As new PPL applications are reviewed, applicants provide any additional SOPs required for the proposed work.

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 1st December 2022.

iv. The Annual NI ASPA Training Day, hosted and organised by QUB, was held online on 15th March with 196 delegates from across NI and 6 external speakers.

v. CPD: AWERB Chair attended several workshops through the year including the Annual Animals in Science Committee AWERB Hub workshop (online on 2nd November 2022).

7.2 To deliver on additional responsibilities of AWERB, subgroups with an academic lead have been established related to (1) establishing and enhancing a Culture of Care, (2) establishing a Rehoming Policy, (3) promoting good breeding practice, (4) promoting 3R's and making the AWERB more transparent and accessible.

7.3 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 which an action plan will be developed.

7.4 On 3rd May 2023, the second Annual Culture of Care Day was held. With over 80 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.

7.5 The Culture of Care Day also saw the launch of our 3Rs Seminar Series which is to become a bi-monthly feature on the calendar with a mix of internal and external speakers.

8. Terms of Reference

The Terms of Reference have been updated to reflect the requirement for technician representation and to amend/stipulate terms of office for each position. The revised Terms of Reference are attached as Appendix 2 and presented as tracked changes for ease of comparison.

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.

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viii. To support named people, and other staff dealing with animals, on animal welfare and ethical issues.

ix. To advise on re-homing animals including appropriate socialisation.

x. To respond to enquiries and consider advice received from the national Animals in Science Committee.

xi. To provide an annual report to the University Research Ethics Committee giving assurances to the University on compliance with the requirements of ASPA.

Membership:

Composition		**Current Members**
Chair:	Nominated by the Establishment Licence Holder	Names withheld
Deputy Chair:	Nominated by the Establishment Licence Holder	Names withheld
Ex Officio:	Academic Staff who are active project licence holders (at least one per relevant School/research Centre)	Names withheld
	BSU Academic Lead	Names withheld
	Named Training and Competency Officer	Names withheld
	At least one lay member	Names withheld
	Two Named Animal Care and Welfare Officers, one of whom should be the Senior Technician for BSU	Names withheld
	Named Veterinary Surgeons	Names withheld

	Two Student Representatives who are personal licence holders	Names withheld
	Two Post-Docs, nominated by the post-doctoral society, who are personal licence holders	Names withheld
	Two technicians who are personal licence holders	Names withheld
	Up to three co-opted members with relevant experience and expertise, one of whom should be a statistician.	Names withheld
In attendance:	Home Office Representative – from DoH NI QUB Establishment Licence Holder	

Serviced by:	Faculty of Medicine, Health and Life Sciences
Reports to:	Research Governance, Ethics and Integrity Committee
Receives reports from:	Non-ASPA Animal Research Ethics Committee Biological Sciences
Quorum:	One third of members
Term of Office:	Academic staff – Four years with possible renewal for further term of Four years Post-Docs – Two years with possible renewal for further term Student Representative – One year with possible renewal for further term Technicians - Two years with possible renewal for further term Lay Member - Four years with possible renewal for further term