Queen's University Belfast

Animal Welfare and Ethical Review Body (AWERB)

Annual Report 2019-20

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 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, Pharmacy and Psychology. This ensures wide involvement of staff within the establishment, as recommended by the DOH.

2.2 At the end of the reporting period, the committee composition was as follows:

i. Academic Staff: Eight 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: Two postdoctoral contract researchers who are currently working within two of the above research areas and are routinely involved with animal research.

iii. Postgraduate Students: Three PhD students who are currently working within the above research areas and are routinely involved with animal research. These committee members are rotated on an annual basis to provide invaluable experience to junior researchers.

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): Academic lead for personal licensee management and training.

vii. External Lay Representative: At least one non-QUB lay member who is 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 five AWERB meetings were held (23rd October 2019, 11th December 2019, 19th February 2020, 17th June 2020, 19th August 2020) at which 12 to

17 members were present, thus satisfying the quorum of five attending members set by the terms of reference. Detailed minutes of discussions and decisions were prepared and will be 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 42 project licences issued to QUB, held by 39 different staff members, which is comparable to 2018-19.

3.2 At QUB, project licence application used to involve the Chair of the AWERB, together with the DOH Inspector, NVS and NACWO, working together with the applicant from an early stage of the process in relation to e.g. structure, content and experimental protocols, with particular regard to animal ethics and welfare. Once the application has undergone several iterations, it was sent to the rest of the AWERB, who then review the completed submission. This changed in 2019-20 and now the process is for the applicant to have 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 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 12 project licence applications.

- New strategies to enhance tissue vascular repair
- Novel therapeutic strategies for the treatment of poor outcome cancers
- Pathogenic mechanisms and treatment of diabetic retinopathy
- Acute Respiratory Distress Syndrome: mechanisms of pathophysiology and therapeutic approaches to cure
- Investigation of neurovascular dysfunction in diabetic retinopathy
- Epigenomics of neural development
- Investigating immune mechanisms in Central Nervous System (CNS) tissue damage and regeneration
- Production of antibodies to food contaminants
- Circadian rhythms in diabetes and their role in diabetic retinopathy progression
- Spatial connectivity of skate & sharks
- Evaluation of pharmaceutical delivery systems
- Creation, breeding and maintenance of genetically altered mice

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 the rest of the AWERB.

3.7 During the reporting period, 4 project licence amendment applications were reviewed and approved. These comprised: (1) addition of topical application of anticancer agents to a protocol; (2) addition of long term infusion of therapeutic drugs via osmotic mini-pump to a protocol; (3) change of licence holder; (4) modification of streptozotocin induction protocol to promote a specific hepatic phenotype associated with experimental diabetes. Minor amendments were reviewed and approved by the NVS and AWERB Chair. Major amendments, such as addition of a new protocol, 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, 5 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 11 final reports,6 of which included retrospective assessment:

- Role of pentraxin 3 in diabetic retinopathy
- Understanding immunological mediators of inflammatory diseases and their therapeutic intervention (including retrospective assessment)

- Studies in ischaemic disease (including retrospective assessment)
- Studies in retinal vascular physiology and pathophysiology (including retrospective assessment)
- Investigating immune mechanisms in tissue damage and regeneration (including retrospective assessment)
- Mechanisms of diabetic vascular complications
- Identifying barriers to upstream migration in lamprey
- Validation of Microneedle
- Arrays for Vaccine Delivery (including retrospective assessment)
- Macromolecular Delivery of anti-cancer and antiangiogenic agents (including retrospective assessment)
- Super Ovulation, Embryo Transfer and Vasectomy
- Acquisition of Amphibian Skin Secretions

5. Other Business

Although the main role of the AWERB relates to project licence application and review, other issues are discussed but only when they have the potential to directly impact upon animal welfare and ethics, and are covered by its remit outlined in Appendix 1. For example, NACWO, NVS, BSU Management and Regional AWERB Hub reports are included as standing agenda items at each AWERB meeting. Specifically, the following additional business was considered and discussed by the AWERB during the reporting period:

i. AWERB Membership: Alongside the usual turnover in academic, postdoctoral and PGR representatives, the AWERB Deputy Chair took over as Chair, effective from the 1st June 2020.

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 has begun and AWERB has reviewed early drafts of some SOPs during the reporting period.

iii. AWERB Hub: A meeting of the AWERB Hub chairs was held on 4th December 2019 in Centre for Experimental Medicine, QUB. There had been plans to hold the annual NI ASPA Training Day in early 2020, however this was cancelled due to Covid-19. The annual Animals in Science Committee AWERB Hub workshop was also postponed and held eventually online on 21st October 2020, which the Chair attended.

Appendix 1

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.