Queen's University Belfast

Animal Welfare and Ethical Review Body (AWERB)

Annual Report 2020-21

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 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, the committee composition was as follows:

i. Academic Staff: Five 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: Three postdoctoral contract researchers who are currently working within the above research areas and are routinely involved with animal research.

iii. Postgraduate Students: Two 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. QUB Named Information Officer: Point of contact for all PIL, PPL enquiries and main contact for DoH

viii. 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 six AWERB meetings were held (14th October 2020, 16th December 2020, 10th February 2021, 14th April 2021, 16th June 2021, 18th August 2021) at which 7-14 members were present, thus satisfying the quorum of six attending members set by the terms of reference. In addition, Strategic AWERB meetings were introduced. These meetings are intended to deal with additional responsibilities of AWERB and as such do not deal with applications or reports. One strategic AWERB meeting was held within the reporting period (19th May 2021). 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 40 project licences issued to QUB, held by 38 different staff members, which is comparable to 2019-20.

3.2 At QUB, the processes involved in project licence applications changed in 2019-20. 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 9 project licence applications:

- Antigen uptake and B cell immune responses
- Dissecting host-pathogen interactions towards developing new therapeutics
- Creation, breeding and maintenance of genetically altered mice
- The Role of Calcification in Visual Impairment
- Evaluating combinations of approved and experimental therapeutics
- Investigation of enzymatic and signalling pathway targets in diabetic retinopathy
- Understanding the DNA Damage
- Driven Immune Response in Breast
- Cancer: Opportunities for Improved
- Stratification and Treatment
- Understanding Pathogen Recognition Receptor pathway control of host immunity
- Passage and treatment of parasitic trematodes in mammalian hosts

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.

3.5 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.

3.6 During the reporting period, 6 project licence amendment applications were reviewed and approved. These comprised: (1) change in adjuvant use; (2) change of licence holder; (3) modification of protocols to include intra-cardiac innoculation and tumour removal; (4) modification of protocol to add colorectal tumour induction by i.p. injection; (5) addition of blood sampling and surgical insertion of acoustic tags to skate and (6) addition of GM mouse with circadian tissue specific deletion and additional circadian rhythm disruption steps to existing protocols. Minor amendments were reviewed and approved by the NVS and AWERB Chair. Major amendments, were reviewed by the committee prior to final review/approval by the NVS and AWERB Chair.

3.7 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.

3.8 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, 13 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 5 final reports, 3 of which included retrospective assessment:

- Evaluation of prostate cancer disease progression and novel treatment strategies for cancer'
- Chemoprevention in BRCA1 model
- Metabolomic profiling of responses to Selective Androgen Receptor
- Modulators (SARMs)
- Novel Strategies to overcome anti-cancer therapy resistance
- Measurement of behaviour and energy expenditure using animal borne loggers

5. Other Business

5.1 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 it was agreed that shorter strategic AWERB meetings would be held in the interim months specifically, for additional business. The following has been discussed by the AWERB during the reporting period:

i. AWERB Membership: Alongside the usual turnover in academic, postdoctoral and PGR representatives, a new lay member joined the committee, effective from the 1st April 2021.

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 is underway with a further period of embedding required.

iii. AWERB Hub: A meeting of the AWERB Hub chairs was held online on 7th December 2020. The annual NI ASPA Training Day, hosted by QUB, was held online on 27th April 2021 with almost 250 delegates from across NI. The annual Animals in Science Committee AWERB Hub workshop was held online on 5th October 2020, which the Chair, NIO and NACWO attended.

iv. Additional Responsibilities: subgroups with an academic lead have been established to take forward activities related to establishing and enhancing a Culture of Care, establishing a Rehoming Policy, promoting good breeding practice, promoting 3R's and making the AWERB more transparent and accessible.

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.