

**Queen's University Belfast**  
**Animal Welfare and Ethical Review Body**  
**Annual Report 2015-16**

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. There is a strong emphasis, on the 3Rs – Replacement, Reduction and Refinement in animal research.

2.2 The AWERB is comprised of representatives from all relevant research areas, including Medicine, Dentistry & Biomedical Sciences, Biological Sciences, Pharmacy and Psychology. This ensures wide involvement of staff within the establishment, as recommended by the DoH. At the end of the reporting period, the composition of the Review Body was as follows:

- i. Academic Staff: Seven representatives from relevant research areas, who are typically current project licence holders. This includes a Chair, who is appointed by the QUB Named Compliance Officer (NCO).
- ii. Post-doctoral Staff: One postdoctoral contract researcher who is currently working within one of the above research areas and is 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. 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 (21 October 2015, 9 December 2015, 24 February 2016, 27 April 2016, 15 June 2016, 24 August 2016) at which 7-13 members were present, thus satisfying the quorum of five attending members set by the terms of reference. Detailed minutes of discussions and decisions were maintained. When required these are made available to Department of Health (DoH) inspector or shared in a redacted form to fulfil requests made under Freedom of Information (Fol) Legislation.
3. Project Licences
- 3.1 A project licence provides authorisation from the DoH for a defined programme of work. At the end of the reporting period, there were 42 project licences issued to QUB, held by 36 different staff members. This number has remained constant compared to 2014-15.
- 3.2 At QUB a project licence application typically involves 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, the 3Rs and animal welfare. Once the application has undergone several iterations, it is sent to the rest of the AWERB, who then review the completed submission.
- 3.3 The process for project licence application has been detailed in a specific Standard Operating Procedure and made available internally to support researchers with the process. The applicant (or appropriate designate) must 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, further revisions are requested by the committee and final ethical approval is only granted by the Chair upon their satisfactory completion. During the reporting period, the AWERB considered six project licence applications (four new projects and two renewals).
- 3.4 A project licence provides authorisation only for a specified programme of work as defined in the original application. 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.
- 3.5 The application process for an amendment 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, 10 project licence amendment applications were reviewed and approved. These included: (1) addition of Place Other than the Licensed Establishment (POLE); (2) inclusion of study of an additional species of parasite; (3) increase of animal numbers; (4) minor amendments to experimental workflow; (5) inclusion of QUB as a POLE; (6) transfer of licence holder; (7) addition of intramuscular route for inoculation; (8) addition of optical imaging technique; (9) addition of collection of intraocular and tear fluids. After review by the committee, these amendments were

typically subject to minor amendment prior to granting of final ethical approval by the Chair of the AWERB.

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 are 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, three mid-term reviews were undertaken, all of which were approved for continuation.

#### 4. Final Reports

4.1 In order to maintain oversight of animal research conducted under QUB project licences and to assess the balance outputs/outcomes against animal use, the AWERB 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.

4.2 During the reporting period, the AWERB reviewed and approved 11 final reports.

#### 5. Other Business

5.1 The main role of the AWERB relates to project licence application and review, however, from time to time, other issues are discussed where these have potential to directly impact upon animal welfare and ethics, and are covered by the Committee's remit. Subsequently the NACWO, NVS and BSU Management reports are included as standing agenda items at each AWERB meeting.

5.2 During 2015-16 the following notable additional business items were discussed to ensure animal welfare and robust compliance with the legislation:

##### i. Animal management software:

The BSU animal management software system, installed in 2014, is operational with regard to animal management and personal licensee training and competency records. The BSU will continue to expand the software's usage, with the next phase focusing on incorporating financial aspects of running the BSU.

ii. Secondary availability of BSU:

The AWERB approved a request from AFBI to conduct a small amount of their antibody generation work at QUB. The BSU was consequently included as a POLE on the relevant AFBI project licence.

iii. Measurement of tumour volumes:

There appeared to be variations on the methods used for the measurement of tumour volumes. Subsequently, AWERB commenced a process to prepare a standard operating procedure for both measurement and recording of tumour volumes that would ensure a consistent approach to all research groups using the BSU.

iv. AWERB Regional Hub:

QUB AWERB has recently been appointed as the Regional Hub to report to the Animals in Science Committee. Subsequently, the University will act as liaison with eight AWERBs in Northern Ireland in relation to e.g. good practice, new initiatives etc.

v. ASPA Training Workshop:

An ASPA (Animals Scientific Procedures Act) training workshop was held at QUB on Thursday 21 January 2016. This was a well-attended and successful event which brought together approximately 100 relevant individuals from across the province to discuss pertinent issues relating to ASPA. The general consensus was that local implementation of ASPA appears to be largely effective although there is scope for improvement. It was agreed that an annual meeting of this kind may be useful and that this would be discussed with other regional AWERB Chairs.

vi. Non-ASPA project approval:

A dedicated non-ASPA animal research ethics committee has been established in the School of Biological Sciences to review all relevant projects, for example, behavioural studies of animals in the wild. Proceedings of this committee will be communicated by the Chair to the BSU Management Committee as a standing agenda item.

vii. Openness:

Members of senior management in the Faculty of Medicine, Health and Life Sciences, Research and Enterprise Directorate and the Marketing, Recruitment, Communications and Internationalisation Office visited the BSU on 20 May. This enabled senior members of staff to be informed of the Unit's work and the importance of research using animals to advance scientific knowledge.