

Minutes: AWERB

Status: Chair approved

Meeting held: 19 June 2018 at 2pm in U5 Camden videolinked to Hawkshead

Council Room.

Attendees: 13 members present; 2 in attendance; 2 by invitation; 4 apologies

1 PROJECT LICENCE HOLDER PRESENTATION

The project licence holder was welcomed to the meeting. He had recently submitted a new project licence for review. There was also a scientist in attendance who had been involved in reviewing the application to provide comments from a scientist's perspective.

This project licence would build on work that had been undertaken under a project licence that was about to expire. The aim of the research was primarily concerned with developing treatments for Duchenne muscular dystrophy (DMD). This research focus was on discovering methods of enhancing efficacy of those therapies that were aimed at restoring dystrophin that have shown some benefit and other potential treatments. As DMD not only affects the skeletal and cardiac muscles but also affects the brain, treatments that could be applied to the central nervous system would also be examined.

This project aimed to test and develop both genetic and pharmaceutical approaches with an emphasis on treatments that could be translated to the clinic. However, as part of therapeutic development, it might be necessary to perform some studies that were not directly aimed at the clinic including transgenic crosses to explore the best possible results, tests in wild-type mice to assess mechanisms and the use of local and not systemic delivery in some initial experiments. The drugs/genetic approaches developed for DMD may also be applicable for other neuromuscular diseases and thus the project licence holder wanted to retain the possibility of testing these therapies in mouse models of additional neuromuscular conditions.

AWERB raised the following queries in relation to the project licence:

- Was it necessary to anaesthetise the animals on every single occasion? If so, would this be done using an inhalation method? It was suggested that anaesthesia per se might be more traumatic than an IM injection unless the injection was particularly painful (in which case a systemic analgesic might be more suitable than a general anaesthetic). It was explained that a general anaesthesia did not seem to cause the mice additional stress. For the tail vein injection, restraining the mice seemed to cause more stress to the mice. Isoflurane was the agent being used.
- How long would the mouse be under in the anaesthetic? They were generally under for about 5 minutes and recovered and interacting within 15 minutes. They were not taken very far under: just enough to stop the mice feeling immediate pain of the injection and moving.
- How much recovery time was allowed between each anaesthesia? It was explained that 24
 hours was allowed for full recovery. AWERB pointed out that there had been a study that
 indicated that rodents tended to show a growing aversion to anaesthesia over a period of time

- had this been considered? The project licence holder advised that he was aware of that study and he had carefully considered the pros and cons of using anaesthesia but decided that the ability to prevent significant pain at the time of treatment made it worthwhile.
- A query was raised about why treated mice could be kept for up to one year. It was explained
 that this would be the exception and that routinely mice would not be kept for 12 months. It
 was useful to have that option though as sometimes just having short term experiments was
 not the best way forward and long term experiments were required.

AWERB confirmed that they were happy with the aims of the project licence. It was agreed that a revised copy of the project licence should be circulated to AWERB for a final review and approval.

2 HARM BENEFIT ANALYSIS

AWERB had been asked to review the "<u>Harm-Benefit Analysis (HBA)</u> in animal-based research and testing" document that had recently been published by The Animals in Science Committee to see if there were any of the report's recommendations that should be introduced at the College. The report was clear that HBA should be an ongoing process, which continues throughout the life of a project licence and the work carried out under it rather than just considered at the beginning of a project licence.

The aim of HBA was to help determine if the overall harm that would occur to the animals was justified by the benefits that were likely to be delivered as a result. HBA should also be used throughout the project to direct efforts to reduce harms and maximise benefits during research and to help recognise at what point, a project, could no longer be ethically justified.

The current process at the College for reviewing project licences was by having a mid term review (which not necessarily at the mid term point, but could be at a crucial point in the project licence work) to assess how things were going; and a review at the end of the project licence to assess how the work had gone and what the results were. It was suggested that an additional component should be added to the reviews that asked the animal technicians for their thoughts on how they though the work had gone/was progressing. By getting the project licence holders and the personal licence holders that worked under the licence and the technicians working together on these reviews, then this should result in a more reflective review of how things have actually gone. A small working group would be set up to review the current form used for the reviews to see where it could be improved and amended to meet the requirements set out in the report.

3 RETROSPECTIVE ASSESSMENT

Retrospective Assessment (RA) was a legal requirement for a report to be written that would then be published alongside the licence's non-technical summary. These are required for projects entailing the use of non-human primates, dogs, cats, equidae and endangered animals, procedures on any species that have been classified as severe, and projects for the purpose of education and training. A template for completing a Retrospective Assessment had recently been put together by the Home Office. Information that was required included the following sections:

- Describe to what extent the programme of work has been carried out
- Describe if, and to what extent, the objectives of the work have been achieved
- Describe the actual harms that have been caused to the animals
- Describe what lessons, if any, have been learned that have contributed to the 3Rs.

The project licence holders that would be required to provide retrospective assessments had been provided with a copy of the guidance from the Home Office. It was important though to work with them so that they clearly understood what their responsibilities were and when they were required to produce the paperwork.

It was stressed that the retrospective assessment was different from the retrospective review. Retrospective review was required of all project licence holders but was for internal use only. Both retrospective assessments and reviews would be covered in the Project Licence Holders workshop that was being put together.

4 ARRIVE GUIDELINES

A copy of a draft ARRIVE template that had been put together for project licence holders to use had been circulated for comment. The aim of the ARRIVE guidelines was to improve the reporting of research using animals, so maximising the information published and minimizing unnecessary studies. This template would help with pulling together the information required.

It was suggested that this template could also be used for the basis of study requests submitted to the Units as well as providing a core summary sheet for the Home Office Inspector. It was important though to keep the document as simple as possible to encourage use of it.

5 MINUTES

The minutes of the AWERB meeting held on 17th May 2018 were agreed to be an accurate record of the meeting.

6 MATTERS ARISING

6.1 Item 1: Presentation from Project Licence Holder (May 2018 meeting)

The Project Licence Holder had recently provided a response to the comments raised by AWERB at the May meeting. This had been circulated to the original AWERB reviewers for their response.

It was agreed that the Project Licence Holder should be invited back to a future meeting to provide more information.

6.2 Item 5: Training Record database (May 2018 meeting)

IT had been e-mailed to ask for their advice on which database would be best suited to meet the requirements. A log number had been received but no response as yet

6.3 Item 14.2: Camden: Teaching Animals (May 2018 meeting)

The teaching department had decided not to bring the teaching animals back to Camden whilst the drilling noise was ongoing as it would have been too stressful for the animals.

6.4 Item 2.2: PPL Refresher training (April 2018 meeting)

The refresher PPL Holder training was still being put together. An e-mail would also be sent to all project licence holders reminding them of their responsibilities in relation to holding a project licence.

6.5 Item 8: New project licence application (April 2018 meeting)

The project licence had now been approved by AWERB and would be submitted to the Home Office via ASPeL. The Lay Panel members had provided a very useful input into the NTS to make it less technical and easier to understand.

6.6 Item 1.1: Environmental Enrichment Audit Report (March 2018 meeting)

The intention was to meet in July to draw up the action plan and discuss the proposed enrichment competition.

6.7 Item 6: Lab Animal Welfare Question (March 2018 meeting)

Academics had been approached to see if they were interested in being involved in the proposed event. What was the best way of attracting students to get them involved though? It was suggested that the event should be made as interactive as possible – not just lectures. The Animal Welfare Society should be contacted to get their input. A query was raised whether it was possible to have a

tour of the Units? It was noted that there was more of a leaning now towards having virtual tours of units, in order to avoid stressing the animals through having strange people walking around the units. It was mentioned that there was an overseas PhD student currently at the College who was doing a project involving a Google camera so he could be approached to see if he could do smart clickable videos of the units.

6.8 Item 6: Lab Animal Welfare Question (March 2018 meeting)

At the last London AWERB Hub meeting it was been suggested that an AWERB Hub workshop on experimental design for AWERB members be held. This was in the process of being arranged with a phone call scheduled for Friday to discuss the proposed programme. The aim was to hold the workshop before Christmas.

6.9 Item 8: Sharing Resources group (March 2018 meeting)

The latest figures had now been circulated.

7 NVS REPORT

A verbal update for Hawkshead was received.

At Camden there was concern that the building work was affecting the animals within the Unit, as one strain of mice in particular was experiencing seizures. Monitoring was being put into place to see whether any particular room was being more affected and whether there was any pattern to the seizures. It was noted that most of the heavy work (i.e. the digging) had now been completed so it should just mainly be building work so hopefully not as noisy or as many vibrations.

8 AMENDED PROJECT LICENCE

8.1 Amendment

It was noted that an amendment to this project licence to allow horses over 2 years old to be used for this study had been approved by the Home Office on 21 May 2018.

A subsequent amendment was now being submitted in order to add the ability to sedate the horses before being put into stocks for protocol 5. They were also requesting an increase in the number of scans allowed (if there was evidence that a pregnancy was not progressing normally) and to have the potential to be able to do blood sampling by a single venepuncture to measure hormone levels. This amendment had been approved by AWERB.

9 ESTABLISHMENT LICENCE

AWERB noted that this had been amended in relation to the Pharmacology Stable Boxes.

10 CONDITION 18 REPORTS

AWERB noted that two condition 18 reports had been submitted to the Home Office. All condition 18 reports were monitored to see if there were any patterns that should be aware of. As part of the session to project licence holders, it would include an item on general husbandry and the importance of careful handling around animals and when moving around.

11 TRAINING RECORDS

It was important to ensure that licensees only carried out procedures that they were authorised to do. Training records were an important aspect of ensuring that was the case. Every personal licence holder that comes into the Units would be issued with a training folder which would include a copy of their induction, PIL and training certificates. The training folder would also highlight the species that they were allowed to work with and the procedures they were authorised to do. A sample copy of the training folder would be circulated for information. Scanned copies of the documents would be

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provided for the training database. The Home Office Inspector had indicated he was very happy with this approach and had suggested that it should be circulated to other institutions for them to use.

The process would be introduced immediately for all new PIL Holders and would then be rolled out to existing PIL Holders.

The new process would also make it easier to identify those PIL Holders that have not undertaken a procedure for a while so that if they needed to carry out the procedure again they would need to be reassessed. The system would also be set up so that PIL holders would be automatically notified when they needed to be reassessed.

The ultimate aim was to provide AWERB with a report on a quarterly basis, of all the active users of each facility and whether they have a training record and have been signed off as competent to do the procedures they are doing or were undergoing training.

12 ESTATES ISSUES

12.1 Hawkshead

12.1.1 Fencing

Fencing for both horses and dogs needed to be looked into. This was being discussed with Estates and the Land Management Group to get new fencing put up/repaired.

12.1.2 Exclusion Techniques for Wild Birds

Following the outbreaks of avian influenza during the past winter, consideration should be given now about what steps would need to be put in place for the birds in case it happened again this winter. The pigeon loft has already been adjusted so that it can be more easily accessed from inside.

12.1.3 Bunny holes

Advice had been received that the holes should be filled in and that the fencing around the unit be replaced and rabbit fencing added to it. This would be going to the Land Management Group for approval.

13 ANY OTHER BUSINESS

13.1 Project Licence Amendment request

An amendment request had been received from the project licence holders that had attended the April meeting. An amendment had now been submitted to AWERB for review.

AWERB confirmed that they were happy with these proposals so long as there were appropriate end points. The end points also needed to be tabulated in a more clear manner so they were no longer subjective.

13.2 Cadavers

AWERB's view on stock animals being scheduled 1 so that the cadavers could be used for studies was requested. Under A(SP)A cadaver tissue was not a regulated procedure. It was agreed that requests like these should be reviewed on a case by case basis to see if there was a good reason for the request. Checks should also be made whether there were other sources of cadavers that could be used for tissue purposes. A record of animals culled for tissue work should be kept.

13.3 Date of next meeting

This was schedule for 19th July at 2pm.

Secretary

21 June 2018