

Minutes: AWERB

Status: Chair approved

Meeting held: 3 December 2019 at 2pm in Camden Council Room VIDEOLINKED TO F82 Hawkshead

Present

Attendees: 10 plus one in attendance, 8 by invitation and 8 apologies.

1 NEW PROJECT LICENCE APPLICATION:

An application for a new project licence application had been received and the project licence holder and his team invited to attend the meeting. The scientist and lay panel member who had been involved in reviewing the application were also in attendance.

AWERB were informed that the project licence they had been sent to review was not the latest version. This had not been realised until AWERB's comments had been received back pointing out that there were missing sections. The project licence would be re-circulated with the missing sections highlighted as well as responding to the comments that had been received.

The project licence holder explained that the aim of their work was to explore the convergence of advancements made in the understanding of the complement system's impact on eye disease, the genetic basis of age-related macular degeneration (AMD) and gene therapy as a mode of sustained treatment delivery. AMD is the most common cause of blindness among the elderly in the industrialised world and accounts for 8.7% of all cases of blindness worldwide particularly in people older than 60 years. Late stage AMD includes a morphological sub-type called "dry" form AMD (dAMD) which was associated with the degeneration of Retinal Pigment Epithelium (RPE) and photoreceptor cells. There is currently no treatment for dAMD with patients generally succumbing to blindness. An intervention had been identified that was thought might halt the progression of dAMD in late stage patients and may ultimately prevent the disease in earlier stage patients. It was this that they were working on. The aim was to generate data in animals with novel vector candidates that would lead to the clinical development of therapeutic interventions for chronic ocular diseases such as dAMD. The data would either be used to support clinical development directly (for example it would form part of the nonclinical data package for regulatory submission to conduct a clinical trial) or indirectly through the development of the gene therapy platform for future therapies.

AWERB made several suggestions for improvements to the project licence. The following comments were also made:

- Did the researchers use microsampling? The researchers were happy to move towards this with guidance on best practice to take the blood samples
- Potential general adverse effects should be included in the project licence
- Experimental design should be thought out in advance before starting to write the project licence as this would demonstrate the specific effects sizes and power calculations the study was based on.

- How would personal licence holders be trained in the technique to be used? A consultant had been identified who would provide hands on training. Once the personal licence holders were competent they would be signed off by the consultant. The technique could be done post mortem. A copy of the consultant's training records would be reviewed to ensure that he was indeed competent before any in-house teaching was done.
- How frequently should the training be refreshed? It was anticipated that the technique would be carried out on a monthly basis. The animals would be carefully monitored after surgery to make sure that they recovered ok. If the animals were taking too long to recover then the consultant would be bought back in to provide more training.
- It was requested that there be a staged training programme to ensure that the work was properly planned. It was agreed that training programme would be formulated and passed to the BSU manager for sign off.
- What percentage failure rate was expected from a competent person carrying out this technique? It was explained that it would be between 10 to 15%. This would be included in the project licence as an adverse event.

The project licence holder was thanked for attending the meeting. They would amend the project licence to take into account the comments received at the meeting and it would then be recirculated. It was possible that the project licence holder might have to attend a future meeting if AWERB had any further queries once they had seen the project licence in its entirety.

2 3RS

The following update was received:

- The Experimental Design (ED) workshop held on 20th November 2019 had been well attended (34 people: half of whom were staff and half students). The format had included an intro, a talk on concepts of ED in reproducibility crisis; a talk on practical examples/tools for randomisation and power calculations and a live demo of EDA. It was hoped that people would be encouraged to use EDA for both grant and project licence applications and 1:1 support sessions were available the system could take some getting used to. Feedback received had been very positive and it was possible the workshop would be run again.
- A seminar on NC3Rs resources and funding and been given:
 - This had been well attended
 - A lot of people had been in contact since wanting to arrange to meet to discuss funding schemes.
- Future plans for ED
 - o opportunities to reach other researchers were being identified to keep the ball rolling on this.
 - o Reminders about the one to one EDA help would be circulated in the New Year
 - Using the EDA should improve ED in PPL applications
 - An 'improving use of animals in research applications' workshop would be arrange to focus on improving grant applications animal justifications, giving context that NC3Rs have trained the grant funders on this topic, so they knew what grant funders were looking for (and how tools like EDA can help them achieve this)
 - o an experimental design workshop for technicians was being run in February.

3 MEETINGS ATTENDED

3.1 LASA Annual Conference (25th and 26th November 2019)

Feedback from the recent LASA Annual Conference was provided.

3.2 London AWERB Hub meeting

AWERB noted the redacted minutes from the London AWERB Hub meeting held in September 2019. Once these had been approved at the next meeting they would be placed on the website.

4 ESTATES ISSUES

4.1 Camden

The cladding had now been completed and signed off. There had been some issues in relation to power and at some stage cabling would need to be replaced

4.2 Hawkshead

The autoclave had been validated and was now in action.

The road leading up to BSU had been re-surfaced but only up to the BSU gate. Estates would have to arrange for the contractors to come back to finish the re-surfacing.

5 NACWO REPORT

5.1 Camden

The large animals were back from Hawkshead. Behavioural monitoring had been carried out to make sure they had not been upset by the cladding work but there seemed to be no issues.

5.2 Hawkshead

5.2.1 Dogs:

Some of the older dogs were showing signs of increased difficult with swallowing and eating but they had not been losing weight, however they were being carefully monitored

5.2.2 Berkshire pigs

There had been complications with the new GLP study, with 2 of the 6 pigs having to be euthanised. It was not known what was causing these problems. No gross abnormalities had been detected. Post mortem and histology were being undertaken to see if the problems could be identified but nothing had been found yet.

6 PROJECT LICENCE AMENDMENTS

AWERB noted that there had been one project licence amended since the previous AWERB meeting.

7 STUDY REQUESTS

AWERB noted that one study request had been approved since the previous AWERB meeting.

8 SCHEDULE 1 REGISTER REVIEW

AWERB reviewed the current list noting that it was up-to-date. Reassessments were being done where required. Three new assessors were being added to the register who would be able to deal with horses. There were no key gaps that needed to be filled.

9 MINUTES OF MEETING HELD ON 5 NOVEMBER 2019

The minutes were agreed to be an accurate record of the meeting.

10 MATTERS ARISING

10.1 Item 3.1: BSU Virtual Tour (November 2019 meeting)

Quotes were being obtained from the alternative contractor on how much it would cost to finish off the BSU virtual tour.

10.2 Item 8: use of animals for teaching in UK Veterinary Schools (November 2019)

Anatomy still needed to be asked to provide some guidelines to how the teaching animals were kept at Camden: this should focus on the length of time spent at Camden and how often they were handled each day by students.

10.3 Item 14: Training records (November 2019 meeting)

A summary of the QA audit on training records would be circulated with the minutes.

10.4 Item 10: Mid Term report (October 2019 meeting)

This had now been received and was being reviewed. It was scheduled to be discussed at the January 2020 meeting. As work was no longer being done under the project licence, it had been suggested that a request would be submitted to the Home Office for the project licence to be revoked.

10.5 Item 11.1: End of project licence reports (October 2019 meeting)

One of the reports had been received and was due to be discussed at the January 2020 meeting. The second one still had not been received so another reminder would be sent.

10.6 Item 1: Project licence amendment (June 2019 meeting)

A meeting had been held with the project licence holder to review the humane end points and to also discuss a proposed traffic light scoring system. No consensus had been reached though.

The proposed traffic light system would be circulated to AWERB so that AWERB had the context of what was being discussed. Once AWERB had reviewed then this should be sent to the Home Office Inspector as he had requested to see it too. It was suggested that there should be a SOP that provided advice to the technicians when they should call in the NVS to make a clinical assessment of the dogs.

11 ANY OTHER BUSINESS

11.1 Animal Welfare Assessment Grid (AWAG)

A meeting had been held with Public Health England who were looking for volunteers to help adapt the AWAG system's scoring factors to fit a wider range of species. The AWAG system scores the welfare of animals based on a number of factors fitting within four parameters - physical, psychological, environment and procedural. The default scoring factors were developed for use with primates but as part of their ongoing NC3Rs funded project they were now looking to develop welfare scoring factors for other species to enable dissemination of the system wider within the animal welfare community. RVC had been asked if they would trial the grid on mice and larger animals.

12 DATE OF NEXT MEETING

This was scheduled for 8 January 2020 at 2pm.

Secretary, 16 December 2019