Royal Veterinary College
University of London

Minutes: AWERB Summary minutes

Status: Chair approved

Meeting held: Wednesday 9 February 2022 at 2.30pm via MS Teams

Attendees: 8 plus 1 in attendance, 2 by invitation and 11 apologies

1 PPL REVIEW OF A NEW PROJECT LICENCE APPLICATION

The project licence holder was welcomed to the meeting. He explained that this was an application for a new project licence to replace one that had recently expired.

This project licence consisted of a number of individual projects, which he would oversee as an experienced project licence holder. The licence was set up this way as it enabled clinicians to carry out research under a project licence without having to be a project licence holder. The individual projects that were carried out were of direct benefit to treating companion animals in the future. AWERB were reminded that he had attended the meeting in December to discuss a proposed amendment to one of the protocols that existed in the expired licence. However since then one of the regulated procedures had been reclassified as not being a regulated procedure (as its primary intention was for the purpose of controlling urination in the dog) and so could be implanted under the Veterinary Surgeons Act for the benefit of the individual dog.

The project licence had been reduced to 3 protocols, to cover 3 studies that would be happening.

There were several queries/comments raised including:

- The licence needed to be clear about the type of animal models that were being referred to and that it was naturally occurring diseases in companion animals rather than laboratory animal models.
- Clarity was needed on what was meant by "where adverse events were more than just minor and transient, animals would be withdrawn from the study": this needed to indicate that it was unpredicted adverse events that were being referred to, as otherwise it clashed with the statements that protocols involving surgical procedures or imaging under anaesthesia was moderate.
- It should be made clear that the information would be stored on a confidential database.
- The question "will you be undertaking non regulatory testing or screening as a service for others" had been answered yes in one place and no in another. This needed to be clarified.
- It was flagged that putting the highest severity that an animal could experience in protocol 1 was "mild" meant there was a risk that a lot of condition 18 reports might be needed if there were any immunological reactions to the infusion, unless there was very high confidence that there would be no detectable immunological response. It was recommended that this be changed to moderate.
- A query was raised about the humane end points for protocol 1, which stated that clients could withdraw their animal from the study at any point. The way it was written made it sound that the client made the decision about the humane end point. However, the humane endpoint should actually be related to the animal experience and be pre-determined by the investigators. This

would be rewritten to indicate that if mild was exceeded then the animal would be returned to its owner.

- The anaesthetic codes needed to be checked.
- The licence referred to a lot of other species but seemed to be only dealing with dogs. Was this a legacy from the previous licence? It was confirmed that although only dog studies were currently being done, it was highly likely that requests for studies with other pets such as cats would be received. The project licence had therefore been written to try and allow that without having to submit an amendment. It was agreed that the wording should be amended to refer to "client owned animals".
- There was mention that there would be a collection of samples which would be made available to the veterinary research community. How would that happen? It was explained that at the end of studies they would take multiple aliquots from a lot of samples, which would be stored in a freezer and were available to researchers to use on request. The PI would need to give permission for the samples to be used; the owner consent form would also need to be checked and then ethics application be submitted so they could utilise those samples for a purpose that was different than what they had originally been collected for.
- "The non-animal alternatives did you consider for use in this project" section needed to be expanded to explain why none had been considered. It was agreed that this would be rewritten to explain that the researchers were testing against spontaneous disease so doing efficacy testing at this stage in the patients so there were no non-animal alternatives available.
- The benefits section of the project licence should be rewritten as it was currently not very clear why the proposed approach was beneficial. It was recognised there was no easy answer though of how to write it. The section could possibly be expanded to explain that the researchers had the capacity to select patients that were more likely to respond to the treatment so potentially increasing the chances of success. The individual animals would also benefit as they would get increased monitoring of their spontaneous disease because of being on the trial. They would also be helping to progress treatments.
- Humane end points: these needed to be clearer as they were the decision points for the way forward and needed to be determined for each of the protocols. Ideally these should be predetermined points and completely independent from the client benefit, though the clients may be reporting the signs that allowed the humane end point decision to be made. At what point should the decision be made that enough was enough? It was explained that this had been discussed with the Home Office as because they were client animals and in a hospital environment, this did not really fit under A(SP)A. It had been agreed with them that the client could withdraw their animal from the treatment being received at any time.

The project licence would be amended to address the comments made and would be sent back to AWERB to do a final review.

2 MINUTES OF PREVIOUS MEETINGS

The minutes of the meeting held on 25 January 2022 were confirmed as an accurate record.

3 MATTERS ARISING/ACTION LOG

3.1 Item 3.4: Senior Management involvement at AWERB (25 January 2022 meeting)

A meeting had been held with the Establishment Licence Holder to discuss AWERB's concerns that the interaction and link between AWERB and senior management could be lost. The Establishment Licence Holder had confirmed that it was his intention to attend as many future AWERB meetings as he could (and was at this meeting). The previous term had been very difficult for him due to clashing commitments, but he was very aware of the importance of attending these meetings and would make every effort to make them.

3.2 Item 3.5: AWERB Budget (25 January 2022 meeting)

The Chair was identifying some potential training courses that might be of benefit for AWERB members to attend and was obtaining prices. This would then be included in the request of how much budget was needed for training.

3.3 Item 3.6: Teaching Ponies (25 January 2022 meeting)

Senior Management had been provided with a quick briefing of the issues that related to AWERB's concerns about teaching ponies being kept at Camden so that they could start looking into alternatives. Extracts from the AWERB minutes would be sent to them so they could see what had been discussed so far.

The Chair added that there had also been developments with the health of the ponies. Of the 4 original teaching ponies, one had to be recently euthanised due to health issues; there were also major concerns over another pony (old age health issues) and so she had been retired from teaching but it was likely she would also need to be euthanised. It was likely that two replacement ponies would therefore need to be sourced. It however was generally difficult identifying suitable replacement ponies.

3.4 Item 3.1: Setting up system to review an outline of proposed dosing regimes (12 January 2022 meeting)

The project licence holder would be invited to a future AWERB standard agenda item meeting to discuss the process and at the same time also do a presentation on tissue requests.

3.5 Item 3.3: Having more small-animal oriented clinicians on AWERB (12 January 2022 meeting)

It had been agreed that a call should be circulated.

3.6 Item 3.4: Working group to revamp mid/end of project licence reviews (12 January 2022 meeting)

This working group had met that morning and gone through the changes that they wanted to make. A revised template would be submitted to the March AWERB meeting for approval.

3.7 Item 3.6: Condition 18 training (12 January 2022 meeting)

Dates were in the process of being arranged.

3.8 Item 3.8: AWERB membership (12 January 2022 meeting)

Four internal lay panel members had been shortlisted and invited to an introductory session. They would also be invited to attend an AWERB meeting as observers and if still interested in being involved, provided with a PPL review training session.

It was noted that a potential new external lay panel member was being proposed to the Nominations and Fellows Committee.

3.9 Item 3.9: Establishment Licence: updating the room names (12 January 2022 meeting)

The building and room plans were in the process of being updated so it was clear what the different areas referred to and these plans and the Establishment Licence all matched: for example, clarifying which were deemed as loose boxes and which were horse boxes.

3.10 Item 3.10: Air Handling Units at Camden (12 January 2022 meeting)

The BMS specialist was still working out what was going on with the air handling. He was determining what the next steps should be.

3.11 Item 4: Communicating the role of AWERB to PhD students (12 January 2022 meeting)
The Head of Graduate School had been contacted to discuss the possibilities of a slot as part of the PhD induction week to run an introductory session on AWERB.

3.12 Item 3.4: ARRIVE Workshop (24 November 2021 meeting)
BSU Users have been notified about the series of short user-friendly workshops that were being set up on this. The dates needed to be circulated.

3.13 Item 6: End of PPL report comments (24 November 2021 meeting)
A response to AWERB comments on this report had now been received.

3.14 Item 3.8: End of PPL report (27 October 2021 meeting)
The updated report had still not been received. The Establishment Licence Holder would be contacting him.

3.15 Item 4: BSU Virtual tour (27 October 2021 meeting)
Discussions were underway about when this could be done.

3.16 Item 4: Interview questions about animal research done at the College (27 October 2021 meeting)
HR had advised that a question about animal research was automatically included in the interview packs. What was not known was how this was carried out in practice so this would be followed up on as well as seeing if the question asked provided context about the purpose of this type of research. It was suggested that interviewers be provided with links to the relevant section of the RVC website that they could provide to the candidates if they had any follow up questions.

4 TERMS OF REFERENCE
AWERB reviewed the mode of operation from the Terms of Reference and agreed that these were all happening, with the exception of one: "From time to time (and no less than once per year) staff and students of the College will be invited to suggest areas or topics for discussion": it was agreed that enquiries would be made at the Technician meetings about what topics they would like discussed at AWERB.

5 3RS

- A 3Rs bulletin was being put together for circulation college wide.
- NC3Rs – International 3Rs prize: this competition was now open for applications (closing date 6 April): applications were welcome from researchers who have published an outstanding paper with demonstrable 3Rs impacts in the last 3 years.
- RSPCA Severe Suffering meeting: the RSPCA were organising a face to face "Focus on Severe suffering" meeting with the University of Manchester. The session would include (i) case studies explaining how severe suffering was reduced and avoided in a range of research fields; (ii) reducing severe suffering in studies of animal diseases and disorders; and (iii) a discussion on how effectively AWERBs were fulfilling the task of assisting with retrospective assessment of projects involving severe procedures. AWERB members were welcome to attend if this was of interest.

6 NVS
An update from the NVS was received. There were no major concerns to report.

7 NACWO

7.1 Camden

- Air handling units: there were still failing and had to be manually reset. This meant the rooms were quite often under the recommended humidity values. Each failure was being reported through the EOS system and regular reports were being sent to Estates.
- Lights: the lights in the building have been replaced (with the exception of the animal rooms). The lux levels were being measured in the animal rooms to see what was required.
- Fish facility move from Amoroso Building to BSU: the building work was nearly completed. Lights were in place and the room had been refurbished. The cable work had also been completed. The next big step was the installation of the water unit. There were no dates as yet for when this would be done.

7.2 Hawkshead

- The change of lights at Hawkshead had also been completed.

8 CONDITION 18 REPORTS

AWERB noted that there had been 3 condition 18 reports submitted since the previous AWERB Standard Agenda items meeting. Two of these were ongoing condition 18 reports rather than new ones.

9 AMENDMENT TO ESTABLISHMENT LICENCE

- AWERB noted that the Home Office had approved the removal of a NACWO from the Establishment Licence as she had now left the College.
- An amendment would be submitted to add a new NACWO and a NTCO for Hawkshead.

10 AMENDMENT TO PROJECT LICENCES APPROVED BY THE HOME OFFICE SINCE THE PREVIOUS MEETING

AWERB noted that one project licence amendment had been approved by the Home Office since the previous meeting.

11 MID TERM PROJECT LICENCE REVIEWS

Two high quality reports had been received. A discussion was requested about how to handle dead non-harmful GA animals. Were AWERB happy with the concept that if dead mice were found that were from a GA colony but that the death rate was equivalent to the death rate that was seen in non-GA animals of the same background strain, then these were not reported? This was because although they were in theory on a procedure as they were genetically altered, they had not undergone any additional procedures as the background colony. Were AWERB happy with that concept though? Did the current guidance on standard condition 18s reflect that?

It was noted that this question had come up at the Condition 18 workshop. The advice provided that if the GA line was bred under the licence and if it exceeded the mortality rate than it needed to be reported as a condition 18 report. This did raise the question whether all the existing licences should be reviewed and amended if they didn't have a death rate in them. Advice would be sought from the Home Office on that.

12 END OF PROJECT LICENCE REPORT

AWERB noted a response that had been received from one of the project licence holders on comments that had been raised on her end of project licence report.

13 STUDY REQUESTS

AWERB noted that four study requests had been approved since the previous meeting.

14 DATE OF NEXT MEETING

This was scheduled for 22nd February 2022 and would be a PPL review meeting.

Secretary
06 March 2022