

University of Leeds

Animal Welfare and Ethical Review Committee, Minutes of meeting 25 January 2023

10 members attended the full meeting, one member for part of the meeting, with one person in attendance.

Minutes

22/48 The minutes of the meeting held on 7 November 2022 were received and approved.

Matters arising

22/49 (Min 22/35) The Chair agreed to discuss the work-loading matter with the PEL holder and report at the next meeting. ACTION: PEL holder and Chair

22/50 (Min 22/46) The Chair agreed to discuss the position statement for University Research Ethics Committee Chairs with the member concerned and report at the next meeting. ACTION: Member concerned and Chair

Establishment Licence (PEL) holder and Named Veterinary Surgeon (NVS) update

(Received paper AWERC/22/12)

22/51 The NVS reported on a non-compliance issue involving a member of staff who had completed the relevant licensee training and started training to perform regulated procedures but had not yet submitted an application for a personal licence. No animal welfare concerns had arisen and the person had been assessed as competent in undertaking the procedures. The incident had been reported to the Animals in Science Regulation Unit (ASRU) and a response was awaited. ASRU report that such occurrences are amongst the most common examples of non-compliance.

22/52 Despite repeated attempts, the University had been unable to contact a retired PPL holder regarding submission of a Retrospective Assessment (RA) due in January. ASRU had been notified before the submission deadline and was satisfied that all efforts had been made to contact the licence holder. It would take no further action.

22/53 A Standard Condition 18 (SC18) report had been submitted regarding two mice found dead while undergoing an intracranial tumour model protocol. A similar incident had been discussed at the November 2022 when it had been noted that this type of tumour is prone to sudden haemorrhage. This is accepted as a complication in which no signs of adverse effects are evident prior to the sudden death of the animals. Following discussion with a Home Office Inspector the licence had been amended, to include an expected proportion of animals to be affected by this complication. The amendment had since been granted and the SC18 report had been closed without further action.

22/54 Further samples had confirmed the range of pathogens present in one of the animal units and a visit from external consultants had taken place. All areas used for research involving the use of animals had been visited and a report on decontamination and future options, including the potential merger of sites, would be included.

- 22/55 Two new non-regulated projects involving pigs were reported.
- 22/56 Refresher training workshops for holders of personal licences would be offered in March and September. Subject to interest, further dates could be arranged.
- 22/57 The PEL holder reported on a recent major security alert that had resulted in restricted access of all PILs and NACWOs from one of the animal units. Animals, including those undergoing procedures, had been checked early in the morning of the incident and the NACWOs regained access to check the animals later the same day. There had been no welfare implications for the animals, but the University would be reviewing procedures for future incident planning. The Committee thanked everyone who did what was required on the day and was grateful that both people and animals had remained safe.
- 22/58 The planning around the proposed merger of facilities would be informed by the external consultants' report findings. An update would be provided at next meeting.

Named Animal Care and Welfare Officers' (NACWO) Report

(Received paper AWERC/22/13)

- 22/59 The NACWO reported that two new members of staff had been appointed and the recently appointed manager would start, initially on part-time basis, in February.
- 22/60 A previously reported environmental issue had been rectified and there were no welfare issues to report.

ULBSC Report

- 22/61 Further discussions on the planned merger had taken place with users.

Review of Membership

(Received paper AWERC/22/14)

- 22/62 One vacancy on the Committee remained for a member who does not work with animals. The possibility of sourcing another statistician was discussed. It was noted that most PPL applications have limited statistics and very few complex calculations. It was agreed that the appointment of another statistician and another lay member was worth consideration.

Arrangements for applications, amendments and reviews.

(Received paper AWERC/22/15)

- 22/63 The Chair introduced the draft proposal to establish a sub-committee. A summary of the procedure was noted: First, the NVS confirms that a draft application is ready for consideration; the applicant is then provided with a list of appropriate review attendees; the applicant arranges the sub-committee meeting and provides the relevant papers; finally, the applicant delivers a presentation to the sub-committee and allows for questions and comments on the project.
- 22/64 The Chair proposed that he should be involved in the review of each application and that the whole Committee should be in receipt of the lay summary and NTS for each. A member proposed that a deputy should be identified for where the Chair was unavailable. More information could be provided for each of the key roles to guide what to look for. In practical terms, since the initiative would be placed on the applicant to arrange a meeting, guidance would be provided regarding who

should be invited to attend. The NVS and NACWO would be in a position to provide the applicant with names of fellow PLHs/PILs and technical staff with experience in relevant scientific disciplines that would be able to look at the detail of a particular application. The benefit of including a wider selection of staff in the AWERC process was acknowledged and the Committee agreed that the proposals should be updated to incorporate suggestions and implemented with immediate effect.

ACTION: NVS, NACWOS and NIO.

22/65 The Committee should conduct a review after one year to reflect on the impact of the change and the approach to consideration of mid-term reviews would also have to be addressed. Discussion of this was deferred until the next meeting. ACTION: NIO

Project licence Applications

A388

22/66 Following the applicant's presentation, the Chair shared comments submitted in advance of the meeting and several aspects of the application were discussed. These included the need for the licence to include studies from proof of concept through to clinical use; the clinical signs that animals would be monitored for, the frequency of monitoring and analgesia used; the rationale for using fewer animals with multiple wounds; and the need for wounds of sizes that would be relevant to specific human conditions. During discussion, the applicant explained the need for scenarios that would be of clinical relevance for patients. A need to anaesthetise animals frequently would apply in some cases but not in all and, even when repeated at the highest frequency proposed the protocols would remain within moderate severity. The Committee was told that animals had historically coped with these procedures very well under the preceding project licence and that analgesia and animal facility holding conditions would have a positive impact on their recovery. The Committee was advised that the smallest wounds necessary to achieve each purpose would be used and that these were significantly smaller than reported in most of the published literature. It was agreed that this information should be included in the application.

22/67 The applicant was asked to include more detail of the experience of the animals in the short lay paragraph and to focus more on the relief of any discomfort or pain they might experience. The applicant was also asked to include more detail in the NTS on the benefits of the work to future human patients. The NVS would share comments with the applicant and the application would be amended before submission to ASRU. The NVS agreed to report at the next meeting. ACTION: NVS and applicant.

A390

22/68 This proposal was an application to extend work on a PPL nearing expiry. Refinements in monitoring and humane endpoints (including a reduction of allowed bodyweight loss and increased frequency of monitoring in certain protocols) were included, after review of work under the previous PPL. Less than 5% of animals were expected to experience severe adverse effects under the proposed licence.

22/69 Matters discussed included how severity would be kept to a minimum; the species most appropriate for translational studies; how breeding numbers had been calculated, particularly when introducing a new strain; the capacity for breeding numbers to be accommodated, which would be staggered during the project; the high percentage of animals which would go into experiment; re-challenge by a different route if necessary with anticipated percentages for re-challenge; the use of tumour scoring and increased monitoring to be able to identify the first signs of pain and stop studies early; references

which would need to be updated; and radiation doses which the applicant agreed to review.

22/70 The applicant was asked to include additional detail in the NTS and work through comments with the NVS to amend the application before submitting to ASRU. ACTION: NVS and applicant.

Schedule of business

(Received AWERC/22/16)

22/71 The Schedule of business was received for information.

External meetings

22/72 The PEL holder, NVS and NIO had attended the Laboratory Animal Science Association (LASA) Annual Conference and PEL Holders' Forum meetings in November and the NVS and NIO attended the LASA Home Office Liaison, Training and Information Forum (HOLTIF) meeting with ASRU in January. The next HOLTIF/ASRU meeting would take place in May.

Date of next meeting

22/73 The next meeting would take place on Wednesday 29 March 1000 to 1200 as a face-to-face meeting. The previously arranged Teams meeting would be cancelled in due course.