University of Leeds, Animal Welfare and Ethical Review Committee Minutes 5 November 2018

11 members were present at the meeting with one person in attendance.

The minutes of the meeting on 26 September 2018 were received and approved subject to the inclusion of one agreed change to minute 18/18.

Matters arising

Received paper AWERC18/06

- 18/24 The process of auditing standard operating procedures (SOPs) of animal units would be discussed in a meeting to be arranged between the Establishment Licence(PEL) holder, Named Veterinary Surgeon (NVS), Named Animal Care and Welfare Officers (NACWOs) and facilities manager.
- 18/25 Two members attending the Royal Society for the Prevention of Cruelty to Animals (RSPCA) Lay Members' Forum agreed to report to the next meeting. ACTION: PEL holder and lay member. Administrator to add Agenda item.
- 18/26 Other items in the update had either been actioned or were included as Agenda items.

PEL holder's and NVS's report

- 18/27 There had been no Condition 18 reports since the last meeting.
- 18/28 With regard to the incident reported at the last meeting (min 18/3) the PEL holder reported that a letter had been received from the Home Office (HO) compliance team. Having sought clarification of some of the details in the letter from the HO inspector, the NVS had been advised that the incident had been viewed as a simple human error with a low risk of repetition and not a systemic issue. The HO inspector had been satisfied with the quick reporting and immediate actions taken to prevent recurrence. There was considerable discussion of the incident. The Committee was told that a meeting between the PEL holder and HO inspector was being arranged, after which the Committee would be updated. ACTION: PEL holder.
- 18/29 The delay in implementing the new unit management IT system had been mainly to do with the platform on which the system currently sat. Discussions with IT had taken place regarding relocation of the system to enable work to progress to the revised timetable.
- 18/30 With regard to the review of non-regulated work, the PEL holder confirmed, as previously reported (min 17/109), that mechanisms were already in place for review of two out of the three categories. In relation to the third category, concerning overseas work, a review of material from the National Centre for the

Three Rs had been undertaken, and principles to adopt for the future had been outlined. The overall principle was that information from staff doing work that would be regulated under The Animals (Scientific Procedures) Act if done in the UK should be brought to the Committee and that the relevant Deans would be responsible. A number of mechanisms for raising awareness were proposed including information on appropriate websites; named persons providing information to individuals; the risk register when grants were awarded; and an additional question to be added to the Animal Welfare and Ethical Review Committee pro-forma.

18/31 It was agreed that the Committee should put the proposals into action, working to these principles whilst taking account of regulatory requirements in the country concerned. ACTION: NVS, NACWOs and NIO.

Project licence (PPL) applications

Application A344

- The NVS provided background information, the applicant was welcomed to the meeting and introductions were made. Following a presentation summarising the work the Committee discussed the application with the applicant. Discussions were concerned with collaboration arrangements; potential harms to particular animals; local facilities' support for the work; and whether the application should be revised to cover what could reasonably be achieved within 5 years. The applicant stressed the importance of retaining the ability to be flexible in pursuing avenues with the greatest potential.
- The applicant was asked to include the calculations that had indicated the number of animals requested, based on experience from previous work, in the refinements section. Some information about the facilities was also requested: these were reported to be in the top two within the UK and as good as any available worldwide. Further information to clarify the method of animal monitoring was also requested. Comments from members were given to the applicant at the meeting and the NVS was asked to provide further comments to assist with the final revision. ACTION: NVS.

Application A345

- The NVS provided background information, the applicant was welcomed to the meeting and introductions were made. Following a presentation summarising the work, the Committee discussed a number of aspects with the applicant. Matters discussed included the need for detailed steps to be outlined in the project plan and concerns regarding the low number of animals to be used. The Committee was told that numbers were based on previous experience when moving to animals as a final step to measure safety, via post-mortem examination, before moving to clinical trials.
- 18/27 The applicant was asked to expand on the experience of the post-Doc; to provide

more detail of what animals would experience; and to describe the measures to be used to determine the success (or otherwise) of a particular device using an example to support this. The Committee recommended that the applicant should speak to regulatory authorities to confirm what would be required at the regulatory stage before submitting the application to the HO.

Application A346 secondary availability

18/28 The NVS explained that the application was for secondary availability on a project licence held at another establishment to allow a limited portion of the work, on one protocol, to be undertaken at the University. The Chair enquired about how the University would be informed about licence approvals, and the process of secondary availability approval, involving sign-off from the PPL holders at both establishments, was explained. The Committee noted that the animal welfare score-sheet would be discussed with animal care staff and amended if necessary before use and confirmed that the secondary availability application could go ahead.

Project licence review MR34

18/29 The licensee delivered a brief presentation to summarise the work that was being done under the licence. Discussions following this were concerned with refinements to reduce intensity and discomfort of exercise; bespoke software developed to extract a greater range of data resulting in the use of fewer animals; and delays, reported in the review form, which had affected the scheduling of studies but which had no adverse effects on animal welfare.

Items deferred

18/30 Due to the time taken to consider and discuss PPL applications and reviews the Committee agreed to defer a number of items. These would be brought forward to be considered at the next meeting in January.

Agenda item 7: NACWOs' report.

Agenda item 8: Animal facilities update.

Agenda item 10: Review of Terms of Reference oversight 1(f).

Agenda item 11: Arrangements for drafting PPL applications.

Agenda item 12: Schedule of business.

18/31 It was agreed that future meetings should be extended to 2.5 hours when project licence applications were to be considered. ACTION: Administrator

Date of next meeting

18/32 The next meeting would be held at 1000 on 30 January. The NVS advised that there would be one new application to consider. With this and the deferred items (min 18/130) members should expect the meeting to last up to 2.5 hours.