The University of Leeds, Animal Welfare ad Ethical Review Committee Minutes 24 July 2019

8 members were present at the meeting with one person in attendance. Comments on the applications were received from two additional members who had sent apologies.

Minutes

The minutes of the meeting on 6 June 2019 were received and approved.

Matters arising

(Received paper AWERC 18/24)

18/107 The update on actions was received for information. The Chair advised that a date for the visit to REDACTED would be discussed following the Meeting. The administrator explained that the licensee training course statistics showed the number of trainees who had achieved the 70% required for successful completion of the assessment on the first attempt.

Establishment Licence (PEL) holder's update

18/108 The PEL holder reported that additional information regarding chronology of monitoring had been requested in relation to one of the condition 18 reports reported at the previous meeting. The named veterinary surgeon (NVS) reported that health monitoring reports had been submitted to the Home Office (HO), data and records were examined and it was found that all necessary protections and monitoring had been in place. Following this the report had been closed without concern. Since the last meeting one condition 18 report had been submitted to the HO in relation to one mouse that had died 10 days after surgery. The HO inspector had accepted this report without further action being required and there were no reports outstanding.

NVS's report

- 18/109 The NVS reported on a visit of the HO inspector the previous day during which administrative matters, including project licence (PPL) applications, migration of licences and applications to the new HO IT system and the planned roll-out to establishments were discussed.
- 18/110 The NVS had attended an Animal Welfare and Ethical Review Body (AWERB) UK meeting at which the main business had been to consider whether training for AWERB Chairs was needed. The outcome of the meeting was that there had been no consensus on this subject with many preferring to continue with informal training such as that employed at the University. This would normally involve use of information such as the induction checklist developed for lay members from the Laboratory Animal Science Association (LASA)/Royal Society for the Prevention of Cruelty to Animals (RSPCA) guidance and informal discussions with named persons and existing members of the Committee. A lay member raised a question about the possibility of attending legislation and ethics training and was invited to attend the

relevant sessions of the course being run at the University in September.

18/111 The NVS reported that annual statistics of animal use had been published by the HO and observed that national and local trends had been similar.

Named animal care and welfare officers' (NACWO) report

18/112 A NACWO reported that the humidity in one animal holding room had increased above the normal range for a brief period due to heavy rain overnight. Although no animals were housed in the room it was being closely monitored following this blip. The need for contingency plans to maintain environmental conditions on all sites was noted and the NACWOs confirmed that backups were in place and no animals had been affected. Apart from this immediate issue there was nothing to report.

Animal Facilities update

18/113 The REDACTED had submitted proposals for consideration by REDACTED and a response was awaited.

Draft Annual Report

(Received paper AWERC 18/27)

18/114 The Committee made a number of suggestions for additions to the Annual Report. These included education, the 3Rs (reduction, refinement and replacement) continuing professional development meeting at the University, attendance at the RSPCA Lay Members' Forum and University oversight of non-regulated work overseas. It was also suggested that the details relating to the number of PPLs considered should be edited to clarify the ongoing flow of work. ACTION: PELh, NVS and administrator.

PPL applications and reviews

Application A356

18/115 The NVS advised that the application was concerned with early development and diagnosis of type II diabetes and would involve the use of genetically altered mice capable of developing diabetes if maintained for more than 16 weeks of age. However, in the proposed work, animals would be used at pre-diabetic period thus minimising potential welfare issues. The applicant gave a presentation detailing the difficulty in providing early diagnosis of type II diabetes and its impact on vasculature. The Committee was told that an appropriate model of genetically altered (GA), diabetic, mice would be used for the studies and that, apart from breeding GA animals and sampling, all experimental work would be done with animal tissues after humane killing under ASPA Schedule 1. During discussions the Committee considered study intervals, the respective ages of the breeding and study animals, randomisation and blinding, the possibility for sharing animal tissues and the arrangements for monitoring and care of the animals. A NACWO confirmed that additional measures would be put in place to provide readily accessible food and water to the animals. Additional matters discussed included the possibility of the use of a larger species prior to pre-clinical application; potential methods for collection of markers; risk stratification and whether data

would be collected for control animals. It was suggested that the applicant should re-visit the statistics to ensure that sufficient animals would be used to ensure statistical significance and that the lay paragraph should be revised to be clear about the use of Schedule 1, the phenotype of the GA animals and the number of animals to be used. ACTION: NVS to assist with revisions.

Application A357

- 18/116 The applicant gave a presentation of the work which was concerned with brain cancer and explained that considerable work had already been undertaken with cell culture systems that had led to the need for further studies in a whole animal in order to study the movement of cancer cells through the body. The Committee was not persuaded however that it could support the application in its current form. Discussions included the need for typical examples for the power calculations; animal welfare score sheets that would be relevant to each of the protocols separately; clear explanation of the use of immunocompromised mice, irradiation and reconstitution of bone marrow; and in general there was a call for greater clarity throughout the application. The Committee also raised the possibility of developing the application as a phased study to gain evidence on the hypothesis before proceeding.
- 18/117 It was agreed in conclusion to ask the applicant to liaise with appropriate colleagues and the NVS to re-cast the application. Due to the planned migration to the new system this should be done using the new Animal Scientific Procedures e-licensing drafting tool and the revised application should be submitted to the meeting in September. ACTION: NVS to assist with identifying PPL holders who would be able to contribute to the revisions.

Section 5B review S5B40

- 18/118 The applicant provided an update on the status of the work at the end of the project. The importance of ongoing application of the 3Rs was stressed by the applicant who acknowledged that the research, concerned with spinal injury, would not provide good results if the animals were not healthy and well cared for. Two examples of ongoing refinements that had been applied were faster surgery to improve recovery and free access to exercise. It was suggested that these examples should be added to the report along with the work (pre-publication) that had been done in conjunction with the RSPCA regarding spinal cord injury research that would be shared with other establishments.
- 18/119 The Committee was told about changes to the arrangements for Section 5B reports and the Committee felt that the report form (marked as "Preliminary") could be improved. ACTION: Applicant to amend the report, Administrator to submit to the HO.

Review of Terms of Reference oversight

(Received paper AWERC18/25)

18/120 Members were invited to consider the Committee's terms of reference and the

way in which it discharged its remit, and to send suggestions, such as possible topics for inclusion/discussion, to the NVS and administrator. ACTION: All.

Harm benefit analysis, improving PPL applications

(Received paper AWERC18/22)

18/121 There was some discussion around a question posed by the Chair "how can the Animal Welfare and Ethical Review Committee help project licence applicants improve the quality of a draft and the presentation to the committee"? The PEL holder proposed that this and the ethics case study could be addressed in a short supernumerary meeting. ACTION: PELh, NVS and administrator

Schedule of business

(Received paper AWERC18/26) 18/122 The updated schedule of business was received for information.

Date of next meeting

18/123 Friday 20 September at 1000. Members were asked to note the change of date.