

University of Leeds, Animal Welfare and Ethical Review Committee

Minutes 15 June 2021

12 members of the Committee joined the meeting with one person in attendance.

Minutes

20/98 The minutes of the meeting held on 8 April 2021 were received and approved.

Matters arising

20/99 There were no updates regarding Min/20/82 to bring to the Committee's attention.

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

(Received paper AWERC/20/22)

20/100 A significant overuse of animals had occurred on a project and been reported by the project licence (PPL) holder as soon as it came to his attention. Work on the protocol had been suspended, a report had been submitted to the Home Office (HO) and a response was awaited. Animal welfare had not been compromised. Possible actions were discussed that would minimise such risks and it was proposed that the Committee should carefully consider animal numbers in relation to applications involving targeted work in future. The IT system would enable licensees to keep track of the number of animals being used on each protocol, but only once detailed protocol techniques and all licensees' training data had been entered.

20/101 The need to be proactive and to demonstrate what was being done to anticipate and prevent issues from occurring was agreed. The PEL holder would consider options and write to licensees. Action: PELh.

20/102 Redacted would remain on long term sick leave at least until August. The PEL holder had met with two of the NACWOs who had confirmed that, after a short period of adjustment, the units were running in a stable manner with no general or animal welfare concerns. It was stressed that the NACWOs were free to approach the NVS or PELh with any problems. The Chair endorsed the PEL holder's comments and the Committee's thanks to the two NACWOs were recorded.

20/103 The NVS confirmed that three PPLs had been granted including one short duration licence considered by the Committee via correspondence which would be discussed in full under Agenda item 8 (A371). Four more PPL applications were known to be in draft.

20/104 Issues relating to the length of PPL applications and the time taken to process them, including the impact on AWERC review, were noted. The NVS advised that these matters had been raised with the HO by individual establishments and stakeholder groups as being an acute problem. However, it was expected that the process would remain the same with communication on applications continuing to take place within the Animals in Scientific Procedures e-licensing system, ASPeL.

20/105 Meetings had recently taken place with the Animals in Science Regulation Unit (ASRU) presenting changes to the way they would regulate and engage with the scientific and wider community in future. Changes, reported to be in part driven by internal HO reorganisation and in part by concerns over lack of consistency, transparency and assurance would take place from 5 July. ASRU compliance assurance would be separated from advisory functions. Stakeholders had been

informed that changes would include audits, the investigation of potential cases of non-compliance and the construction of dedicated action plans for establishments. A profile would be developed for each establishment and some establishments could go into “special measures”. However, it remained unclear what “special measures” would entail, and what conditions would apply to going in to or coming out of “special measures”. Establishments would not be assigned to a specific HO inspector, but requests for advice would be submitted via new contact helplines established to triage queries in order to develop and ensure a consistent response. PPL applications would feed into a “taxi-rank” style system for consideration. Concerns that direct communication with the inspectorate would be lost from 5 July had been expressed by the scientific community as had concerns over the lack of consultation, particularly since the inspectorate provided such a valuable source of advice and assurance.

20/106 It was agreed that it would be helpful for the next few meetings to add a separate item to the Agenda to receive updates regarding the ASRU changes. Action: Administrator to update the Schedule of Business.

20/107 The NVS agreed to share the ASRU Change Programme Stakeholder Presentation with the Committee. Action: NVS.

Named Animal Care and Welfare Officers’ (NACWO) Report

(Received paper AWERC/20/23)

20/108 A NACWO advised that flexibility in sharing staff between sites would help to cover work following the recent resignation of one member of unit staff until a decision on a replacement had been received. Since adequate staffing was important for animal welfare the AWERC would provide support if needed.

University of Leeds Biomedical Services Committee Report

(Received paper AWERC/20/24)

20/109 User group meetings had taken place in November 2020 and April 2021 with the next meeting due to be held in July. During the early part of the pandemic some initial problems with contemporaneous records had been experienced while animal records were being added to the IT system, and there had been some complaints related to this. However, these had been resolved with the roll out of the IT system once researchers had been trained in its use. Concerns had also been raised about delays experienced in the granting of new PPL applications by the HO, and the impact on the continuation of work as well as on the maintenance of lines of unique genetically altered mice. Existing procedures in place for multiple transfer of animals to and from conventional facility to [Redacted] for imaging and surgical procedures had been causing some concerns with regards to flow of work. The procedures had been reviewed and a new SoP was now in place. Users from [Redacted] had requested if the standard of the rodent surgical facility on the conventional side of [Redacted] could be raised to a similar level as on the clean side or in [redacted]. This would require a significant investment on the part of [Redacted].

Animal Care and Welfare Group Report

(Received paper AWERC/20/25)

20/110 After a long period, the Group had been re-started in May. Moving forward the NACWOs planned for the Group to involve research users and provide opportunities to share refinements and other subjects of interest relating to animal care and welfare between users.

20/111 The ability of staff to participate in online training was welcomed and noted as a demonstration of the technical staff contribution to the culture of care.

Project licence application A371

20/112 The application to continue breeding and maintenance carried out under a previous project which was approaching its expiry had been submitted following expedited review by the Committee. Animal numbers had been reduced following discussion between the HO inspector and applicant, and the licence had since been granted. Two further applications were being prepared to include the research protocols following advice from the HO inspector. These applications would be submitted to the Committee in due course and when granted an amendment to the breeding and maintenance PPL would also be submitted to increase its duration up to 5 years and increase the number of animals to meet requirements for the research work.

20/113 Following a presentation by the applicant which provided an overview of the three proposed licences discussions included the reasons for splitting the work; non-harmful phenotypes of the animal strains; high welfare of animals under the previous project; and use of animals for in-vitro studies. The complexity and length of applications with no clear animal welfare gain and concerns in relation to ASRU changes were also discussed. The applicant was asked to consider adding information to the lay summary to provide details of the type of breeding lines.

Project licence application A374

20/114 The applicant provided background to the project, which would start with non-animal studies followed by an in-vitro step, working towards finding new drugs to meet clinical need. The licensee sought to publish negative as well positive results from this research in order to identify successes that would lead to further study. Collaboration with external institutes with greater expertise were explained as were approaches to minimise stress to animals including environmental considerations and the importance of exercise. The Committee was told how the research had drawn from the human patient experience in order to refine protocols in mice and reduce adverse effects. However, it was noted that human studies would often drive the need for further studies in mice.

20/115 Discussions included phenotypes; monitoring; welfare assessments and enhanced quantitative scoring sheets based on human findings; the potential for sudden death of a small number of animals under a severe protocol (<1% of animals on the protocol) and how this could be minimized or avoided; plus the likely experience of those animals.

20/116 It was agreed that an academic member would provide example score sheets and that the NVS would assist the applicant in making changes to the application which could be submitted to the HO subject to agreed modifications. Action: member and NVS.

Review Schedule

(Received paper AWERC/20/26)

20/117 The review schedule was received for information.

Schedule of Business

(Received AWERC/20/27)

20/118 The Schedule of business was received for information.

Date of next meeting

20/119 The next meeting would be held on Wednesday 28 July at 1400 on Microsoft Teams.