

University of Leeds, Animal Welfare and Ethical Review Committee

Minutes 21 March 2022

Ten members of the Committee joined the meeting (two members for part of the meeting). The Establishment Licence (PEL) holder agreed to chair the meeting since the Chair had given apologies.

Minutes

21/77 The minutes of the meeting held on 17 January 2022 were received and approved.

Matters Arising

21/78 The appointment of the new PEL holder had been confirmed by the Animals in Science Regulation Unit (ASRU).

21/79 The retirement of a long-standing member was noted and the PEL holder agreed to convey the Committee's thanks to the member concerned in view of their valuable service to the Committee over several years. Action: PEL holder.

21/80 CPD arrangements (min 21/56) remained outstanding and the member concerned agreed to follow up on this and report to the Committee at the next meeting: Action: member concerned.

21/81 IT arrangements (min 21/63) had been delayed due to a recent incident affecting the University. The facilities' interim manager agreed to follow up with IT and provide an update in the Named Animal Care and Welfare Officer's (NACWOs') report for the next meeting: Action: Facilities' interim manager and the member concerned.

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

(Received paper AWERC/21/18 and PEL holders' Forum correspondence)

21/82 The NVS reported that a recent request for the appointment of a new NACWO, arising from the interim facilities' management arrangements, had been confirmed by ASRU.

21/83 The NVS/Named Training and Competence Officer (NTCO) had been working with one of the NACWOs with the aim of handing over the NTCO role when appropriate.

21/84 The compliance issue reported to the Committee in March 2021 (min 20/100) had been resolved without any further action being required of the University or the individuals concerned. An email from the ASRU compliance team in relation to the Standard Condition 18 (SC18) report notified on 17 November had been received but a response was still awaited regarding the report submitted on 8 February. Two further SC18 reports had been submitted more recently and quickly resolved with no further information requested and no action necessary.

21/85 Further meetings regarding the ASRU change programme had been held during which ASRU had presented their progress. Following these meetings, the Laboratory

Animal Science Association PEL Holders' Forum, representing a broad range of animal research establishments and organisations, had written to Ministers, the Chief Veterinary Officer and Chief Scientific Advisors to express widespread concerns about the ASRU change programme. The Committee was told that ASRU had been delivering lengthy presentations with limited or no opportunity for discussion, input, or challenge. The Committee was told that the main areas of concern for the University were likely to be that:

- new project licence (PPL) applications for basic research could take 9 months to receive ASRU approval;
- none of the inconsistencies previously known to ASRU had been addressed or resolved;
- ASRU resources, and Inspectorate staffing levels, were becoming a serious issue;
- there was some uncertainty regarding what would be required for ASRU audits and the potential impacts/outcomes of them;
- future routes of engagement would be separated between the new Policy function, when established, and ASRU.

21/86 During discussion concern was expressed regarding the resignation of the RSPCA Chief Executive from the ASRU change programme steering committee, it was noted that meetings of this steering committee had been announced at very short notice, inevitably affecting some members' ability to attend. It was anticipated that the main change to affect the Committee would be the introduction of an Animal Welfare and Ethical Review Body (AWERB) assessment report that ASRU would consider before looking at a new PPL application. PPL applications would only be considered if the information provided in the AWERB report was found to be satisfactory and if not, the application would be returned. The report template and requirements for its use are expected to be received by the end of March with changes expected to take effect from the end of April.

21/87 The Committee was told of plans for closure of the REDACTED facility, announced with a 2023 deadline, and that senior Faculty managers had begun consultation with unit staff and researchers.

21/88 Committee membership discussions had been taking place with the PEL holder and would be shared with the Committee in due course.

Named Animal Care and Welfare Officers' (NACWO) Report

(Received paper AWERC/21/19)

21/89 The NACWO reported that unit staff were facing a period of uncertainty due to the planned closure of the REDACTED facility and that one to one discussion with staff and fact finding had been taking place. The Committee was given assurances that the NACWOs' priority would be to ensure that there would be no animal welfare issues as the plans moved forward. During discussions the Committee was assured that any ASRU requirements for registration and de-registration of animal rooms would be routinely addressed. However, concerns were raised by members regarding the extremely short time-frame for the closure and the evident lack of understanding,

from those driving and managing the process, of the complex legal and regulatory requirements underpinning animal research. The importance of ensuring that NACWOs on both sites would be involved in discussions regarding how and when animals could be moved was stressed. Members also raised the importance of arrangements being made to ensure that associated equipment and lab space would be in place and that staff wellbeing should be considered to be as much a part of the closure plan as the potential for disruption to research work. A joint user-group meeting had been arranged to facilitate communication between researchers across sites, with a view to obtaining accurate details of current animal research use and associated requirements. A member advised that the challenge would be in understanding what people really need and making the infrastructure and kit available to all the people who need it. A member stressed that all the people who need to be consulted and involved in the practicalities should be involved at an early stage. It was felt that some spending would be necessary to make the move happen and there was some concern over the impression that had been given to indicate that there would be little funding available for this. The PEL holder agreed to speak to the two REDACTED concerned to flag up the complexities. Action: PEL holder.

- 21/90 Work was ongoing to provide the documentation likely to be required for future ASRU audits. This would involve combining existing Standard Operating Procedures (SOPs), reviewing and updating them, drafting new SOPs, related Direct Observations of Practical/Procedural Skills assessment sheets (DOPS) and other documentation as necessary.
- 21/91 Outline plans for arranging researcher seminars for unit staff had been agreed. The NACWOs were now working out how to fit these into the working day and would liaise with researchers to get them up and running.
- 21/92 There had been no animal welfare issues to report.

Report from the REDACTED veterinary surgeon

(Received paper AWERC/21/20)

- 21/93 The Committee received the report from the veterinary surgeon at REDACTED. The NVS advised that the REDACTED veterinary surgeon was employed as a consultant to advise on the health, welfare, and treatment of commercial pigs. Inspections took place twice a year, based on AHPA requirements rather than ASPA, and the vet remained in close contact with the manager and staff at REDACTED between visits. Some non-regulated dietary work was being done at REDACTED and there had been some interest in doing some work under ASPA which would involve blood sampling. Such work would require licensing under ASPA and if licences should be approved and granted, a NACWO would be appointed to oversee this work and the animals involved would come under the jurisdiction of the NVS.

ULBSC Report

(Received paper AWERC/21/21)

- 21/94 The user group representative reported that several REDACTED users were only just

beginning to realise the likely impact that closure of the REDACTED facility would have on them, with concerns relating to additional pressures on the facilities, such as increased difficulty in booking operating theatres, already identified. As mentioned during discussion of the NACWOs' report (min21/89), the user groups would be reaching out to research users to understand their existing research needs. Levels of use had not yet returned to pre-pandemic levels and this was thought to link into ASRU delays in granting PPL applications.

Speaking up

(Received paper AWERC/21/22)

21/95 The mechanisms currently in place at the University were briefly explained and the Committee noted that the University's whistleblowing procedure stated that people wishing to "whistle blow" should contact the REDACTED, who would be an appropriate contact in this instance as PEL holder. It was noted that most of the Home Office Liaison, Training and Information Forum members who had responded to the request for information about speaking up processes had similar arrangements in place. The Committee discussed the few ideas presented in the paper and it was felt these would not be appropriate to the University. Members welcomed the detailed animal welfare reporting procedure and were not in favour of making changes to this since current arrangements were reported, by research members, to have been working well. The NVS confirmed that any matters of significance, including those relating to speaking up, were already included in the regular PELh, NVS and NACWOs' reports. It was proposed that speaking-up should be included in the annual report, if it would be possible to do this without identifying individuals, as appropriate.

Annual statistical report

(Received paper AWERC/21/23)

21/96 The annual statistical report was received for information and it was noted that 74% of all regulated procedures undertaken at the University, under the Animals (Scientific Procedures) Act, had been reported as being within the sub-threshold and mild categories. Brief discussions were concerned with the type of animal research undertaken and species being used at the University. Members were directed to the University's animal research web pages for further information on specific projects and it was felt that cross-site meetings would help researchers to learn from each other about the work being done throughout the University. Action: ULBSC representatives to arrange meetings with researchers/groups as appropriate.

Project licence applications

A381

21/97 The Committee considered the presentation that had been circulated prior to the meeting and the general view was that the application required significant further work. Discussions were concerned with repeated interventions and there was some concern that these would increase the severity which could have been underestimated. It was suggested that a table with all the numbers would be helpful, particularly where multiple samples would be taken. The applicant was asked to work on refining the application to incorporate suggestions received from members before and during the meeting and to make it more concise.

21/98 The applicant should be invited to present again at the next meeting with a request for clear information on the ethics and welfare aspects to be provided in a more succinct presentation. Action: NVS to liaise with the applicant regarding changes, NIO to provide the applicant with meeting details.

A382

21/99 During a presentation of the work by the applicant the Committee received information about the methods to be employed; the basis of experimental design; block randomization and blinding where possible for researchers assessing the effects of the treatment; the prospective severity of the protocols and analysis of the results. Full details of pain scoring were provided with the applicant explaining that animals would be monitored closely for pain over a period of 5 days following procedures. Information about each of the three Rs was provided with comprehensive in vitro evaluations being used to inform experimental design.

21/100 The Committee raised and discussed questions with the applicant around the control group; the analgesia animals would receive; the type of randomization to be used; dose levels; the anticipated change between baseline controls which would be measured daily; potential rare complications; and the possibility of using skin glue or clips for welfare reasons to avoid chewing of sutures. The most important days were reported to be days 1 and 2 and it was suggested that it would be important to determine which day should be selected for the primary outcome. Members suggested that, due to the likelihood of the Home Office (HO) asking about adverse outcomes, it would be helpful to provide data to support the application, such as existing data regarding grimace scoring after laparotomy.

21/101 The applicant was asked to incorporate suggestions received from members, before and during the meeting, after which the application should be ready to submit to the HO. Action: NVS to liaise with the applicant regarding changes and confirm the final draft on behalf of the Committee prior to submission to the HO.

Schedule of business

(Received AWERC/21/24)

21/102 The updated schedule of business was received for information.

Other business

21/103 A request for retrospective ethical approval of non-regulated work undertaken outside the UK had been received. The University's position on this was clear in that no such undertaking would be given in retrospect.

Date of next meeting

21/104 The next meeting, planned to take place at 1400 on Monday 16 May 2022 on MS Teams, would be rearranged. Members would be advised of the new date in due course.