

Meeting:	Animal Welfare and Ethical Review Body (AWERB)		
Date:	23 March 2022	Time:	13:30 – 16.30
Location:	Microsoft Teams		
Members present:	AWERB Chair Deputy Chair Establishment Licence Holder Named Animal Care and Welfare Officers (NACWO) Two Named Veterinary Surgeon (NVS) Named Information Officer (NIO) Chair of Biomedical Research Facility (BRF) User Forum Non-Establishment Ethics Review (NEER) Officer Personal licence (PIL) holder representative Four members with relevant research experience Independent, external lay members Statistician		
In attendance:	Research Integrity and Governance (RIGO) officers, AWERB Secretary		
Minutes:	RIGO Officer		
Acronyms	AWERB – Animal Welfare and Ethical Review Body BRF – Biomedical Research Facility ECR – Early Career Researcher FEO – Favourable Ethical Opinion HOLC – Home Office Liaison Contact NASPA - Non-Animal in Scientific Procedures Act NACWO – Named Animal Care and Welfare Officer NEER – Non-Establishment Ethics Review NIO – Named Information Officer NVS – Named Veterinary Surgeon PILh – Personal Licence (holder) PPLh – Project Licence (holder) PELh – Establishment Licence (holder) RIGC – Research Integrity and Governance Committee RIGO – Research Integrity and Governance Office SAGE-AR – Self-Assessment for Governance and Ethics – Animal Research URIC – University Research and Innovation Committee		

Agenda Items:

Item #		Action
1.	<p>Welcome and Apologies The Chair of AWERB welcomed all committee members and introductions were made. Apologies were received from: Head of RIGO, RIGO Officer.</p>	<p>Apologies for absence to be sent to Chair in advance of meetings. (ALL)</p>
2.	<p>Approval of minutes and Update on actions from previous meeting (26th January 2022) Minutes of the previous AWERB meeting (held on 26/01/22) were circulated following the meeting, and are to be revised off-line following comments from the NACWO. The revised version will be circulated before being approved and uploaded to the BRF website and made publicly available.</p> <p>Action log An update was provided on ongoing and completed actions (items references from previous minutes as per action log).</p> <p>4. The new Self-Assessment for Governance and Ethics in Animal Research (SAGE-AR) platform, and subsequent NASPA and NEER processes are being reviewed and tested and will update later in meeting. Items 6iv and 6v are linked to this and will be included in this discussion.</p> <p>4i. Development of Induction pack for AWERB members. Members have submitted some materials and NACWO suggested inclusion of those given at recent external training, so they will be included. Carried forward and AWERB will be updated at next meeting.</p> <p>6iv. Further guidance for NEER process being developed. Linked with 4. Tabled for later in the meeting.</p> <p>6v Raising awareness to Faculty on Ethical review at the level of the Intention to Bid form. Linked with 4. Tabled for later in the meeting.</p> <p>7iii Update with progress on purchase of a database for the BRF: previously looking at 5 options and have now chosen one which has been demo'd and seen by the Chair at the Technicians in BRF. In discussion with Procurement, IT and Legal, and will hopefully sign a contract in next few weeks.</p> <p>8 Concordat Action Plan document and 8i Commitments to concordat tasks to be allocated/volunteered among AWERB members. Action Plan has not yet been created. To be discussed later in meeting.</p> <p>10. AWERB minutes to be made available to the public. NACWO confirmed that September and December 2021 meeting minutes now uploaded and publicly available.</p> <p>Discussion then followed about possibility of returning to face-to-face meetings, and whether a morning training session – for example inviting UAR to present – could be held in combination with an afternoon physical meeting. Suggestions were made about opening the morning training sessions to members of NASPA and the BRF User Group.</p>	<p>Minutes from 26/01/22 to be re-circulated (RIGO Officer)</p> <p>Minutes from 26/01/22 to be uploaded to BRF website (NACWO)</p> <p>Induction pack update at next meeting (Chair)</p> <p>Ongoing (NACWO to provide updates at each meeting)</p> <p>On-going</p> <p>Complete</p> <p>Update at next meeting (Chair)</p>

	<p>13. Outcome of institutional NC3Rs self-assessment. Online assessment could not be completed earlier due to ‘bug’ at NC3Rs end, but this has now been resolved and outcome will be presented later in meeting. Institutional 3Rs strategy document (action 14).</p> <p>15. ASRU audit: in addition to the items on the ASRU audit Action Log, there is now a new requirement of providing an assessment report for every new project licence or amendment to demonstrate that it has been reviewed by the AWERB, and subject to due consideration and due diligence has been paid.</p> <p>Update on ASRU visit – there will be no physical visit this year, but they require the Establishment to submit a portfolio of evidence by the end of the year, where we will outline our systems and processes to demonstrate compliance. The activities we have already started will very much support the gathering of that evidence.</p> <p>ASRU updated guidance documents were due out at end of February, but have been delayed March, so we will continue with our existing processes until more guidance is released. Each Self-Reported Non Compliance and SC18 now require submission of a CAPA Report (Corrective and Preventative Action). The timing of this submission needs clarification from ASRU.</p>	<p>On-going - future updates to be shared when released & ASRU audit items to be brought to AWERB as necessary (Chair)</p>
<p>3.</p>	<p>Discussion: papers from Named Persons, NASPA Chair, NEER Officer</p> <p>Reports submitted ahead of meeting and shared with AWERB members via Sharepoint site. All members to review reports prior to meeting.</p> <p>NACWOs’ Report</p> <ul style="list-style-type: none"> i. Condition 18 event report of adverse events in oncology study involving euthanasia of 79 mice. Waiting for final pathology report –and will follow up. May be related to drug being used – first time of use. No update from drug company yet. <p>PILh in attendance. Issue developed 2 days after injection, so not an immediate reaction, but based on clinical symptoms and pathology, what may have happened was potential hyperstimulation of immune system with cytokine storm with capillary leak and pulmonary oedema. Massive lymphoproliferation may have produced round cell tumour (haematopoietic origin) as appears in pathology report. Distressing episode for all, and concerns about welfare of staff were raised. Chair reached out to offer support of AWERB and is happy to discuss issues with those involved.</p> <p>NVS’s Report</p> <p>Last report from Interim NVS.</p> <ul style="list-style-type: none"> i. Viral contamination from UK supplier meant that animals had to be euthanised on arrival. Issue was concomitant to adverse effects in oncology study described in NACWO report, but PCR confirmed oncology animals were not contaminated by virus from supplier. 	<p>Read Named Persons reports before next AWERB meeting (ALL)</p>

	<ul style="list-style-type: none"> ii. Zebrafish facilities to be developed with ongoing liaison with researchers and suppliers. iii. Discussed and reviewed procedures and care for synaptic plasticity project with researcher. <p>Question about number of rats euthanised. Pregnant females were euthanised as part of normal procedure, and foetal rats used in studies as previously planned.</p> <p>The NVS was thanked for their contribution and service to the AWERB.</p> <p>NIO Report</p> <ul style="list-style-type: none"> i. Recent condition 18 (discussed elsewhere). ii. MRC Working Grp recommendations for inclusion of both sexes in experiments involving animals, tissues and cells. Links to report and survey provided. AWERB members encouraged to complete survey, which has also been shared with NASPA members and will be shared more widely in University. Stance is likely to be taken up by other Research Councils. Issue will be tabled for discussion by AWERB at a later date. iii. Various training and meeting opportunities shared. iv. Speciesism article by John Meredith of UAR highlighted. <p>NASPA Chair's Report</p> <ul style="list-style-type: none"> i. Number of applications and amendments reported. ii. TORs revised. iii. SOPs for dog use in teaching – review with view to developing others for other species. iv. Revised SAGE-AR and NASPA process to be discussed later in meeting. <p>NEER Chair's Report:</p> <ul style="list-style-type: none"> i. One application for review. Local ethical approval and funding information provided. Work being performed in Philippines, but would come under standard veterinary practice in the UK, with no extra samples being taken. ii. Sharepoint site requires NEER folder for sharing with AWERB members. <p>Question about why work was being done Philippines – focus of work to provide rapid diagnostics for deployment in low to medium income countries.</p> <p>Question about review process – since it is 'non-ASPA', does it then move to NASPA for review? Do we need to extend process to include NASPA or have extra process in NASPA for work done elsewhere. Discussions ensued but based on current processes, members approved the project.</p> <p>ELH Report None given.</p> <p>NTCO:</p>	
		<p>Folder added to sharepoint (Chair)</p>

	<ul style="list-style-type: none"> i. Training given to researcher for IP injections & now deemed competent. ii. Reassessments for schedule 1 – cervical dislocation of mice. iii. Long term anaesthesia training ongoing. iv. All assessments done using DOPS. <p>Question about training for taking blood from tail veins using 3 attempts. Dep Chair suggested models used in Vet School should be used for training. Researchers should start with rodent tail models in Vet School rather than cadavers in BRF.</p> <p>Comment that all mice are not the same; there are important strain differences so limiting. If using one attempt at bleeding may result in more animals being used in a study.</p> <p>HOLC Report: Numbers reported and will be uploaded to website. Rat returns have a mistake due to pups arriving same day. Will be corrected before statistics are published on website.</p> <p>BRF Users Group Report:</p> <ul style="list-style-type: none"> i. New ASRU Audit processes: 2nd meeting researchers from Oxford & UCL came to talk about their own experiences of audit. Oxford named person gave access to their audit documents to help Surrey’s process. ii. New zebrafish facility highlighted. Question around how they may contribute to 3Rs. Mention of non-regulated vs. regulated animal research, most of the research is carried out before the animals reach developmental stage of free-feeding and swimming. iii. Question around 3Rs assessment tool from NC3Rs suitability for small research groups. Request for volunteers with larger research groups to complete tool, and suggestion to feed back to NC3Rs about issues with smaller groups completing the assessment tool. 	<p>Contact details to be shared with BRF team (Deputy Chair)</p> <p>Update and upload stats to BRF website (HOLC)</p> <p>Feedback to be given to NC3Rs (User Forum Chair)</p>
4.	<p>PPL project amendment: Targeted Tumour Therapy – Treatment of Orthotopic Mammary Gland Tumour</p> <p>Presentation given by PILh representative of licence holder. Amendment involves adding a new protocol and amending an existing protocol to allow increase volume for gavage. Justification as to why needed was given and relates to lack of peptide testing in a ‘model’ with full immune system, or when the tumour in the right ‘microenvironment’.</p> <p>New protocol was described in a step-by-step manner, with emphasis that treatments could be delivered by several routes, starting with the least invasive. Protocol could last maximum 274 days, but few experiments will last that long. Both scientific and humane endpoints are in place. Power calculations were used to give minimum number of animals required to answer research question. Adverse effects described, with humane endpoints explained.</p> <p>Increased volume for use in oral gavage to requested for another protocol. Volume change was required due to need to deliver at</p>	

	<p>working dose. Consideration was given to using oral route of dosing rather than gavage, but this would require more animals.</p> <p>Questions around:</p> <ol style="list-style-type: none"> i. Gavage twice a day for 6 weeks - would have significant impact on animals, and whether this represents mild pain and distress. Repetitive administration has cumulative effect on severity. ii. Humane endpoints difficult to follow – reference made to clinical scoresheets later in the licence. iii. Protocol recorded as moderate as tumours are growing in the animals – retrospective severity to be reported based on whether tumour grows or not, and whether additional procedures add to this. Researcher and NVS to discuss reporting actual severity offline. iv. Consistency of numbers between presentation and amendment document. v. Frequency of checks of animals that have undergone procedures, and whether 24 hours may elapse before animal is killed to prevent further suffering. vi. Number of animals undergoing surgery at any one time point. <p>Four members submitted questions; not all were asked in time allowed and the remainder will be shared with the Licence holder with responses sought by email. Final revised copy of updated Licence will be circulated for approval by email.</p> <p>Chair encouraged all to submit questions or comments for each licence application or amendment.</p>	<p>Further queries/approval to be given by email (AWERB Chair & PPL)</p>
5	<p>Comfort Break</p>	
6	<p>Culture of Care & Application of the 3Rs</p> <ol style="list-style-type: none"> i. Update on NC3Rs self-assessment, the formation of Concordat working group and an institutional 3Rs strategy <p>Chair gave presentation on outcome of NC3Rs 3Rs assessment tool. Six thematic areas, Leadership, People, Research and Infrastructure, Experimental Design and Reporting, Training, and Publications and Wider Dissemination. Previous Chair and Named Persons and Licence Holders inputted into the tool in November 2021. Each thematic area represented as points on organogram. Some scores are at 40-60%, one area ranked poor, with overall score of fair.</p> <p>Message is that we have some work to do. Chair has seen one other Institute's scores. They were comparable, apart from the poorly scored theme.</p> <p>Questions and comments around benchmarking – both in relation to other Institutions and internally to how Surrey improves as an establishment.</p>	

	<p>done. Involve NASPA committee in this discussion and activities, to feed into the report.</p> <p>Reminder that Concordat obliges signatories to talk about harms and limitations as well as benefits.</p>	<p>Action Plan/Task allocation required (Chair/NACWO & Comms team member)</p>
<p>7</p>	<p>Ethical review of projects falling outside ASPA at the University</p> <p>i. Update on revised Self-Assessment for Governance and Ethics in Animal Research (SAGE-AR) and NASPA forms</p> <p>SAGE-AR been reviewed to ensure it captures all animal information needed to direct researchers to appropriate ethical review process, if it is required. The NASPA ethical review forms have also been revised and updated. Small working group has fed into revisions.</p> <p>NASPA and RIGO working together to work out how best decide how to review. Concurrently, University is procuring Ethics Management platform, primarily for use by the University Ethics Committee, which will in time, will facilitate automated submission, review and query process for NASPA activities too. Plan for the new SAGE-AR will go live within the next few weeks, and all relevant documents will be made available on the RIGO webpage.</p> <p>ii. Boundary between ASPA and the Veterinary Surgeons Act</p> <p>Presentation by NVS:</p> <p>Scope of VSA, and who may perform procedures and delegated procedures e.g. Vet, Nurse and owner of animal. This point links to revisions required in 7i. What is not covered by the Act was also outlined (e.g. fishes, invertebrates, wild animals)</p> <p>Scope of ASPA and who may perform procedures e.g. Only PIL apart from Schedule 1 killing. What is not covered also outlined (e.g. invertebrates other than cephalopods, wild animal capture)</p> <p>When thinking about whether an activity is covered under ASPA or VSA, then the focus should be on the purpose of the procedure.</p> <p>Example 1: dog with tumours in their lymph node. Biopsy taken to investigate tumour and identify potential treatment and prognosis vs. biopsy to compare tumour characteristics with human samples. Discussion around what happens when one biopsy is taken, but cut in two, and then used for two different purposes.</p> <p>Example 2: blood sample taken for diagnostic purposes. Residual blood within vacutainer could be used for research purposes, with appropriate ethical review and consent in place (Non-ASPA). If having to take further blood sample for research, that would fall under ASPA.</p> <p>Rules should be established by AWERB/NASPA for size/volume of sample to be taken if to be used for standard of care and any excess for scientific purposes.</p> <p>Home Office advice when asked about whether a study falls under VSA or ASPA, they will always look to purpose.</p>	<p>New process and documents to be updated, uploaded and made live (RIGO Officer and NASPA Chair)</p>

	<p>Gaps in legislation: fish, capture of wild animals for use as pets or Schedule 1 killing.</p> <p>Establishment's ethical responsibility extends beyond UK legislation, and UK boundaries. Emphasised need to look at bigger picture.</p>	<p>Action to explore if guidelines are possible to aid future project review (NVS / NASPA Chair)</p>
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Next AWERB Committee Meeting

25 th May 2022 14:00 – 16:30	Microsoft Teams - TBD
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