

**CONFIDENTIAL MATERIAL**

THE UNIVERSITY OF BIRMINGHAM

ANIMAL WELFARE AND ETHICAL REVIEW BODY (AWERB)

29<sup>th</sup> May 2025 via Teams

MINUTES

25/04-01	<u>Apologies</u>
25/04-02	<u>Minutes</u> The minutes of the meeting held on 10 <sup>th</sup> April 2025 were considered by the Committee and were approved.
25/04-03	<u>Matters Arising</u> 25/03-07-01 <i>Amendment to PPL “Exploring the role and function of fibroblast subsets in inflammatory arthritis.”</i> The amendments have been made, and the application has been submitted to ASRU. 25/03-07-02 <i>Amendment to PPL “Repairing the damaged brain after traumatic brain injury”.</i> The amendments have been made, and the application has been submitted to ASRU.
25/04-04	<u>Chairperson’s Items</u> Additional members of AWERB are being sought.
25/04-05	<u>Verbal Reports from the Director of BMSU, NVS and NACWOs</u> <u>Director:</u> <ul style="list-style-type: none"><li>• PIL refresher training is being provided for BMSU technicians as part of their ongoing CPD.</li><li>• A technician from a local organisation has visited BMSU to learn how we perform anaesthesia and surgery.</li><li>• The UoB Registrar, who is the Establishment’s Named Person Responsible for Compliance (NPRC), is retiring in September 2025. Their replacement is currently PELh at another Establishment, and so the Director of BMSU is working with the individual and the Home Office to ensure a smooth transition.</li><li>• A communication has been received from the Home Office advising that there will be a facilities audit on 14<sup>th</sup> July 2025. The Director of BMSU reassured AWERB that everything is in place and there are no concerns regarding this visit.</li><li>• There has been an incident with a personal licence holder who had performed surgery. The NACWO and NVS advised that the animal had reached the humane end point, and that the animal should be humanely killed. The individual challenged the advice, and the incident was escalated to the Director of BMSU, who insisted that the animal be humanely killed. The PIL agreed and the animal was immediately culled. Due to the severity of this situation, meetings have subsequently taken place with the individual and their Head of Department. Meeting notes have been recorded, and HR have been made aware as this behaviour is taken extremely seriously. The project licence holder will also be made aware.</li></ul> <u>NVS:</u> <ul style="list-style-type: none"><li>• Some aged mice (over 18 months old) have come into BMSU. There were some issues with fighting upon first receipt, leading to some of the animals being separated. They are however now doing well under the advice of the NACWOs and care of the wider BMSU technical team.</li><li>• Some common techniques (e.g. gavages) which are used in BMSU are being reviewed with NACWOs and users to ensure the techniques remain as refined as possible. If users have not undertaken a technique for 12 months, additional refresher training is being provided.</li><li>• The NVS and the Director of BMSU had discussions with an animal supplier regarding biosecurity. It is not practical to quarantine every animal, and the health status of the animal is reliant on the animal suppliers. There are no concerns at present, but discussions are ongoing.</li><li>• A new health monitoring supplier is being considered. As and when the switch is made, there will be overlap in the screening initially to ensure that the results provided by the new supplier are comparable and as expected.</li></ul>

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	<p><u>NACWOs:</u></p> <ul style="list-style-type: none"> <li>• A new batch of tadpoles have hatched, and a batch of young frogs have been moved to tanks ready for use. There is now a self-sustained supply of frogs rather than buying in from external companies. This should ensure that there are no issues with disease and avoids the stress of transporting animals from overseas.</li> </ul>
25/04-06	<p><u>Report from the Fast-Track Procedure</u></p> <ul style="list-style-type: none"> <li>• All fast-track applications are uploaded to Teams for comments by AWERB.</li> <li>• The new Deputy Director of BMSU will be responsible for facilitating applications for the use of animals outside of the PEL.</li> <li>• Advice was sought regarding an individual at the Dubai campus (still legally part of UoB) who wants to use surplus tissue from an overseas third party (ie, the purpose for which the animals underwent procedures is not related to the Dubai campus research), and whether this should be approved by AWERB. Currently, projects involving the use of surplus animal tissue obtained in the UK from animals held under ASPA do not come to AWERB, whereas any animal work overseas does come to AWERB. Following discussion, it was proposed that the individual should complete the use of animal's overseas form which will capture whether a local ethics procedure is being used, what type of research is being undertaken, what the animal's lifetime experience will be and the methods of killing to be used. This will then be submitted via the fast-track process for consideration by the committee.</li> </ul>
25/04-07-01	<p><u>PPL Application for Consideration:</u>  <i>"Autoimmune diseases of the CNS and their treatments"</i>          Summary          The project aims to:</p> <ul style="list-style-type: none"> <li>• Understand how the insulating material around nerves (the myelin sheath) is destroyed by the autoimmune disease multiple sclerosis (MS) and then to identify and screen agents that are reparative or control the associated symptoms of this disease.</li> <li>• An estimated 2.9 million people suffer from MS worldwide with a 150,000 (i.e. 1 in every 450 people) people living with MS in the UK alone.</li> <li>• The symptoms of MS include vision problems, muscle weakness, pain, numbness and tingling, fatigue, dizziness, hearing loss, and speech, cognitive and bladder problems.</li> <li>• At present there are no therapies that reverse the debilitating disease symptoms of MS, as current treatments are palliative and only provide support to the body's natural defence system (the immune system) to fight the consequences of MS rather than tackle the underlying causes.</li> <li>• This project aims to identify and test effective therapeutic agents that have the ability to alter the immune system so as to fight the development of MS, and to test agents that will ultimately protect neurons and prevent nerve cell damage and death, stop the loss of insulating material around nerves (called myelin), and avoid eventual loss of nerve function.</li> </ul> <p>The following points were discussed:</p> <ul style="list-style-type: none"> <li>• The Committee stated that the purpose of Protocols 1 and 2 was clear, however there was a query regarding Protocol 3 and the use of Raman Spectroscopy (RS). It was questioned whether this aligned with the overall aims of the project, or if this was a standalone study to test a novel approach to analysing biomarkers. It was stated that a pilot study would be undertaken to identify biomarkers that correlate with the disease severity in terms of experimental autoimmune encephalomyelitis (EAE) and progression. The biomarkers should be able to indicate whether there is myelin damage or is there just an opening of the blood bone barrier. Nobody has used EAE animals previously, and it is anticipated that using Raman Spectroscopy (RS) will identify a biological signal that corresponds to the key biomarkers that are used to indicate the progression of the disease.</li> <li>• It was queried whether the RS-based measurements will involve longitudinal scoring in the same animals, or whether it will be a terminal measurement requiring different cohorts killed at different time points. It was explained that at present, due to logistics around size and method of attachment, longitudinal studies in the same animal will not be possible. Work is however being undertaken with Chemical Engineering to miniaturise the kit.</li> <li>• Objective 1: Validate the use Raman spectroscopy (RS) to non-invasively detect retinal changes states a Go/No-Go element, and it was queried whether this related to the whole study or part of it. It was confirmed that this relates to whether RS can be used or not.</li> <li>• It was stated that Protocols 1 and 2 have a mandatory step to induce EAE. It then goes on to state that there are various controls which do not have EAE induced, and this needs to be clarified within the document.</li> </ul>

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	<ul style="list-style-type: none"> <li>• It was queried when the rat model had last been undertaken in BMSU. It was stated that whilst the applicant had experience in the model, it was last performed in 2015 and so pilot studies would be undertaken with the support of the BMSU staff in order to re-establish the model in-house.</li> <li>• There were some concerns raised regarding the workload involved and support available to the applicant as these are intensive models requiring a lot of resource. Each animal will need to be reviewed and scored twice a day until the end of the study which is a considerable workload. The applicant acknowledged the amount of resource required and provided reassurance that there will be additional team members in place to support this work. Training will also need to be undertaken by these individuals.</li> <li>• The licence states that the RS work is non-invasive, but there is reference to intercranial bolts. It was also queried whether a severe model was the most appropriate to use for proof of concept if the aim is to prove that RS works in mice. It was stated that tests have already been undertaken in normal tissue, and now there is a need to undertake work in EAE mice to test for disease biomarkers. This needs to be clarified in the application.</li> <li>• There was a query relating to the cannabinoid model in rats and the need to allow them to get to stage 3 where they get hindlimb paralysis even though there is no myelin damage. It was stated that rats don't get myelin damage and it's the opening of the blood brain barrier which causes the paralysis. This needs to be rephrased in the application.</li> <li>• There was some concern regarding what the animals may experience as the humane endpoint is based upon the model progressing beyond hindlimb paralysis (e.g. could there be any issues due to impact on the diaphragm, breathing, bladder and bowel issues etc). It was explained that historically, where animals had been permitted to progress beyond stage 3, the diaphragm, breathing etc had not been affected and the first sign of progression was that the forepaw went limp. However, reassurance was provided that this model has been refined, and whilst scientifically animals do need to remain at a stage where they experience hindlimb paralysis for a period of time, from experience it does not progress beyond this.</li> </ul> <p><b>Decision: The Committee agreed that the application should be amended following discussion between the NVS, BMSU, NACWO and PI and the finalised version to be resubmitted to AWERB with a summary of the changes made.</b></p>
25/04-08	<p><u>3Rs Update</u></p> <ul style="list-style-type: none"> <li>• There have been several tissue requests submitted to BMSU. These have been co-ordinated by the BMSU team to enable tissue sharing across the Colleges, ensuring that post-mortem animal use is maximised.</li> <li>• <b>Sex Inclusive Research Framework.</b> <a href="#">Online resource</a> with <a href="#">accompanying paper</a> on use of male and female animals in <i>in vivo</i> research, including what impact this may or may not have on the numbers required and how to analyse the data appropriately. There is also an interview in the <a href="#">news article</a> that discusses the resource more as well as the use of males and females in research. May be of particular importance to those putting together grants proposals as most UK funders now have the expectation that both males and females will be used as the default.</li> <li>• <b>Togeth3R webinar series.</b> A series of webinars from 3Rs centres across Europe, <a href="#">recordings are now online</a> for all the sessions, covering infection &amp; immunity, oncology, neuroscience and cardiovascular science.</li> </ul>
25/04-09	<p><u>Condition 18 Reports</u></p> <ul style="list-style-type: none"> <li>• There have been no Standard Condition 18 reports or non-compliance reports since last meeting</li> <li>• The non-compliance reported at the previous meeting has been acknowledged by the Home Office and is undergoing their consideration.</li> </ul>
25/04-10	<p><u>Retrospective Review</u></p> <p>There have been no licences that have expired which legally require a retrospective assessment.</p> <p>The UoB retrospective review process for all licences remains in place with the reports uploaded to the AWERB Teams site for awareness.</p>
25/04-11	<p><u>Any Other Business</u></p> <p>One of the lay members has taken a new job and will be leaving Birmingham. Their last AWERB will be July 2025.</p>

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	The NC3Rs AWERB member has taken a new job within the charity sector. The Chair of AWERB thanked the NC3Rs member for all their contributions.
25/04-12	<p><u>Date of Next Meeting</u> - please note the amended dates for 2025. Updated calendar invites have been sent.</p> <p>3<sup>rd</sup> July 2025 via Teams 7<sup>th</sup> August 2025 via Teams 18<sup>th</sup> September 2025 venue TBC 30<sup>th</sup> October 2025 via Teams 18<sup>th</sup> December 2025 venue TBC</p> <p>All will be from 10am until 1pm.</p>

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### GLOSSARY

3Rs	Replacement, Reduction and Refinement
ARRIVE	Animal Research: Reporting of In Vivo Experiments
ASPA	Animals (Scientific Procedures) Act 1986
ASRU	Animals in Science Regulation Unit
AWERB	Animal Welfare and Ethical Review Body
BMSU	Biomedical Services Unit
CNS	Central Nervous System
EAE	Experimental autoimmune encephalomyelitis
NC3Rs	National Centre for the Replacement, Refinement and Reduction of Animals in Research
NCTO	Named Competency and Training Officer
NACWO	Named Animal Care and Welfare Officer
NIO	Named Information Officer
NTS	Non-Technical Summary
NVS	Named Veterinary Surgeon
PEL	Establishment Licence
PI	Principal Investigator
PIL	Personal licence (Procedure Individual Licence)
PPLs	Project licence (Procedure Project Licence)
RS	Raman Spectroscopy
UoB	University of Birmingham