DRAFT

CONFIDENTIAL MATERIAL

THE UNIVERSITY OF BIRMINGHAM

ANIMAL WELFARE AND ETHICAL REVIEW BODY (AWERB)

6th June 2019

MINUTES

Present:

19/06-01	Apologies
19/06-02	Minutes The minutes of the meeting held on 7th March 2019 were considered by the Committee and were approved subject to minor amendments.

19/06-03	Matters Arising There were no matters arising.
19/06-04	Chairperson's Items The licence application from the last AWERB meeting is approved and operational. Birmingham hosted Central AWERB Hub meeting to share best practice and will add value to AWERB. The old West Midlands Hub and part of the East Midlands Hub have now joined to form this new Hub. This will provide a better flow of information across AWERBs. Meetings will be twice per year and representatives from Birmingham will attend.
19/06-05	Verbal Reports from the Director of BMSU and Named Persons BMSU is running well at the moment and there are no reported issues. There will be two new pre-apprenticeship staff joining for training positions followed by a 12-week summer placement. There will be a small amount of Estates work undertaken including fire alarm work, chiller work to control temperature and humidity and the lift is being replaced. Disposable cages will be used on the breeding floor for around 6 weeks. There is also refurbishment of transgenic room. There is an increased number of project licence applications at present. Additional meetings may be needed in August prior to moving over to new system. The old ASPeL system closes down on 31st August 2019 and all of the legacy licences will be transferred over to the new system. Some work is being undertaken with the Web and Communications Team about how animal work can be effectively communicated. The external website needs to be updated and there will be a number of initiatives including 360 video tours of facilities for transparency. The University of Manchester site was given as an example of sharing information: https://www.manchester.ac.uk/research/environment/governance/ethics/animals/
19/06-06	Report from the Fast Track Procedure There were no Fast Track Procedures to be reported.
19/06-07-1	Project Licence Applications *a) Mapping Mechanism for Energy Homeostasis in Rodents* Summary: • The overall aim of this project is to look at why and how we develop diseases related to loss of control of energy balance – principally to study the mechanisms that lead to obesity and diabetes, specifically looking to the role of the fuel sensor PASK • PASK is involved in regulating blood glucose levels and food intake / appetite, but is a difficult protein to study. • The project will induce obesity and diabetes with administration of diets with high caloric value and / or chemical / genetic manipulation. The obesity and / or diabetes will then be reversed using drug treatment and / or alteration of diet regiment.

	The Panel asked what exactly would be happening to the animals. The PI will look at breeding capacity, and blood glucose. They will be kept for no more than 16 weeks, measuring randomly fed mice and doing fasting blood glucose tests and 3-day food monitoring tests. 2nd cohort, looking at injected insulin tolerance. Each mouse will be weighed every week and tissue taken from pancreas and brain to validate excretion. The monitoring of blood glucose was raised, and how tightly this will be monitored? There are spikes in glucose throughout the day, so testing is only undertaken at specific times. Data has already been collected over a number of years. The PI was asked whether telemetry had been considered. It had, but adds additional stress to the animal and is not necessary for this project. It was queried whether there is in-fighting in groups. Animals live within groups but are isolated when needed. If bedding materials are maintained, this prevents any in-fighting. Animals have a 2-day acclimatisation followed by 3-day monitoring. The different end points were discussed. There is no plan on keeping each animal for more than 16 weeks. If blood glucose levels drop below 2, the animal would be culled at a humane endpoint. If mouse goes into coma, the endpoint would be reviewed. The normal range of blood glucose is 14-15 for non-diabetic (highest) and wouldn't normally be lower than 4. There are no estimations of number for protocols 2 and 3, and NC3Rs will provide a list of written refinements for further discussion. Scientific background information mentions a range of techniques that require equipment that may not be able to be accommodated in BMSU e.g. Echo MRI. It was stated that these are not critical for the project. **Decision: Committee has some concerns and further discussions will be undertaken between the NVS, BMSU, NACWO and PI. The project will be recirculated for electronic approval.**
19/06-07-2	*b) Breeding and Maintenance of Genetically Altered Rodents* Summary: • The purpose of this license is to breed rodents with genetic alterations and supply them for work that supports research into understanding treatments of diseases. • This is a service licence has to be renewed every 5 years. • Breeding and maintenance is split into two categories – mild and moderate. The number of animals in the moderate category has been reduced. The majority are in the mild category. Home Office has changed reporting categories, so a number are sub-threshold. • BMSU follow Home Office regulations on efficient breeding of GAAs, and UoB were instrumental in producing the Home Office documentation as an example of best practice. • BMSU has 326 active strains and 452 cryopreserved lines. BMSU has breeding expertise, allows sharing strains across project licences, and have an active and free cryopreservation service provision. • Creation of novel genetic strains in collaboration with the Technology Hub. The Panel asked whether it is possible to work out benefits of Transnetyx (genetic testing company)? There is a lack of failure rate, and results provided within a 72 hour turnaround period. BMSU suitably manage breeding programmes depending upon the research need. Breeding to demand / robust science rather than having to maintain large colonies. Would BMSU consider commercial supply? No. Breed is only for internal supply of animals and sharing of resources across collaborators, but not commercial supplier. Males are vasectomised rather than purchasing sterile males. Continuing with surgical transfer of embryos, as non-surgical methods are not as reliable and it's not appropriate

	Decision: Committee agreed with licence
19/06-07-3	*c) Transfer of PPL from Oxford* Summary • The aim of this project is to better understand a group of human inherited heart diseases called cardiomyopathies. These diseases are caused by genetic mutations in the blueprint of cardiac proteins. • The research will help gain insight in how mutations in a group of proteins can cause heart disease, and will generate mouse models for human disease. • This license has already been granted by the Home Office Inspector at Oxford and the research is currently underway, but it needs to be transfered to UoB. There are four severe protocols, rather than moderate. The Panel had no concerns about the science involved. If application had been drafted at UoB, it would possibly be classed as moderate, but with the proviso that approximately 5% may have unplanned end points due to surgery or cardiac arrest. Oxford will be secondary site. The Panel queried who is responsible if something happens at Oxford? It was confirmed that the Licence Holder is responsible. The difficulty is keeping an overview of the two sites. Would it be useful for the PI to come and report to AWERB? The PI would need to monitor what has been undertaken on the licence so far, and there should be a reporting condition on the licence. **Decision: Committee agreed to transfer of licence, and PI will present to AWERB once relocated to UoB**
19/06-07-4	*d) Role of Cellular and Molecular Therapies in Liver Injury* Summary: • There is a large clinical unmet need in liver disease, for which cell therapy offers new possibilities • Cell therapy has potential to help reduce scarring in liver disease, reducing liver inflammation and also contribute to replacing liver cells. • The project will provide important data that improve the action of cell therapy alongside our understanding of how cells exert their benefits. This will underpin new clinical trial submissions to the MHRA. The last licence was applied for 5 years ago and this licence has since been refined. NC3Rs asked whether there is a suitable replacement e.g using human samples of liver. They are developing liver slice samples, and use samples which are unable to be used for transplant. This would be useful as an alternative option, but does not allow for in vivo analysis. The PI needs to address randomisation and refining. Refinements have been made but need to be made more explicit. The protocol needs to explain why only single sex animals rather than mixed mouse groups, and any side effects. Different protocols have different weight loss end points. This needs to be tidied up and BMSU can provide standard wording. General anaesthesia is used for general imaging. Re-imaging wouldn't take place until the animal fully recovered (48 hours) and maximum of 6 imaging events. All liver disease is immune-mediated, not alcohol related. **Decision: Committee agreed that further discussions will be undertaken between the NVS, BMSU, NACWO and PI. The project will be recirculated for electronic approval.**
19/06-08	Matters relating to the 3Rs The experimental design, randomisation and blinding workshop has been held at Leicester with good feedback. The intention was to hold a similar event at Birmingham but the MDS Research Development Manager has since been in contact with the NC3Rs Regional Programme Manager to discuss providing a lunchtime workshop as part of the ECR workshop series. A meeting is

	pending to discuss this further and the most impactful approach will be taken. Two researchers have met with the NC3Rs Regional Programme Manager to discuss how to strengthen their funding applications (to the MRC and BBSRC). Advice on experimental design was provided. The NC3Rs Regional Programme Manager is supporting the BMSU Director and Communications Manager for Health Sciences in organising a 'Animals in Research Communications Workshop' at which the Regional Manager will be speaking about the 3Rs. The NC3Rs held a Pint of Science event in Birmingham at which two of Birmingham's NC3Rs Training Fellows spoke. The Home Office Inspector has confirmed that she will be attending the next Midlands 3Rs Symposium held between the Universities of Birmingham, Leicester and Nottingham. The NC3Rs Technicians Symposium is being held in October. Attendance and posters from the animal technicians are welcomed.
19/06-09	Any Other Business AnNex (Animal Research Nexus) are organising a workshop in Oxford on 30/09/19 – 01/10/19 – which is designed to stimulate discussion about what happens when animal work moves out the laboratory and into the 'field' at POLEs, and how the general public perceive animal research at POLEs.
19/06-10	Date of Next Meeting The date of the next meeting will be 11th July 2019.

GLOSSARY

3Rs	Replacement, Reduction and Refinement
ASPeL	Animals Scientific Procedures e- Licensing
AWERB	Animal Welfare and Ethical Review Body
BBSRC	Biotechnology and Biological Sciences Research Council
BMSU	Biomedical Services Unit
GAA	Genetically Altered Animals
MHRA	Medicines and Healthcare products Regulatory Agency
MRC	Medical Research Council
MRI	Magnetic resonance imaging
NC3Rs	National Centre for the Replacement, Refinement and Reduction of Animals in Research
NACWO	Named Animal Care and Welfare Officer
NVS	Named Veterinary Surgeon
PAS	Per-Arnt-Sim protein domain
PASK	PAS Domain-containing protein kinase
PI	Principal Investigator
PPL	Project Licence
POLEs	Places Other than Licensed Establishments
UoB	University of Birmingham