DRAFT

CONFIDENTIAL MATERIAL

THE UNIVERSITY OF BIRMINGHAM

ANIMAL WELFARE AND ETHICAL REVIEW BODY (AWERB)

3rd October 2019

MINUTES

Present:

19/10-01	Apologies Apologies were received from
19/10-02	Minutes The minutes of the meeting held on 22nd August 2019 were considered by the Committee and were approved subject to minor amendments.

19/10-03	Matters Arising There were no matters arising. Still having ongoing IT issues in getting the server backed up.
19/10-04	Chairperson's Items There were no Chairperson's Items
19/10-05	Verbal Reports from the Director of BMSU and Named Persons BMSU building work is ongoing, and there does not appear to be any issue with animal mortality. Plant work has been updated and upgraded. Following the building work, there has not been any related health issues. There has been a FOI request from PETA asking whether UoB run a forced swim test, and this is not being undertaken at UoB. All further information will be available on the external BMSU website. BMSU had a stall at the UoB Fair, and raised the profile across the University. Two technicians went to 3Rs symposium. BMSU is hosting the RSPCA meeting in November. There is a rapid response from HOI for amendments to licences. BMSU are currently busy with training courses due to the new student intake.
19/10-06	Report from the Fast Track Procedure There were no Fast Track Procedures to be reported.
19/10-07-1	Project Licence Applications *a) Dropping the Needle: Non Invasive Drug Delivery to the Eye* Summary: • The aim of this project is to demonstrate that drugs can be delivered to the back of the eye using eye drops rather than injections. • Age-related macular degeneration (AMD) is a leading cause of vision loss in Europe and the US. • Current therapy for AMD is intravitreal injections into the patients' eye on a monthly basis which is distressing for the patient and has a number of side effects. • The primary output for the work will be the information of the MPPA system demonstrating its efficiency as a novel ocular drug delivery technology. The Panel asked how the animals will be restrained during testing. Animals will be handled while eye drops are administered, but blinking will not be an issue. The harvested tissue will be tested for drug mobility, penetration and rate of decay. The animals will only be given a single dose. This will then be modelled for multiple doses rather than giving the animals multiple drops. Once it is confirmed whether the drugs reach the specific target, an amendment may be required for a multiple drop protocol. If the technology works, the data will be published and will benefit the broader community.

	The Panel asked why use rats rather than mice, and it was stated that the eye size is the main issue. The issue of eye size was discussed, and industry tend to use rats then rabbits prior to human. Ex-vivo work used porcine eyes, but does not have blood flow and blood pressure. The issue of irritation was discussed, and the Panel raised whether irrigation and pain relief would affect the outcomes. Wording should be amended to state that irritation should be minimised. The Panel asked what the process was to progress this technology through to industry and whether any controls need to be put in place. The PI has already spoken to MHRA regarding what controls need to be put into place, and it has been confirmed that for this optimisation protocol, positive controls are not currently needed. Power calculations were advised to ensure that animal numbers were appropriate, and a pilot study was advised. The process of the systematic review was discussed, and if it is not being performed, this should be removed. The experimental unit was discussed, and each animal will have the same treatment to both eyes. If one eye is treated, there is the issue of transfer between eyes. The issue of dose variability was discussed. The concentration of the drop will be controlled, and the animal will be handled to ensure the whole drop is administered to the eye. **Decision: Committee agreed with the licence with some minor amendments for clarity.**
19/10-07-2	*b) Regulation, Mechanism and Targeting of Platelet Receptors in Thrombosis and Haemostasis* Summary: • Heart attack and stroke are two leading causes of death in the developed world. These events happen when a clot blocks blood flow to parts of the heart or brain. This process is termed thrombosis. • Thrombosis is often started by the switching on of a cell type in the blood called the platelet. • Platelets are small cells in the blood involved in prevention of bleeding and controlling inflammation and other processes in the vasculature. • The overall aim of this project is to deepen our understanding of how platelet activation is controlled by tyrosine kinase-linked receptors as these are the targets for development of novel anti-platelet drugs. • This is the renewal of a current licence. The Panel asked about the number of injections per animal. There would only be 1-2 injections. When a new drug is introduced, a pilot is undertaken initially for optimisation, and then the terminal anaesthesia is administered prior to any protocol being undertaken. Standard wording is going to be added for time limits, injection frequencies, and humane end points. More information needs to be included on what PK/PD data is available so that dosage can be determined. The mode of culling was discussed, and it was confirmed that all processes are undertaken under terminal anaesthesia. It was suggested that a section needs to be added on randomisation and blinding. It was also confirmed that platelets are not affected by time of day, and this also needs to be added. The NTS is auto-produced in the licence software, and this needs to be amended and ensure that it is "lay-enough". The PI was advised to avoid 'see above' and look at all of the questions first and pull out the relevant information throughout the questions, rather than putting everything in the first question. The process of the systematic review was discussed, and if it is not being performed, this should be removed. This should cover what has already been done, and what aspects can have a non-animal alternative going forward. There will be additional standard wording which will go into all licences relating to adverse effects due to anaesthesia. Clarification of animal numbers should be included. **Decision: Committee agreed with licence with some minor amendments for clarity.**
19/10-07-3	*c) Identifying New Treatment Strategies for Lymphoma* Summary

	• The overall aim of this project is to identify and evaluate new treatment strategies for lymphoma. • Lymphoma is the fifth most commonly diagnosed cancer in the UK. While many lymphoma patients are cured with chemotherapy, they can experience significant long-term effects from treatment. • We are trying to identify new treatments to attack lymphoma cells and the non-cancerous cells that support them. • By targeting specific genes or proteins important in lymphoma growth, it is hoped to find new treatments that work without the toxic side-effects. The Panel asked how the animal model was developed, and whether cells are matched. Matching is the ideal method, but this is not always possible. The mechanism needs to be modelled and the pathways identified. Therapeutic models tend to involve small molecules, and models will initially use approved drugs. New drugs may be used, and maximum tolerated doses will be optimised. The Panel asked about single sex cohorts and they are coming from a single source. Cardiac puncture was raised, and the procedure was clarified and confirmed that this takes place under terminal anaesthesia. Regarding end points, the animals will be culled as soon as the animal starts to indicate a health decline e.g. changes to coat. It was confirmed that funding is available to cover the research for the next two years, and further grants applications will be made to cover the duration of the licence. There were some inconsistencies throughout the licence regarding measuring of tumours, and this should be amended. The NTS is auto-produced in the licence software, and this needs to be amended and ensure that it is lay-enough. **Decision: Committee agreed with the licence with some minor amendments.**
19/10-08	Matters relating to the 3Rs The NC3Rs Regional Programme Manager (RPM) is supporting the Communications Manager and BMSU Director in preparing content for the improved website. The RPM held an experimental design, randomisation and blinding workshop in Birmingham on Thursday 25 July as part of the ECR workshop series. Around 20 people attended with 100% of attendees finding the workshop to be very or extremely useful. A second workshop is planned for November depending on interest. Training was also provided to Midlands Innovative Biosciences Training Partnership (MIBTP) MSc students in Leicester, which includes Birmingham students in the cohort. The RPM has held a number of meetings with PIs for various reasons. These include providing advice on strengthening funding proposals for other funders (BHF and MRC), advising a PI on their PPL application, providing one-on-one training on the Experimental Design Assistant (EDA) to two individuals, and discussing a potential NC3Rs studentship funding application. The RPM was also invited to join a meeting with the HOI, NVS, BMSU Director and the new Chair of the Animals in Science Committee. The RPM introduced the regional role to the new Chair and explained how the role supports local 3Rs activities. The Midlands 3Rs Symposium took place on the 10 September at the University of Leicester. There were 10 people in attendance from the University of Birmingham, which contributed three posters. The 3Rs poster prize in the category 'Exploring different ways of advancing the 3Rs' was awarded to a University of Birmingham poster. This poster was invited by the AWERB, as the 3Rs efforts of the PI were identified during an AWERB review of a new PPL application. The NC3Rs/IAT Animal Technicians' Symposium was held on 2 October. Delegates received 5 IAT CPD credits for full attendance. Two technicians from the University of Birmingham registered to attend.
19/10-09	<u>Any Other Business</u> The RSPCA are hosting an AWERB Lay Members' Forum in London on 11th December.
19/10-10	<u>Date of Next Meeting</u> The date of the next meeting will be 14th November 2019 at 10am in the Stanley Barnes Meeting Room

GLOSSARY

3Rs	Replacement, Reduction and Refinement
AWERB	Animal Welfare and Ethical Review Body
BMSU	Biomedical Services Unit
CPD	Continuing Professional Development
ECR	Early Career Researcher
EDA	Experimental Design Assistant
FOI	Freedom of Information
HOI	Home Office Inspector
IAT	Institute of Animal Technology
MHRA	Medicines and Healthcare products Regulatory Agency
MIBTP	Midlands Innovative Biosciences Training Partnership
MPPA	Membrane Penetrating Polyamine
NC3Rs	National Centre for the Replacement, Refinement and Reduction of Animals in Research
NACWO	Named Animal Care and Welfare Officer
NVS	Named Veterinary Surgeon
NTS	Non-Technical Summary
PETA	People for the Ethical Treatment of Animals
PI	Principal Investigator
PK/PD	Pharmacokinetic and Pharmacodynamics
PPL	Project Licence
RPM	Regional Programme Manager
RSPCA	Royal Society of the Prevention of Cruelty to Animals
UoB	University of Birmingham