

**CONFIDENTIAL MATERIAL**

THE UNIVERSITY OF BIRMINGHAM  
BIOMEDICAL ETHICAL REVIEW SUB-COMMITTEE (BERSC)

25<sup>th</sup> January 2018

**MINUTES**

Present:

18/01-01                      Apologies

18/01-02                      Minutes

The minutes of the meeting held on 14<sup>th</sup> December 2017 were considered by the Committee and were approved subject to minor amendments.

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18/01-03

### Matters Arising

The application discussed in minute 17/12-07-2 has now been approved and the licence is active. It was noted that the Home Office Inspector is dealing with new applications very promptly.

18/01-04

### Chairperson's Items

The Chairperson will post slides from the recent RSPCA Lay Members Forum online for the Committee's reference. Some key issues arising from the Forum were discussed as follows:

#### *AWERB responsibility for training and education*

A presentation was given at the Forum on the workings of an AWERB at another institution and how that AWERB fulfils its responsibilities. It was felt that the AWERB at the University of Birmingham operates very similarly to the one which was the focus of the presentation, working both efficiently and effectively.

Prompted by this presentation, the Chair encouraged members of BERSC to consider whether BERSC is currently fulfilling its responsibilities in relation to training and education within the institution about the 3Rs. Whilst there is currently no official training and education plan drawn up by BERSC, there are numerous training and educationally-focused activities undertaken by BMSU and reported back to BERSC for information (including training for undergraduate and post-graduate research students and refresher training for existing Project Licence holders). The NC3Rs Midlands Programme Manager also plays a significant role in training and education, liaising with those student and staff researchers undertaking animal research and arranging training sessions and an annual symposium.

The Committee discussed whether a dedicated 3Rs sub-committee would be of value. On balance, it was felt that given the level of training and educational activities already being undertaken, a sub-committee is unnecessary. However, it was agreed that it would be helpful to keep a formal record of training activities and that the best way to do this would be to provide an update on planned and undertaken training activity under the regular '3Rs update' item on the BERSC agenda.

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### *Culture of care*

Another presentation given at the Lay Members Forum was about assessing an establishment's 'culture of care'. Again, it was felt that Birmingham's practices stood up well against the standards discussed and that there is a strong culture of care within BMSU. However, it was agreed that it would be particularly helpful to raise awareness of the University's whistle-blowing policy. Whilst new Personal Licence holders are given training on this and information on the policy is available on the University webpages and has recently been circulated within the Medical School, it was felt that a reminder in the form of a poster to be displayed in all areas where animal work is carried out would be very helpful. It was noted that PERCAT may also be a useful channel via which information about the whistle-blowing policy can be relayed to more junior researchers.

18/01-05

### Verbal Reports from the Director of BMSU and Named Persons

#### *Report from the Director of BMSU:*

- Two FOI requests have been received so far during January 2018, one from PETA and one from the Animal Justice Project. The information requested was AWERB minutes, which are available from the University website, and animal numbers which will be published shortly when they have been collated.
- Annual returns of animal numbers are being submitted within BMSU. Workshops have been held to assist PIs in compiling these but there has still been a need to request clarification in many cases.
- Researchers have been advised that at some point soon the old boilers will be removed from BMSU and that this is likely to cause some disruption.
- A Named Persons meeting has taken place this week.
- Despite one of BMSU's most experienced NACWOs recently retiring, BMSU has been able to maintain the quality of service provided. Another long-term member of staff will be retiring at the end of January, but they will continue to work with BMSU on a casual basis for a period to ensure a smooth handover.
- The Home Office Inspector will be holding a surgery this week and will be working with PIs to get two large applications ready for submission.

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### *Report from the Named Veterinary Surgeon:*

- In relation to animal welfare, a new particularly soft type of bedding is being trialled for mice used in arthritis models.
- The NVS is in continued discussions with a researcher who wishes to use fin clipping in fish experiments as it would be preferable to avoid this if possible.
- A very useful meeting has recently been held with all personnel on the experimental floor of BMSU to consider how best to approach upcoming work as a team and to share best practice. This meeting will now be held regularly going forwards.
- Three new racks of zebrafish tanks have been installed in BMSU to accommodate additional lines being introduced by a new PI.

### *Report from the Named Animal Care and Welfare Officers:*

- No items to report.

18/01-06

#### **Report from the Fast Track Procedure**

The fast track procedure is up-to-date and a record of matters discussed is stored on the Committee's Collaborate pages.

18/01-07-1

#### **Application Ref TBA – Leukocyte recruitment and retention in acute and chronic inflammation.**

The overall aims of this project are to investigate how galectins (a family of proteins made by endothelial cells and white blood cells, which have actions that influence inflammation) influence monocyte recruitment in laboratory models mimicking human blood vessels; their location in arteries of humans with atherosclerosis and in mice developing a similar disease; and, how their manipulation influences development of murine atherosclerosis.

The PI gave a presentation explaining the application to the Committee.

The Committee noted that whilst the potential for developing new drugs was discussed in the presentation, it was not mentioned in the application. The PI explained that the work described in the current application represents the very first stages of the project and that amendments will be submitted over time to cover subsequent aspects of the work.

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Written comments on the application were provided on behalf of one of the Committee's NC3Rs representatives who was unable to attend the meeting and the PI will work through these with the NC3Rs Midlands Programme Manager. One of the questions raised was why it is necessary to use the intra-scrotal route for injections and the PI explained that this was needed due to the use of the cremaster preparation.

Further information was requested about the air pouch model. The PI explained that it will involve three injections, one to generate a bolus of air in the dorsal space, one to later re-inflate the pouch created and then a final injection of the stimulus. Each injection will be carried out under isoflurane anaesthesia. Animals are expected to recover completely and to be fully mobile after each injection. In previous work using this model the animals have not shown any signs of pain nor distress. It was suggested that it may be helpful to use the mouse grimace scale to confirm that the animals are experiencing no pain. In the very rare event that a pouch collapses because of a leak, the animal will be humanely killed. It is not anticipated that the animals will need to be shaved, but this will be discussed further with the NVS.

The PI was asked to revisit the numbers of animals stated in the application to ensure that they are correct and consistent across the document.

In relation to the feeding of a high fat diet, it was explained that food will be put on the floor of the cage to reduce the risk of skin lesions, as if the food falls onto the animals' skin it tends to make them scratch. Special bedding will also be used to minimise irritation. It was noted that in the unusual event that any animals develop open skin lesions, they will be humanely killed.

In the ApoE<sup>-/-</sup> knock out model, the work will start by looking at earlier time points before moving on to longer durations, to inform the power calculation and the number of animals required. This should be mentioned in the application as a reduction.

More information should be included on the in vitro studies which will accompany the animal work.

If the systematic review tool SyRF has been used, further information should be provided about the nature of its use.

Within the study statistics, mean and variance should be stated.

The numbers of animals in each group and the nature of the groups (experimental or control) should be clarified as it was felt that this was confusing in places.

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If the EDA was used to generate study statistics, the print out should be included as an accompanying document.

Whilst the Home Office Inspector has advised the PI to publish in journals which are in compliance with the ARRIVE guidelines, it would be preferable to report the research in accordance with the ARRIVE guidelines, regardless of the journal involved.

The PI was asked to ensure that all discussion of the 3Rs which featured in the presentation is echoed within the application form.

Further justification should be provided for the use of each of the substances which will be injected to induce peritonitis. It should also be clarified that these will be used in relatively low doses.

The humane endpoints currently stated in the application are not sufficiently specific and the NVS will work with the PI to rectify this. BMSU has standardised score sheets which can be used for much of the proposed work and it may be possible to develop such sheets for any new elements.

The PI was asked to consider whether treatment with cortisol might impact upon the results of the experiment and if so, whether its use is appropriate.

After the PI left the meeting, the Committee continued its discussions.

It was felt that the NTS was overly technical and this will need to be addressed.

*Resolved that:*

The revisions discussed above will be made and incorporated into the application. Once this has been done, a recommendation will be made that the Establishment Licence Holder submits the application to the Home Office.

18/01-08

### Matters relating to the 3Rs

#### *Report from the NC3Rs Midlands Programme Manager*

- As reported at the last meeting, a University of Birmingham PhD student who attended the last NC3Rs Summer School has been awarded an NC3Rs Training Fellowship. Once the award has been publically announced, it was agreed that the Press Office will help to generate some appropriate communications

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activity relating to this.

- The NC3Rs Midlands Programme Manager has met with various groups and individuals to discuss the 3Rs and how best they can be promoted within the University. This has included meetings with the Research Support Team within the Medical School, a number of research groups and a presentation at a drug discovery workshop.
- Upcoming activity will include scoping venues for the NC3Rs Midlands symposium and a fish workshop to be held at the University of Leicester. The latter will include a master class on swabbing and presentations on fish enrichment, feeding and sourcing which will be aimed at both technicians and researchers who work with fish.
- It was emphasised that sufficient information should be included in Project Licence applications to illustrate the PI's understanding of and/or compliance with any 3Rs-related guidance or tools which are quoted (e.g. the ARRIVE guidelines and the use of the EDA). In relation to this it was suggested that it would be helpful to provide PIs with a list of resources for reference and to raise awareness in the BMSU newsletter.

18/01-09

### **Any Other Business**

- It was highlighted that in general, the NTSs included in Project Licence applications are overly technical. The Committee was informed that the whole Project Licence application form will shortly be reviewed by the Home Office. Reviews will also be carried out of the Establishment Licence and the Personal Licence application forms. Once the new Project Licence form is available, further consideration will be given to how to advise/support PIs on the completion of the NTS. It was suggested that it may be beneficial to ask PIs to complete the NTS prior to writing the body of the application and to share examples of best practice NTSs. A representative of the Press Office agreed to provide some brief guidance on writing for a non-technical audience.
- It was agreed that at the next meeting, the Committee will discuss mid-term reviews of Project Licences.
- The Committee was informed that the Home Office Inspector is hoping to attend a Committee meeting in the near future.

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Date of Next Meeting

The date of the next meeting will be 8<sup>th</sup> March 2018.



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### **GLOSSARY**

3Rs	Replacement, Reduction and Refinement
ApoE-/-	Apolipoprotein E knockout
ARRIVE	Animal Research: Reporting of In Vivo Experiments
AWERB	Animal Welfare and Ethical Review Body
BERSC	Biomedical Ethical Review Sub-Committee
BMSU	Biomedical Services Unit
EDA	Experimental Design Assistant
FOI	Freedom of Information
NACWO	Named Animal Care and Welfare Officer
NC3Rs	National Centre for the Replacement, Refinement and Reduction of Animals in Research
NTS	Non-Technical Summary
NVS	Named Veterinary Surgeon
PERCAT	Postdoctoral and Early Researcher Career Development and Training
PETA	People for the Ethical Treatment of Animals
PI	Principal Investigator
RSPCA	Royal Society for the Prevention of Cruelty to Animals
SyRF	NC3Rs Preclinical Systematic Review & Meta-analysis Facility
TBA	To Be Announced