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

1st October 2015

MINUTES

Present:

15/10-01 Apologies and introductions

15/10-02 Minutes

The minutes of the meeting held on 3rd September 2015 were considered by the Committee and were approved subject to amendments.

15/10-03 Matters Arising

There were no matters arising from the minutes of the last meeting.

15/10-04 Chairperson's Items

There were no Chairperson's items to report.

15/10-05 Verbal Reports from the Director of BMSU and Named Persons

The Committee was informed that three Inspectors had recently left the Home Office and the University was being assigned a new Inspector. A handover between the old and new Inspectors will take place on 16th October 2015.

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It was reported that the system for handling electronic Personal Licence applications is working efficiently, and that the Home Office's target to process such applications within 20 working days is currently being met.

As mentioned at a previous meeting, the University will be early adopters of the new electronic Project Licence application system which will be introduced soon. It is anticipated that there may be some glitches with the new system when it is first rolled out, but it is hoped that in the long-term the new system will be simpler and will allow both the PI and the submitting institution to better track the progress of applications.

A new outreach initiative from the NC3Rs was reported to the Committee. The NC3Rs has approached Birmingham and two other Midlands Universities to seek contributions towards the funding of an outreach worker for the Midlands area, for an initial twelve month period. It is hoped that this new resource will benefit the wider community in terms of education and awareness raising. The NC3Rs are also keen to offer their Summer School to graduate students from Universities involved in this initiative. The final decision about Birmingham's support for the initiative will be made by the BMSU Strategic Group.

Work is continuing to upgrade BMSU's facilities and the service area is currently being renovated with the financial support of the Registrar. The refurbishment of the room used for metabolic studies will also soon be completed.

The Home Office training courses offered at Birmingham are well-subscribed and all new personal licence holders are attending the induction meetings.

Animal health and welfare within BMSU is currently good, and the latest health screen was clear. Previously reported concerns about infection coming into the Unit via animals provided by a commercial supplier have now been resolved, as some imported animals were identified as infected whilst in the Unit's isolation facility.

It was reported that an FOI request relating to the numbers of animals used in research has been received from Cruelty Free International.

15/10-06

Report from the Fast Track Procedure

The fast track procedure is up-to-date, and there are no outstanding issues.

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15/10-07

Reconsideration of revised PPL application – The physiological role of B3 vitamins in energy metabolism

The Committee considered this revised Project Licence application. The Home Office Inspector believes that the current version is now in an appropriate form to be submitted to the Home Office.

Members of BMSU staff have some concern about the proposed single housing of male mice and it was proposed that sterile female mice should be used as companion animals to avoid single housing and the fighting and potential harm which could arise from reintroducing singly housed males into group housing.

The likelihood of success in exercising aged mice as proposed is an unknown factor and caution will be exercised until the animals' tolerance for the exercise is established. It is helpful that the NACWOs can draw upon their previous experience of other models of exercising mice.

The protocols should be amended to remove the collection of blood from a superficial vessel where this is not necessary for the proposed experiments.

In the Non-Technical Summary it is stated that adverse effects are expected to be mild, but it is also stated that weight loss may be up to 20% before the animal is humanely killed – this should be rewritten and made consistent.

More generally and beyond this particular licence application, it was suggested that a specific person be identified to provide assistance with licence applications. It was explained that the Director of BMSU does provide such support and there are currently no plans to change this system.

The Legal Advisor will provide comments on minor issues relating to the Non-Technical Summary, to be incorporated into the application before it is submitted to the Home Office.

Resolved that:

The revisions discussed above will be made. Once the Committee Chair is happy with the changes, a recommendation will be made by the Chair that the Establishment Licence Holder submits the application to the Home Office.

15/10-08

3Rs day

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The Committee was informed that the University of Birmingham will be joining together with two other Midlands universities to hold a 3Rs day in March 2016. The event will be held at one of these two collaborating institutions.

15/10-09

Interim review – alcohol model and the more general matter of interim review within BMSU

A recent review was provided to the Committee as a typical example and as a starting point for discussion about how to structure a local interim review process within BMSU. It was noted that interim reviews are obligatory if a protocol has been classified as being severe.

It was explained that results obtained so far under this licence have been variable and have differed from those anticipated in light of the one published work in this area. It has been observed that some of the animals are recovering rapidly after the end of injury and the experiments have yet to reach the stage where therapeutic agents will be administered.

It is proposed that gavage should be piloted in an effort to ensure that all animals receive the same quantity of alcohol and thus increase penetration, as some of the variability may be due to the administration of the alcohol via diet. Also, the length of time over which the alcohol is administered has been increased in an attempt to reach the required outcomes.

It was emphasised that the model itself has not been found to be problematic; rather, it is the results coming from it which are unexpected in light of previous work elsewhere. It is felt that the results obtained at Birmingham are valid, given the stringency of the arrangements in place here.

In relation to the more general matter of local interim review within BMSU the Committee favoured a graded scheme of review, with the level of review being proportionate to the issues raised by the project.

It was suggested that a list should be compiled of those factors indicating that interim review is required (for example, novel techniques, welfare issues, concerns raised by BERSC during the original review, condition 18 notifications, particularly high animal numbers, positive learning points, notable matters relating to the 3Rs, etc). This could be the basis for a tick box form used to triage applications. The PPL holder would submit this form and it would be initially filtered by the NACWOs.

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If interim review is required, it was suggested that the PPL holder might be required to submit: a brief statement of what the research involves, an indication of what has gone particularly well and what has been less successful, the numbers of animals used and a statement of what has been achieved so far.

Some concerns were expressed that the PPL holder might find it difficult to provide meaningful responses to the review questions if they have not yet achieved statistical significance. This was acknowledged, but it was felt that there is still value in reviewing the progress of methods and models used prior to research yielding statistically significant results.

It was emphasised by the named persons that interim review should be prompted by positive, beneficial learning points arising from projects as well as from projects which have proven problematic or which have raised particular ethical issues.

It was agreed that effort should be made to follow up on any claims made within project licences about the likely benefits of the research. However, it was agreed that this should be done as a retrospective, rather than interim review.

An initial proforma for the tick box triage form, guidelines for the submission of interim review and requirements for the retrospective review of benefits claimed in Project Licence applications will be circulated to the Committee for comment.

15/10-10

Education and training

The Committee discussed the nature of its remit for education and training. It was clarified that the Committee has a responsibility to encourage the University's strong commitment to education and training in matters relating to animal research. However, it is not BERSC's responsibility to make arrangements for the provision of training or educational activities; instead, this lies more generally with the University.

There is no regulatory requirement for BERSC's remit to extend to the training and education of wider society, in addition to University researchers; however, it was felt that BERSC should be aware of such activities (for example, outreach work in primary/secondary schools) and aware of the involvement of some members of the Committee in such activities. Understanding Animal Research maintains a list of outreach activities and it was felt that it would be helpful for the University to keep a similar list of activities undertaken by its staff and students. It was suggested that BERSC might wish to consider communicating the availability of educational and training opportunities to a wider University audience. The RSPCA and LASA

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will soon be launching new guidance on education and training which will inform the Committee's stance on these matters.

BMSU provide in house, Home Office-accredited training modules for researchers who will be carrying out research involving animals.

Members of BERSC were reminded that they should undertake continuing professional development (CPD) activities when possible. Much CPD already takes place; for example, Personal and Project Licence holders and NACWOs are required to have CPD, and lay members have the option to attend the RSPCA Lay Forum. The Committee was reminded that relevant reading also counts as CPD (for example, the NC3Rs monthly newsletter). It was agreed that it would be helpful to document the various sources of CPD to which Committee members have access.

Efforts are being made to develop the material available on the externally facing BMSU webpages. In particular, there are plans to include Birmingham-specific case studies on animal research. It was felt that there should also be additional information available on these webpages about the role of BERSC.

Action points:

- A discussion will be had with the BMSU Strategy Committee about the consolidation of the education, training and outreach activities already taking place, and about the need for the development of a record of these.
- It was agreed that 'Education and Training' will be added as an annual agenda item for discussion, and an annual summary of education and training activity during the year will be provided.
- It was agreed that a brief paper will be prepared to clarify BERSC's remit and responsibilities in relation to education and training.

15/10-08

Any Other Business

It was reported that the annual training day for members of the Universities Training Group has recently taken place. There has also been a small event for trade representatives which was well attended

The University recently hosted the Home Office Liaison, Training and Information Forum (HOLTIF), which was very successful and attracted approximately 60 delegates.

There will be another BMSU Users' forum organised once the new Home Office Inspector has started to work with the University.

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Date of Next Meeting

The date of the next meeting is 12th November 2015.

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GLOSSARY

3Rs	Reduction, Refinement and Replacement
BERSC	Biomedical Ethical Review Sub-Committee
BMSU	Biomedical Services Unit
CPD	Continuing Professional Development
FOI	Freedom of Information
HOLTIF	Home Office Liaison, Training and Information Forum
LASA	Laboratory Animals Science Association
NACWO	Named Animal Care and Welfare Officer
NC3Rs	A UK-based scientific organisation dedicated to replacing, refining and reducing the use of animals in research and testing
PI	Principal Investigator
PPL	Project Licence
RSPCA	Royal Society for the Prevention of Cruelty to Animals
TBA	To Be Announced