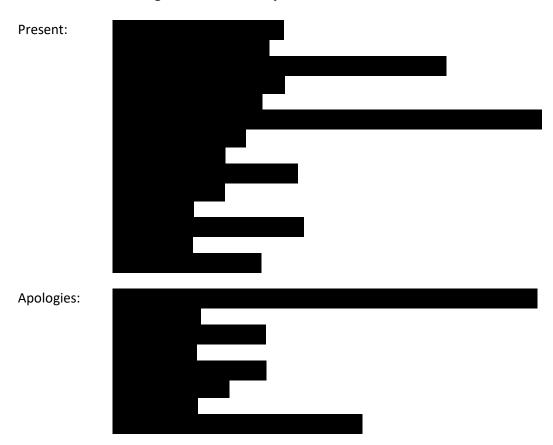


ANIMAL WELFARE AND ETHICAL REVIEW BODY

Minutes of the meeting held on 17 January 2019



1. Minutes

Agreed: That the minutes of the meeting held on 8 November 2018 were approved subject to correction of typographical errors.

2. Matters arising not covered elsewhere in the agenda

2.1. Using SharePoint for AWERB papers

Reported:

- a) Comments that are entered into the Excel sheet by the Committee members will not be circulated to the applicants.
- b) The comments will be collated by the AWERB Secretary on the morning of the AWERB meeting and printed copies brought to the meeting for the committee members.
- c) Additional comments or queries that are not already on the collated Excel sheet can be raised at the meeting.
- d) Links to the SharePoint folders will be emailed to committee members 10 working days before the meeting. This will replace the email which is currently sent 10 working days before the meeting which contains the papers for the meeting.

e) For those individuals who prefer all papers within one file, this will still be created by the AWERB Secretary and placed in the relevant SharePoint folder.

Agreed:

f) SharePoint will be used for the March 2019 AWERB meeting. Committee members will make a note of any comments they have about applications on the Excel sheets provided by the AWERB Secretary by the agreed deadline of the day before the AWERB meeting.

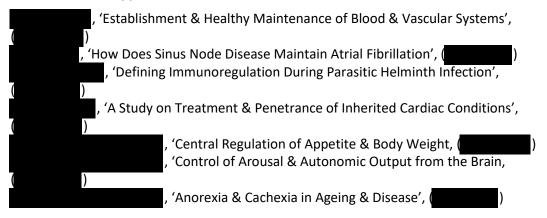
2.2. The requirement for a confidentiality agreement for AWERB members external to the University

Agreed:

- a) The AWERB Secretary will report at the next meeting if a confidentiality agreement for AWERB members external to the University is required.
- 2.3. Response to AWERB recommendations from March 2017 review

Noted:

- a) Item 1.1: The starting date for should be 2019 not 2018.
- b) Item 1.5: The appointment letters for current committee members will be disseminated by the Chair and AWERB Secretary before the next meeting.
- 3. Update on applications considered at the 8 November 2018 meeting
 - 3.1. Revisions for the following applications have been accepted and approval letters have been sent to the applicants:



3.2. Revisions for the following application have been approved and the application is awaiting sign-off by the Establishment Licence Holder

, 'Regulation miR-29 Targets in Wound Repair',)

3.3. The following application will be resubmitted to the March 2019 AWERB meeting:

, 'Novel Targets for Anti-Epileptic Drug Design', (
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4. NW region AWERB hub

Noted:

- a) The NW AWERB hub meeting is taking place on Friday 8 February 2019 and AWERB members are invited to join the meeting, subject to space.
- b) The Chair of AWERB will be attending a Chair Workshop on 13 March 2019.

Agreed:

c) The NW AWERB hub agenda will be circulated to AWERB members and if they would like to attend then they should inform the AWERB Secretary.

5. Report on amendments processed from 19/10/2018 to 20/12/2018

5.1. Amendments to Project Licences

5.1.1. The following amendments were approved by the executive committee:

, Establishment of Animal Models of
Neurodevelopmental Disorders.
, Understanding Vision & Developing Therapies for
Blindness.
, Preclinical Evaluation of
Cancer Therapeutics.
, Determining Important Regulatory Pathways that
Control Immune Responses to Infection.
, Microenvironment Signalling in
Cancer.
, The Role of Circadian Clocks in Immunity.

5.1.2. The following amendment was considered by the AWERB committee:

, The Role & Regulation of Reactive Oxygen Species in Development & Regeneration ()

Considered: A track-changed, amended PPL licence.

Interviewed:

Discussed:

The Committee is generally supportive of the amendment given the appointment of a new member of staff who is experienced in the techniques to be used.

Revisions: •

- In the Refinement section of the NTS, the committee would like the sentence amending to "This makes these model organisms particularly useful in studying both the development of tissues and their repair following injury, in organs such as the heart".
- The period that respiratory distress is allowed for should be reduced from 24 hours based on advice from the BSF staff.
- Clarity is required in the application regarding if repeat injections will be administered should a drug be observed to have no effect. The Committee want to know how you will determine if repeated injections will occur. The Committee would like you to clarify if you are taking any measurements of the pharmacodynamics of the drug to determine that it is having no effect.

- In the 'Expected adverse effects, refinement controls and humane end-points' section, you discuss rare possible adverse effects. Please specifiy what is "rare".
- The injuries to the heart should be made in the early part of the day so that the animals can be observed to ensure they are fully recovered from any bleeding and anaesthesia.

The study was given provisional approval based on the applicant making the changes/clarifications listed above to the satisfaction of the Chair/AWERB.

5.2. Amendments to Project Licence Generation, Breeding and **Maintenance of Genetically Altered Rodents** , To Produce an Opn4flx-mChFLPo Mouse Line.

Amendments to Project Licence Generation & Breeding of Genetically Altered Rodents To Create a Tg(CD3p:GRLuc) Mouse Line.

To Create a Tg(IL2p:CBR_2A_mKO2) Mouse Line. , To Create a Hras^{LSL-Q61K} Mouse Line , To Create a Kat6a Q654E/G657E Mouse Line Using CRISPR

5.4. Applications for secondary availability for new or current project licences

, Studies of Cancer Inflammation & Immunity In Vivo (

6. Applications for New Project Licences

5.3.

6.1. , Immunoregulation During Parasitic Helminth Infection (

Considered: A completed AWERB2 form, PPL application, and minutes from the Local Management Committee Meeting

Interviewed:

Discussed: •

- Only sham experiments that are required will be carried out. Information available from previous experiments will be used as controls where possible.
- All the data from the project licence will be made available.
- Germ free mice can be prone to developing torsion of the caecum, and if that occurs in the study the animals will be humanely killed. Most of the work on the licence will involve the introduction of bacteria back into the germ free mice which would reduce the likelihood of this occurring.

Revisions: • The NTS should include some simple steps of what is being done, as currently it focusses on why the work is being done.

The study was given provisional approval based on the applicant making Outcome: the changes/clarifications listed above to the satisfaction of the Chair/AWERB.

, Type 2 Inflammation in Health & Disease (

Considered: A completed AWERB2 form, PPL application, and minutes from Local Management Committee Meeting

Interviewed:

Discussed:

- The Schistosoma mansoni mouse model, which is associated with a
 higher level of mortality than other parasitic helminths, is required
 for the project licence as it has a lung migration stage which is critical
 to investigating the pathogen interaction with the immune system.
- There are other parasites of the Schistosoma genus which can affect the urinary tract; the mouse model is more severe due to the increased number of eggs that the worm produces.

Revisions: • The NTS requires some revision with who will provide guidance on the suggested changes.

- The Committee would like the application to be revised to reflect that while "up to 25% of animals across experiments succumb to infection from week 5 onwards, <u>from your previous experience you would</u> <u>predict this to be approximately 10% (for example) over the lifespan</u> of the licence".
- The maximum dose of radiation should be consistent throughout the application and if the split dose can be a combination other than 2 x 600 rads this should be clarified.

Outcome: The study was given provisional approval based on the applicant making the changes/clarifications listed above to the satisfaction of the Chair/AWERB.

6.3. , Cardiac Conduction System in Health & Disease (

Considered: A completed AWERB2 form, PPL application, and minutes from the Local Management Committee Meeting

Interviewed:

Discussed: •

- Of the 300 mice in Protocol 2 which has a severe categorisation, the applicant expects to return 1% as severe in his annual return.
- The Committee requires the applicant to speak with the Home Office Inspector assigned to the BSF to obtain guidance on the severity level of the application; discussions took place regarding if the application should be allocated a moderate or severe banding.
- Surgery must take place in the morning to ensure adequate monitoring of the animals can be carried out.
- Advice from the BSF staff should be sought on the tick sheets and/or score sheets to be used in the studies.
- The Committee had considerable concerns regarding Protocol 7: Effect of thyroid dysfunction on heart function. The Committee requires clarity on how the applicant will determine if the changes to the ion channels are due to the administration of the drugs or the hypothyroidism. Given this aspect of the project licence has not been funded and therefore not peer reviewed, the Committee require additional information on if the drugs to be used are known to affect

ion channels. Alternatively the Committee suggest that you remove protocol 7 from the application.

Revisions: •

- The following sentence in the NTS should be removed "Night time working for laboratory staff can have problems, for example, there is unlikely to be any one else in the building if there was a problem or accident."
- The NTS section on Replacement would benefit from additional information on why you are required to use mice and rats.
- The NTS states that the mice will be swim trained up to 1 hour but the licence states 90 minutes; please update all documents to be consistent.
- Protocols 3 and 6 involve the option of inserting a device so the Committee would like clarification on if these should be a moderate severity category instead of mild.

Outcome:

Given the concerns expressed by the Committee regarding Protocol 7, the application cannot be supported in its current format. The Committee recommend either:

- the removal of Protocol 7 and proceeding with the project licence application based on the completion of the other points above, or
- the inclusion of Protocol 7 in this project licence application after this section has undergone an internal scientific review. This review of the science in protocol 7 would involve academics at Manchester with the necessary experience and expertise and would be a swift process. Rest assured this is our policy when looking at licence applications that are not externally funded and therefore have not been scientifically reviewed.

7. Any other business

7.1. Report from the RSPCA Lay Members' Forum Dec 2018

Papers were circulated on behalf of who discussed some of the key points raised at the meeting.

7.2. Recommendations to improve the EU non-technical summaries of animal experiments

A publication by Katy Taylor from the Cruelty Free International Charitable Trust was circulated and discussed.

7.3. Publishing on the website the numbers of animals that were bred for scientific procedures but were killed or died without being used in procedures

reported that there is an interest in publishing the statistics for numbers of animals that are killed but do not fall under a licence at The University of Manchester.

The next meeting is on 14 March 2019 at 11am-1pm, in	
Dates of meetings for the 2018/2019 academic year are:	