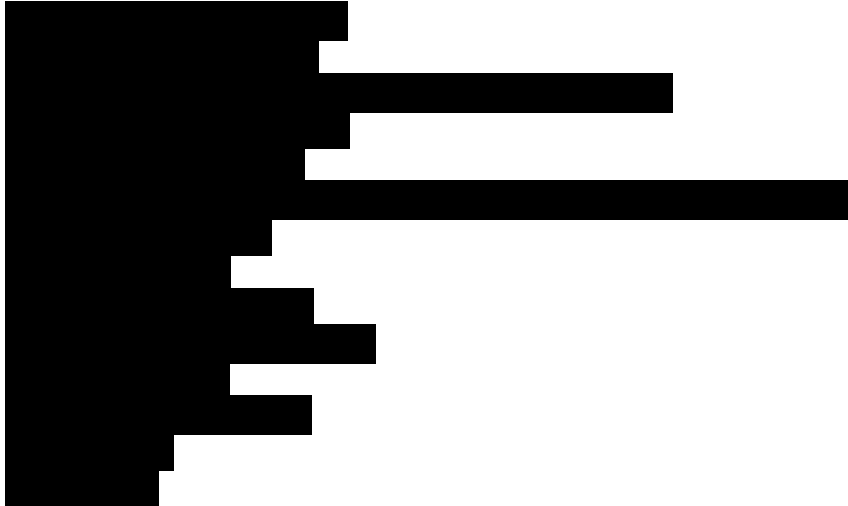


ANIMAL WELFARE AND ETHICAL REVIEW BODY

Minutes of the meeting held on 16 April 2020 via Zoom

Present:



1. Minutes

Agreed: That the minutes of the meeting held on 12 March 2020 were approved subject to a minor correction for item 6.5.

2. Applications for New Project Licences

2.1. [REDACTED], Dental Pulp Stem Cells: Investigations Into Methods of -Bone Regeneration Using 3D Printed Scaffold

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

Interviewed: [REDACTED]

- Discussed:*
- The Committee discussed the statistical approach and that this was a 12 month licence using a small number of animals, with the work being somewhat exploratory.
 - The Committee highlighted the presence of similar work in the field and required the applicant to explain further what was different in the submitted licence application to work already done.

- Revisions:*
- Please expand the section on previous work, including what has been done before (the Committee discussed with you the previous work at KCL) and what you will be building on and doing differently from the previous work.
 - Page 9 specifies male and female rats to be used, page 10 says only one sex will be studied - this is repeated throughout the application. Please clarify? If only one sex is to be used, which variables will be reduced by this?
 - Protocol 1, Step 1 - please define SC and SO at first instance.
 - Protocol 2, Adverse events - surely recovery anaesthesia may have some adverse effects, but none are listed here. Please update to include any adverse effects.

- The sections regarding animal numbers and experimental design could perhaps be swapped. Greater detail on power calculations are needed in page 17 - but should not be discussed in the section on page 22.
- On page 22, Estimated animal numbers - where the 'NC3Rs Assistant' is mentioned, please clarify if you are referring to the Experimental Design Assistant? Also please clarify why the naive control is needed.
- Please clarify in the application the plan to analyse the data in a sequential manner, looking at the data from 4 rats at a time.
- Page 9 and 14, There is a difference in the size of the bone defect to be created. Page 9 states 4mm, page 14 states 5mm. Please update to be consistent.
- Please include some more information about why you are using rats rather than mice.
- Please update your application to include the points raised at the pre-AWERB meeting if not already amended in your application, including:
 - The group discussed the total of 20 rats for the project and advised [REDACTED] to increase this to ~40.
 - The group discussed the inclusion of possible weight loss >20% and advised [REDACTED] to reduce this figure to 15%.
- Please contact the lay members of AWERB to discuss how the Non-technical summary (NTS) can be improved.
 - [REDACTED]

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

2.2. [REDACTED], Development & Validation of Animal Models for Neurodevelopmental Disorders

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

Interviewed: [REDACTED] and [REDACTED]

- Revisions:*
- On the Cat A form the animal number is down as £6000, rather than 6000 rats. Please update.
 - Please include some information on the time of day that the administration of Poly I:C and LPS will be given, and the point you made during the meeting that this will be kept consistent across animals.
 - P48, please revise the table in terms of weight loss.
 - Protocol 1 step 3 needs maximum number and frequency for each intervention.
 - Protocol 1 step 4 needs specific Humane End Point for IP injection of pregnant females- e.g. "animal will be culled if it shows anything other than mild, transient discomfort or displays any signs of abortion after IP injection of inflammatory mediators"
 - Please contact the lay members of AWERB to discuss how the Non-technical summary (NTS) can be improved.

○ [REDACTED]

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

2.3. [REDACTED], Understanding the Role of the Body Clock in Behaviour & Physiology

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

Interviewed: [REDACTED]

Discussed: • At the pre-AWERB meeting the applicant did not agree with some of the recommendations from the BSF executive committee. A meeting with the Home Office Inspector was to be arranged to discuss a number of points, and the HOI supported the view of the BSF staff. The changes requested by the HO/BSF staff have been made by the applicant.

Revisions: • First noted on pg 31 but then repeated throughout - under the step that covers singly housing mice, it is stated that there are no adverse effects, even though single housing is proposed for up to 14 days. Please include details of the enrichment you are using for single housing.
• Please ensure the weight loss is consistent throughout the application 'weight loss >20%', as 25% is mentioned in some parts.
• Please contact the lay members of AWERB to discuss how the Non-technical summary (NTS) can be improved.

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

3. Mid-term Review not requiring licence holder attendance at the meeting

3.1. [REDACTED], [REDACTED], Circadian mechanisms underlying organ rejection

Considered: AWERB Mid-term review form

Discussed: • The licence holder has indicated that they want to revoke the licence given the negative findings.
• The Secretary will contact the licence holder to ask for feedback on the questions raised by the committee.

Queries to PPL: • Have the negative finding been published to ensure others do not repeat this work?
• Are there any plans to investigate any further links between the circadian clock and tissue rejection?
• For item 16 of the review form, please can you clarify if the actual severity was for all the number of animals, i.e. did all 14 animals from Protocol 1 get reported as Moderate, or were some mild?

4. Report on licences processed from 28/02/2020 to 26/03/2020

The following amendments were approved by the executive committee.

4.1. Amendments to Project Licences

[REDACTED], How Does Sinus Node Disease Maintain Atrial Fibrillation? A Study of Electrical & Structural Changes in the Heart.

4.2. [REDACTED]; Generation, Breeding and Maintenance of Genetically Altered Rodents

[REDACTED] To Generate a CRE-Inducible Dendra2-Col1A2 Mouse Line Using CRISPR
[REDACTED] To Generate a CRISPR KI Nluc-Col1A2 Mouse Line Using CRISPR.

4.3. [REDACTED], Breeding and Maintenance of Genetically Altered Rodents

[REDACTED] Transfer PPL Holder to [REDACTED] to Cover [REDACTED] Maternity Leave Period.

4.4. [REDACTED], Generation & Breeding of Genetically Altered Rodents

[REDACTED] Addition of Protocol 7: To Allow Embryonic Electroporation (Amendment Granted at Primary Establishment).

5. Update on applications outstanding from previous meetings

Given the current situation with covid-19 the Home Office have returned a number of project licence applications that they have classed as non-urgent.

6. NC3Rs Regional Programme Manager update

[REDACTED] is trying to continue business as usual during the lockdown. Some events may take place online where possible.

A number of NC3Rs schemes are still running to timetable.

7. Standard Condition 18s

There was a meeting with the Home Office Inspector regarding a Standard Condition 18 submitted for licence. The HO require justification for continued use of sGO:OVA complexes. The NVS/NACWO will report on the outcome of this at the next meeting.

8. Any other business

8.1. AWERB Chairs meeting

- This took place on 5 March 2020.
- [REDACTED] attended on behalf of the Chair who was not able to attend.

- The next meeting will probably take place in Manchester.
- ██████ spoke about compliance and audit, and AZ felt that audits only take a snapshot of work being done.
- There was a lot of discussion about the development of the 3D phantom project:

<https://www.manchester.ac.uk/research/environment/governance/ethics/animals/outcomes/replacement-reduction-refinement/dummy/>

8.2. NTS process

A discussion took place regarding the best way to consider the NTS, i.e. prior to or after the AWERB meeting. ██████ will discuss how they want to proceed. The Secretary will send these members the schedule of dates that are given to applicants so they can see how review of NTSs may be fitted in in-between the pre-AWERB meeting and full AWERB meeting.

8.3. Incorporation of pre-AWERB comments into applications

It was raised that a number of comments from the minutes of the pre-AWERB meeting are not being implemented by applicants. ██████ will liaise with ██████ to ensure that final submissions for AWERB have incorporated all the required comments from the pre-AWERB meeting.

8.4. Research misconduct investigation

It was reported that following a research misconduct investigation (which took place alongside a Home Office investigation) a non-compliance letter has been sent from the Home Office to the Establishment Licence Holder. Both the Respondent and Complainant in the case are no longer at the University of Manchester.

The next meeting will be on 28 May 2020 at 10am-12pm.

Dates of meetings for the 2019/2020 academic year are:

9 July 2020
27 August 2020

Dates of meetings for the 2020/2021 academic year are:

8 October 2020
Wednesday 18 November 2020
21 Jan 2021
4 March 2021
15 April 2021
27 May 2021
8 July 2021
19 August 2021
30 September 2021