

ANIMAL WELFARE AND ETHICAL REVIEW BODY

Minutes of the meeting held on 24 February 2022

Present:

[REDACTED]

Apologies:

[REDACTED]

1. Applications for New Project Licences

1.1. [REDACTED], Biocompatibility of a Prototype Fully Implantable Auditory Implant
Microphone

Considered: A completed PPL application

Interviewed: [REDACTED]

- Discussed:*
- The possibility of histological changes due to the procedure itself rather than the implant, and if this would affect the interpretation of the work. The applicant explained that they did not think there was justification enough for having a control group. It was suggested that should inflammation still be present after 6 weeks the applicant could look at an amendment to include a control group.
 - The submitted application requires further work and input from the Named Persons however the applicant is aware of what needs to be updated prior to submission to the Home Office.
 - The applicant is different from those usually considered at AWERB as it is testing a medical device rather than a disease, for example. The study is therefore of a more qualitative nature than collecting quantitative results.

- The work to develop the prototype should finish around June/July.
- In the experience of the BSF staff, the animals will try to remove the dressing covering the wire, especially given they are to be group housed.

Revisions:

- The changes highlighted by the BSF staff regarding details within the protocols needs to take place including defined steps with adverse effects and appropriate humane endpoints.
- Page 7 - The number of animals to be used is not clear. Page 7 suggests 9 animals but later there are statements that suggest 18.
- Page 11 – please include more information on what the staff from the [REDACTED] will do on the licence.
- Page 12 – this will require internal peer review by staff at the University of Manchester prior to submission to the Home Office.
- Page 23 and page 25 – please include further details of what will happen to the wire that is connected to the microphone. It was considered unlikely the animals would leave this in situ.
- Page 26 - You say here that the level of suffering should be mild though the license is for a moderate level of suffering. Please can you clarify this.
- A number of comments were made regarding your Non-Technical Summary which are listed below. Please update your NTS based on the comments and send it to the following lay members for their review [REDACTED]

- It is not clear from the NTS if you are implanting a microphone into animals that have normal hearing? How will that affect them if so? Please can you clarify this.
- Page 3 – the section 'Important to undertake' would be made more succinct.
- Page 4 – Benefits section - Could 'Better cosmesis' be expressed in more simple language.
- Page 5 - Suggest editing point number 9 to (as it's otherwise confusing): avoiding the irritation of the skin associated with an external processor and avoiding the risk of losing or damaging the processor should it become dislodged.
- Page 7 - I am assuming the 'anticipated deaths during the study', refers to 10% of guinea pigs being prone to the 'respiratory depressant effects of anaesthetics' or are you also anticipating deaths from something else? I would suggest this should be added to the adverse effects section on P6. But also, 10% seems like a high number. Can you explain if you anticipate this figure will be less if you take the precautionary steps as explained on page 9?
- Page 8 – 'what measures' section. Line 2 – 'Humanely killed of' should be changed to 'Humane killing of'...
- Page 9 - Anaesthesia paragraph: This is the first point at which it felt as though technical material had been cut-&-pasted into the NTS: the non-technical reader would be helped by this paragraph being shortened - there is more detail than is

necessary - and any remaining technical terms being explained. [e.g. pedal reflex, capillary perfusion, "i.m.", reversing agent].

- Mike Addelman in the media office who is lay member would be willing to work with you when you are ready to publish as he would think there would be a great deal of interest in this work.

- Outcome:*
- The study was given provisional approval based on the applicant making the changes/clarifications listed above to the satisfaction of the Chair/AWERB.
 - Procedures must take place on one animal at a time and input sought from the NVS and other Named People within the BSF before work continues on another animal.

1.2. [REDACTED], Animal Models of Fibrotic Diseases

Considered: A completed AWERB form and PPL application

Interviewed: [REDACTED]

- Discussed:*
- This application was a resubmission after AWERB did not give support for the previous version to proceed to submission to the Home Office.
 - The applicant had taken on board the suggestion to remove a number of protocols on the licence.
 - The ability of a specific type of cell to be isolated from the kidney was raised, however the applicant stated that they would be able to do this.

- Revisions:*
- Use of 'mice models' should be updated to 'mouse models'.
 - Page 8 – while AWERB appreciate there are considerations will disseminating results from commercial sponsors, we would encourage you to urge companies to engage in dissemination of negative results so that studies are not repeated unnecessarily. Could the fibrosis database be used for this purpose?
 - Page 23 – please include the concentration of carbon tetrachloride.
 - Page 33 – please check the wording in the sentence beginning with "For drug testing.....".
 - Page 34, 49 and 64 - You say these models are all 'one of the most useful models in fibrosis research'. Please update to 'a useful model in fibrosis research'.
 - Page 39 – please include details of how you will monitor the feeding habits of mice after you change the diet. Will this be as a whole or individually?
 - Page 25 and page 41 - The sentence beginning "Gavage is associated" should have "with" not "of".
 - Page 43 – please include details of how you will measure renal function.
 - Page 44 – please include details of how you will isolate "primary cells" in the kidney. Any kidney slice contains a mixture of proximal tubular cells and distal tubular cells as well as some from the collecting ducts and loops of Henle.

- Page 52 - In the sentence beginning "High-fat feeding" It should be "is" not "are".
- Page 61 - The third paragraph in "Animal Experience" refers to carbon tetrachloride. Please clarify if you are using it in these animals.
- A number of comments were made regarding your Non-Technical Summary which are listed below. Please update your NTS based on the comments and send it to the following lay members for their review

[REDACTED]

- Page 4 - "Typically..." paragraph: I found this difficult to follow - starting from the "In some instances" opening: does this imply that tissue will not be removed in other instances? Maybe explain "renal" at its first usage [p.5].
- Page 7 and page 17 - Principal should be Principle. This section contains too much scientific detail.
- Page 8 - "Refinement" section: this lapses into the use of technical terms without explaining them, particularly in the paragraphs beginning 'models such as rodent cafeteria diet', and 'animals remain an invaluable tool for research'.
- Page 8 – we suggest you remove the phrase "an invaluable tool for research".

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. Retrospective Assessment of Project Licences requiring full committee review

2.1. [REDACTED], Immunopathology of experimental malaria infection

Considered: Responses to the questions asked in ASPeL regarding the Retrospective Assessment

Interviewed: [REDACTED]

- Discussed:*
- The number of animals reported as experiencing severe suffering was high at 13% however this reflects the severe nature of cerebral malaria in the clinic, therefore the results obtained from the study would not have been possible without animals entering this banding.
 - The researchers refined their grading system to a 9-point scale to provide clarity on the expected progression of experimental cerebral malaria syndrome. Animals reaching 6 on the scale have cerebral malaria and animals were humanely killed or treated before a score above 6 is reached. This refined scale is being used in a subsequent Project Licence. The researcher explained that this monitoring system will be included in publications so that the refinement is made available to other researchers.
 - The researchers had made significant progress with the objectives set out in the licence leading to refined objectives in a subsequent Project Licence.

Outcome: Support was given for submission of the retrospective assessment to the Home Office.

3. Applications for Amendments to Project Licences requiring full committee review

3.1. [REDACTED], The Role of Inflammation in Cerebrovascular Disease.

Considered: A Home Office amendment summary sheet and granted licence with details of the amendment highlighted.

Interviewed: [REDACTED]

- Discussed:*
- The amendment seeks to allow stroke to be induced without anaesthesia.
 - The researchers explained that the stroke would not be worse than if induced in anaesthetised animals however it would mean that animals would feel some effects of the stroke depending on where the lesion was induced. For example, a stroke in the somatosensory cortex may lead to a tingling sensation. Strokes will not be induced in certain areas, such as the parietal cortex, which is known to be involved in fear.
 - The researchers will carry out the work one animal at a time and closely monitor the animals.
 - The work will more accurately mirror what happens clinically.

Outcome: Support was given for the amendment to be submitted to the Home Office.

4. Radiotherapy and behaviour licence

Interviewed: [REDACTED]

- Discussed:*
- [REDACTED]

Outcome: Support was given for the amendment to be submitted to the Home Office.

5. Response from [REDACTED] from his mid-term review

5.1. The committee received a written report from the Project Licence holder detailing projected and actual number of animals for each severity band.

6. NVS report for January 2022

Received: A written report dated January 2022 from the Named Veterinary Surgeons.

7. Any other business

7.1. External Website

Mike Addelman reported that the external facing website had been updated. Links will be provided to the AWERB Secretary who will circulate to the committee.

The next meeting will be on 17 March 2022 at 10am-12.30pm.

Dates of meetings for the 2021/2022 academic year are:

11 November 2021
16 December 2021
10 February 2022
24 February 2022
17 March 2022
28 April 2022
26 May 2022
23 June 2022
21 July 2022