

Minutes

Date Friday, 11/12/2020

Time 10:00 AM

то Sub-Standing Committee

At Virtual via Teams

Subject AWERB Standing Committee

Our Ref DOC.UBS.AWERB.11.12.2020

Present:

MINUTES

1. Project Licences

a) Amendment:

The committee discussed the following:

- Recommend the justification for the need to administer immune cells be added to the Project Plan
- Suggested lowering the number of intraperitoneal injections
- Suggested additional monitoring checks and the use of different sites and locations should be mentioned
- If using subcutaneous injection justify clearly in the project plan why this route is needed.
- The addition of the injection of immune cells should be added to protocol 1 Adverse Effects.

b) Amendment:

The committee discussed the following:

- Suggested the addition in the Project Plan section 3.1 work done in vitro previous to this work being needed.
- Clarification in section 3.2 regarding the use of controls in these studies. Amend wording of use of pilot studies and the PK/PD studies.
- In Protocol 10 recommend clarifying which steps are carried out using juvenile animals.
- Clarification regarding the calculation of the AAV dose.
- Suggested adding information regarding the monitoring of the adverse. The use of monitoring sheets should also be included.
- Change Schedule 1 protocol to Schedule 1 method.
- Clarify in the Project Plan the use of immunosuppressant drugs instead of immunocompromised animals.
- Suggested changing the severity of Protocol 16 to mild.
- Suggested reducing the number of optional steps or further information is added.
- Clarify the use of imaging with immunocompromised animals and the problems cleaning the imaging equipment before the animals are used



- Ensure the implantation of the minipump is separated out from the administration by a minipump. The committee gave suggested wording.
- Update the refinement section of the Non-Technical summary.

c) Amendment:

The committee discussed the following:

- Clarify the rationale behind the amendment in the Project Plan
- Explain in the Project Plan why the overall number of animals in unchanged.
- Add the use of the DigiGait as a possible option for measuring the motor coordination in Protocol 11
- Under Adverse Effects explain that only the male breeding mice are expected to show these adverse effects. Remove the word 'severe' from the 3rd paragraph.
- Please remove 'or exceeding the clinical signs' in the last paragraph, but include how long the clinical signs would be seen before the animals were no longer useful for mating and are killed.
- 2. Minutes of the last meeting 6 November, 2020 The minutes were approved
- 3. Minutes of AWERB Standing Committee meeting The minutes were approved

4. Retrospective Reviews [RR]

a.

The committee discussed the following:

- Tick box in section 1.
- Add the total at the bottom of the columns in section 2.1, for protocol 8.
- Clarify the number of animals in section 2.4 so that it is the same in section 2.1
- Explain in section 2.5 why the number of animals used overall in the PPL was much lower than requested
- Clarify in section 2.7, if any of the 70% of animals not useful were shared with other people or used for tissue'
- Clarify in section 3.1 if it was not possible to carry out culture work for some of the other protocols in order to investigate the misfolding of proteins?
- Estimate the total number of animals that were not used in section 3.2
- Complete the final sentence in section 3.7.
- The committee was complimentary on the welfare and monitoring traffic light system.
- Ensure the document is spell-checked for typos

b.

The committee discussed the following:

3.1 change the number of animals reported to mild as per 3.2



С.

The committee discussed the following:

• The committee commended on the quality of this RR and requested its use as an example to be put on the UBS website.

5. Any other business

A Non-Regulated Procedure request was reviewed by the committee. They agreed this should be approved and signed off by the AWERB chair and another needed further comments returned before it was signed off.

It was noted that the **second** licence had been moved to **second** and that MRC as primary was removed so that University of Cambridge was now primary.

It was noted that **the second** had experienced problems with surgery affecting some mice ears and the Home Office had requested this was added to the amendment.

6. Date of next meeting: 15th January, 2021