

Minutes

Date	Friday, 10/05/2019
Time	10:00 AM
То	Sub-Standing Committee
At	
Subject	AWERB Standing Committee
Our Ref	Doc.UBS.AWERB.10.05.19
Present:	
Scientists in attendance for 1a) N/A & 1b) N/A	

Apologies:

# MINUTES

Date Time То At Subject Our Ref

- 1. Project Licences
  - a) Amendment: unable to attend on behalf of

The committee discussed the following:

- The recommendation that attend the next AWERB meeting to answer the • committee's questions not answered by the presentation provided.
- Further justification, clarification of end points and specific adverse effects expected in regards to the administration of specific substances.
- Evidence that appendix 3 has been amended. •
- Further information around experimental design and pilot studies in regards to specific procedures • planned.
- Information around how specific substances will be administered.
- Further clarification of refinements included in the applicant's presentation.
- Further update of the Non-Technical Summary to reflect the amendment planned.

The committee agreed changes should to be made in a different colour before the applicant returns to the AWERB committee.

## b) Amendment:

The committee discussed the following:

- Further information included in the Part C: Background section. •
- Further information included in the Part C: Benefits section.
- The addition of anaesthetic codes in the Part E: Protocols.

The committee agreed minor changes needed to be made before submission to the Home Office.

#### 2. Minutes of the last meeting 05/04/19

After a minor change the minutes were approved.



## 3. Minutes of AWERB Standing Committee meeting 24/04/19

The minutes were approved.

## 4. Retrospective Reviews [RR]

#### a)

The committee discussed the following:

- The AWERB 3Rs committee comments where this RR has already been reviewed.
- Standard Condition 18 reports in Section 1.3.
- Further detail around the objectives that were not addressed and the impacts on the benefits in Section 2.6.
- Typographical errors that require amending.
- Further information required in Section 3.2.
- Further information included in Section 4.5.

## b)

The committee discussed the following:

- The AWERB 3Rs committee comments where this RR has already been reviewed.
- Concerns around specific adverse effects encountered in Section 2.2.
- The need for reassurance that lessons were learnt and refinements were introduced in reference to the Standard Condition 18 reports submitted.
- Concerns around how the benefits have been stated in the RR and reassurance that the PPL holder is aware and takes into consideration published human data.
- Whether refinements included in Section 3.7 will be published.

# c)

The committee discussed the following:

- The AWERB 3Rs committee comments where this RR has already been reviewed.
- The lack of engagement the PPL holder has had with the RR process and whether they wish to amend their RR before this is sent to the Home Office.
- Further information around whether papers published were undertaken under the authority of this licence.

#### 5. Any other business

The committee discussed the information submitted to the committee by **second second s** 

agreed to circulate last year's annual AWERB report to committee members giving a date for feedback. This will give the committee the chance to suggest any improvements to the format and items to highlight for this year's AWERB report.

6. Date of next meeting: 07/06/19