Date: Friday, February 10, 2017
Time: 10.00am
At: [REDACTED]

Subject: AWERB Standing Sub-Group Committee Minutes

Present: [REDACTED]

Invitees: [REDACTED]

Apologies: [REDACTED]

MINUTES

1. Project Licences
   a) Amendment: [REDACTED]

   [REDACTED] attended the meeting in [REDACTED] absence. The committee discussed the following:
   - Reword the justification for this amendment in the plan of work
   - Clarification of new protocol studies in project plan
   - Justification for numbers of animals to be used under protocol 12
   - Justification and explanation for use of intraperitoneal osmotic minipumps compared to other methods
   - Justification for using animals for PK studies under 3Rs section
   - More information on clinical signs and monitoring for moderate severity
   - Explanation or correction of imaging procedures without anesthetic
   - Recommendation to include amendment and summary of description of the relevance of Pulmonary Arterial Hypertension to human health in Non-technical summary

   b) Amendment: [REDACTED]

   [REDACTED] also attended the meeting with [REDACTED] Comments from the 3Rs committee were reviewed. The committee discussed the following:
   - Clear explanation on post-op care in study plans
   - Include refinement details of post-op care under 3Rs section
   - Recommendation that animals that are killed or die on study are sent for post mortem
   - Recommendation that detailed records are kept for animals used
   - More information in project plan on sham surgery
• Revise undertaking surgery wording from ‘HO minimum standards’ to ‘aseptically’
• Additional information Under 3Rs section on number of animals used
• Include information about anticipated severity in adverse effects section, and explanation under 3Rs
• Recommendation to aim for an amendment in the future to change the severe severity in protocol 7 to moderate
• Include information of Bile Acids on the enteroendocrine axis in scientific background
• Justification and explanation about the use of pair feeding in project plan
• Further consideration of single housing

c) Amendment:
The committee discussed the following:
• Include intraperitoneal injection technique and use of small needles under Refinement section
• Advised to use a chart to monitor where injections are given to each animal
• Revise wording for NVS inspection after every batch of 24 injections
• Include expected average number of injections required under adverse effects section
• More detail of clinical signs from repeated intraperitoneal injections under adverse effects section
• Explanation in project plan for scientific justifications and specific need for the changes to techniques in protocols
• Confirmation statement under project plan of animal usage after drug discrimination study
• Sample of rats used for the drug discrimination procedure to be submitted for post mortem to confirm absence of effects from the procedure
• Explanation and justification for weighing of animals
• Advise training more staff to undertake intraperitoneal injections

It was advised that the amendment will be seen again by a virtual committee after advised amendments have been made to the application

Other agenda items deferred to a subsequent meeting.

2. Date of next meeting: Wednesday 22nd February 2017