
Summary Minutes: AWERB meeting

Status: FINAL

Meeting held: Wednesday 16 July 2025 at 10am: MS Teams

Present:

12 plus one in attendance, three by invitation and 17 apologies

1 CRERB APPLICATION: INTERACTION OF METHANOGENS WITH THE IMMUNE SYSTEM

A researcher was welcomed to the meeting. He had been invited to attend to discuss his Clinical Research Ethical Review Board (CRERB) application for a pilot study in Spain involving 21 calves. The study aims to investigate the colonization of methane-producing bacteria in the gut of calves. If conducted in the UK, this research would require a Home Office project licence due to the involvement of animal subjects, so AWERB had been asked to contribute to the review process.

The study design had raised concerns. As the next scheduled CRERB meeting was not until October, he had been asked to attend this AWERB meeting instead, to address these issues.

The pilot study seeks to identify the timeline and conditions under which methane-producing bacteria colonize the calves' intestines. The findings are intended to guide future research and explore the potential for developing a vaccine to prevent the colonization of these bacteria.

The following concerns had been raised:

- **It would be difficult to maintain consistent environmental conditions for the calves.**

The calves would be born around the same time and remain on the farm throughout the project. While temperature conditions may fluctuate slightly, existing literature does not provide clarity on whether methane-producing bacteria exist in the environment, given that they require anaerobic conditions to thrive. This was one of the questions the study aimed to address.

- **Sample size justification: although the low sample size is typical for a pilot study, it was questioned whether a proper sample size calculation tool had been used, particularly as a multi-omic analysis was planned?**

Discussions with data analysis specialists have indicated that a minimum sample size of three is necessary for meaningful results. This was supported by existing literature and cytokine data from cows and calves.

Constraints including timeline and available personnel, meant there was also insufficient capacity to increase the sample size. The challenges of using a small sample size, such as increased variability and statistical power issues, was recognised but the researchers were committed to minimizing animal use whilst still gathering meaningful data. The aim was to include multiple analyses beyond microbiome profiling, such as tissue analysis, to better understand gut immune

system development.

Had alternative study designs been considered, such as reducing the number of time points while increasing the number of calves per time point? This approach could provide greater certainty regarding the research question.

This option had been contemplated but then rejected in favour of a more comprehensive examination of weekly time points.

- **What would happen if any of the calves got sick during the study?**

Any calf that becomes sick or has a high temperature for over 48 hours will be excluded from the study to receive treatment.

After the researcher's departure, the study was discussed further. The participants acknowledged the study's validity and euthanasia methods but there were still concerns regarding the adequacy of the sample size for generating reliable data for future research. It was recognised though that this was a pilot study and that the research had to begin somewhere.

Whilst minimising animal use is important, it must be balanced with the need for reliable data to avoid flawed conclusions in future studies.

Discrepancies were noted in the documentation regarding the sampling age and the number of time points, with one document indicating a range of zero to 30 days and another stating zero to 55 days, along with conflicting counts of six versus seven time points.

To determine ethical approval for the study, members were asked to vote on whether they felt ethically comfortable granting approval for the study plan to move forward. The majority approved the proposal with the condition that a final definitive protocol clarifying sampling age points and the number of calves at each timepoint be provided. The researcher should also be strongly advised to consider increasing the number of calves used (up to five per group) while potentially reducing time points to enhance the study's robustness and insights into the timing of the vaccination window.

2 AMENDMENT TO A PROJECT LICENCE THAT HAS SECONDARY AVAILABILITY AT THE RVC

An amendment to a project licence was introduced, which concerned a study involving sheep undergoing recovery studies. The study aims to evaluate the safety and efficacy of drugs administered via Convection Enhanced Delivery systems for treating neurological diseases, including brain tumours.

The project licence includes several optional steps (imaging and blood sampling), followed by mandatory steps (brain surgery and termination). However, it had been noted that if issues arise during the imaging or blood sampling stages that render the sheep unsuitable for the study, the mandatory surgery and termination would still need to be performed. To address this, it was proposed to designate brain surgery as optional. Additionally, a provision for "keeping alive at a licensed establishment for non-regulated purposes or possible reuse" would be added under the 'Fate of animals' section. These changes would allow the animals to be potentially utilized in other projects instead.

AWERB expressed support for these proposed changes, recognising them as ethically valid. However, they requested additional work on the wording of the amendment to ensure clarity. They

emphasised that the protocol steps must clearly and accurately reflect the requirements necessary for the project.

3 RAGWORT CONTROL CONCERN

A concern was raised regarding ragwort problem in the fields, which was posing a significant risk to animal health and causing issues for both the Biological Services Unit (BSU) and the equine department. AWERB expressed support for the establishment of a RVC-wide control programme to effectively manage and mitigate the ragwort issue. It was noted that a joint BSU and equine paper would be going to the next Land Management Committee to discuss this issue.

4 MINUTES OF 5 JUNE 2025 AWERB MEETING

The minutes of the 5 June 2025 AWERB meeting were confirmed as an accurate record.

5 DATES OF NEXT MEETINGS

- 30 July: Standing agenda items: 10am to 12pm
- 27 August: PPL review meeting: 10am to 12pm

AWERB Secretary
13 August 2025