Home Office

PPL Standard Condition 18 Notification Form

Please use this form to notify the Animals in Science Regulation Unit (ASRU) of procedural-related adverse effects that have exceeded or are likely to exceed the severity limitations or controls described in the project licence. ASRU will use this information to determine whether any further action is required.

Do not use to report:

- adverse effects that are due to non-procedural issues;
- potential non-compliance (report by other means);
- issues without adverse welfare consequences.

If you are in doubt whether or not you need to fill in this form, please contact your assigned Inspector.

Please clearly title your document: **'ASRU_establishment name_PPL number_PPLh surname_date_sc18'** and send to your Inspector (e.g. using cjsm) with the subject heading 'PPL SC 18 Notification PPL [Number] – **Check Home Office's Updated Bridging Ways of Working for updated advice on email addresses and subject headings. Cjsm no longer necessary.**

Establishment Licence name	University of Cambridge (Mira)
Establishment Licence number	X81BD37B1
Name of PPL holder	Rachel Watson
PPL number	PP6298217
Protocol no	08
Protocol title	Investigation of the biodistribution of test agents (Mice)
Severity classification	Mild
1. Date of incident	24/06/25
2. Species	Mouse

3. Brief details of study and how the limits or constraints have been breached	The aim of this study is to examine the biodistribution of blood-brain barrier crossing adeno-associated virus (AAV) serotype in male C57Bl/6J mice, as well as a time course to assess peak expression. There are two vector groups and one vehicle group. The study started on May 20th with an i.v. injection and the mice have been weighed weekly (after an initial 48-hour monitoring period). Today (24/06) mouse 59 (in a viral vector group) has a body weight of -11.9% (24.2g) compared to peak weight (27.4g, 14 days ago). Last week the mouse weighed 26.9g. The mouse has no clinical signs and is bright and alert (short video available if needed). There may be subtle signs of fighting in the cage (unstructured, scattered bedding) but no witnessing of it and no wounds. The cage was also partially cleaned out yesterday. Furthermore there are discrepancies in the HEPs of the protocol this study is on; in the substance administration step the mouse fulfils staying within HEP for the adverse effects observed (up to 10% compared to day 0 weight, 23.6g, which is +2.5% on today's weighing), but peak weight is used for monitoring and the comparison is not specified for the actual HEP. We will submit an amendment to clarify which comparison the step uses. **Therefore with no clinical signs and unclear HEP, we would request to keep this animal alive as its scientific value is high.**
4. Have you taken advice from the Named Animal Care and Welfare Officer/Named Veterinary Surgeon/others?	We have been in touch with the animal care team to improve the enrichment in the cage if social disruption is an issue. They will also going forward disturb the animals as little as possible on the cleaning day.

5. Cause of Problem, if known	Social disruption in the cage may be contributing to the weight loss in this animal if he has reduced access to food. There is no indication that the treatment group is contributing as all other animals are fine.
6. Action that has been or will be taken *(For example, formulation of drug changed, supportive treatment given, study design modified). If no action needed, indicate why (for example, none required as study has been terminated and will not be repeated)*	Enrichment has been increased (cardboard houses added so mice can build separate nests, and floor food has been provided). If by the end of the day (if KAR is granted), we will weight mouse again and separate if little to no improvement is seen.
7. Reported by (name)	Amy Warner (on behalf of Rachel Watson)
8. Date	24/06/25

**********For official use**********

Inspector's comments and recommendations:

Comments and recommendations	
Inspector name	
Date	