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	06
Protocol title	Investigation of the tolerability of test agents (moderate)
Severity classification	Moderate
1. Date of incident	24/09/2024
2. Species	Rat

3. Brief details of study and how the limits or constraints have been breached	The aim of this study is to determine tolerability and pharmacokinetics of novel therapeutics for the treatment of inflammatory bowel disease over 7 days of oral gavage dosing. On 24/09/2024 one team member (Rob Carrington) was being assessed to be signed off as competent for rat oral gavage by another team member (Sam Hilton), following a previous successful training session that was completed without incident. Rob had previously gained competence in rat oral gavage at a different establishment in 2017 with his last reassessment being carried out at the same establishment in September 2020. Having been observed dosing multiple rats in that dosing session and spoken through the various aspects of the assessment the assessor was happy with Rob's technique. One rat at the end of the session was unfortunately inadvertently dosed into the lungs in error. This was realised within seconds; upon placing the animal back into its home cage it was observed to have gone limp and was frothing at the nose and was promptly Sch 1 killed. All other animals on the study were closely monitored for the proceeding 2 hours and no clinical signs were observed in any other animals dosed.
4. Have you taken advice from the Named Animal Care and Welfare Officer/Named Veterinary Surgeon/others?	The NACWO and NVS have been informed of this incident.
5. Cause of Problem, if known	The clinical signs observed were due to the inadvertent administration of the dose to the lungs.

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)*	Rob will undergo further supervised sessions prior to being signed off as competent for this technique.
7. Reported by (name)	Rachel Watson
8. Date	24/09/24

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

Inspector's comments and recommendations:

Comments and recommendations	
Inspector name	
Date	