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	27/09/2024
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 27/09/2024 one team member (Antonios Eleftheriou) was carrying out the oral gavage dosing for this study with two other competent team members in the room. Antonios was first assessed in rat oral dosing in February 2022, but due to lack of dosing opportunities he had not yet undergone DOPS assessment (training notes attached). After 16 animals, one rat was 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 be unsteady, gasping and was frothing at the nose. The rat was removed from the other rats to perform sch1. Unfortunately, the heart had stopped seconds before the point of cervical dislocation, however this method was still immediately carried out. A different researcher (Michael Penn) completed the remainder of the dosing without incident.
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. The gavage needles are the same as previously used in other studies, with all other animals successfully dosed, so they don’t appear to be a factor. It was noted that the cohort of study animals appear a bit active on restraint, but again this is not unusual.

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)*	Antonios will continue to undergo training sessions before being signed off as competent.
7. Reported by (name)	Rachel Watson
8. Date	27/09/24

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

Inspector's comments and recommendations:

Comments and recommendations	
Inspector name	
Date	