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]

Establishment Licence name	University of Cambridge - Ann Mclaren Building
Establishment Licence number	X81BD37B1
Name of PPL holder	Professor Brian Huntly
PPL number	PP3042348
Protocol no	8
Protocol title	Study of the impact of genetic alterations on HSPC function during the development, progression and treatment of blood cancers (Mice)
Severity classification	Moderate
1. Date of incident	21/08/2022
2. Species	Mouse

3. Brief details of study and how the limits or constraints have been breached	The study is taking place to study the effects of therapeutics on the treatment of leukaemia. Specifically in single treatment or combination. The mice are weighed and checked regularly (latest weights 19th August). It is known that the mice are likely to develop a leukemic disease with enlarged spleens, lethargy and tumour burden. Treatment with ABT-199 can also cause the mice hair to turn grey. The limits were breached as a mouse was found dead on the 21st August.
4. Have you taken advice from the Named Animal Care and Welfare Officer/Named Veterinary Surgeon/others?	I have taken advice from the NACWO and will check the mice closely and continue with regular weighing. The identifying technician noted that there were no obvious signs as to why the mouse would have died.
5. Cause of Problem, if known	The mouse was found dead but the spleen and bone marrow were taken to investigate the infiltration of the cancer. Both tissues were shown to have engraftment of the tumour. No other abnormalities were seen.
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)*	Mice remaining in the study will continue to be monitored and weighed regularly to observe for clinical signs.
7. Reported by (name)	Andrew Moore
8. Date	22/08/2022

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

Inspector's comments and recommendations:

Comments and recommendations	Have read and noted the above. It is clear from this and other studies that rapid deterioration and death can occur, and that increased monitoring may not detect all of these before they have died. Although death as an endpoint should be avoided (PPL SC5), have you considered amending the licence to allow for a low level of mortality on studies such as this one?
Inspector name	Neil Smith
Date	7 Sep 22