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, Anne Mclaren Building
Establishment Licence number	X81BD37B1
Name of PPL holder	Brian Huntly
PPL number	PP3042348
Protocol no	7
Protocol title	Study of the impact of cell extrinsic factors on normal, pre-malignant and malignant haematopoiesis through transplantation

Severity classification	moderate
1. Date of incident	02.09.2021
2. Species	Mus musculus
3. Brief details of study and how the limits or constraints have been breached	Study plan: SP124805. The study involves the generation of a mouse chimaera to study the impact of mutations to the development of CLL. The mouse was injected i.v. to generate a diseased mouse model. This model does not involve a development of full leukemia and only a partial human engraftment over the time.
4. Have you taken advice from the Named Animal Care and Welfare Officer/Named Veterinary Surgeon/others?	n/a
5. Cause of Problem, if known	The mouse was found dead with no obvious cause few hour post injection.
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)*	No action needed. The same experiment was performed 4 additional times previously without obvious sign of distress for the animals. This particular experiment will be terminated and will not be repeated with this sample.
7. Reported by (name)	Maurizio Mangolini
8. Date	03.09.2021

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

Inspector's comments and recommendations:

Comments and recommendations	*Dear Maurizio Mangolini* *Thank you for this PPL Standard Condition 18 notification. The severity classification of protocol 6 is moderate and therefore there has been a breach of protocol severity, triggering a SC18 report.* *Further information is required as described below:* 1. *Please write acronyms in full at first use. In this report does CLL denote chronic lymphocytic leukaemia?* 2. *Please provide details of what was injected intravenously into the mouse.* 3. *From the adverse effects noted in the protocol there appears to be no expectation that mice would die a few hours after the injection and so it would be pertinent to fully investigate why death occurred in this case. Why were steps not taken to do so e.g. a postmortem examination?* 4. *Who was the PILh that performed the injection? Was he/ she experienced, and thus signed off as competent by your Named Training and Competency Officer (NTCO) or was the PILh being supervised by an appropriate person?* 5. *You state that the mouse died after a 'few hours'; please give details of the exact timeframe.* 6. *Who discovered that the mouse had died and what actions did that person take e.g. contacted PPLh, NACWO?* 7. *Regarding point 4 (have you taken advice from NACWO/ NVS), I note that you believe that this was not applicable. Please note that it is expected that advice would be taken from named persons, particularly the NVS, when unexpected adverse effects occur to try to ascertain cause of the death /adverse effects, and to review the experiment to make appropriate changes to try to prevent recurrence of the problem in the future. Why was this not done at the time? Has NVS and NACWO advice since been sought and if so what was it?* ***Please note*** *that any additional information should be returned on this report form by adding to the information that is already present in a colour other than black e.g. red to make the additional information clear to the reviewing Inspector.*
Inspector name	Karen Mason
Date	06 September 2021