



## 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                    |
| Establishment Licence number | X81BD37B1                                  |
| Name of PPL holder           | Darren Schofield                           |
| PPL number                   | PCBA9AEC1                                  |
| Protocol no                  | 1                                          |
| Protocol title               | Production of Potent Monoclonal Antibodies |
| Severity classification      | Mild                                       |

|                                                                                                                                                                                                                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
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| <b>1. Date of incident</b>                                                                                                                                                                                                                                                    | 13 <sup>th</sup> February 2024                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>2. Species</b>                                                                                                                                                                                                                                                             | Mouse                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>3. Brief details of study and how the limits or constraints have been breached</b>                                                                                                                                                                                         | <p>Animals under this study receive five rounds of immunisation following a standard RIMMs model. This consists of two subcutaneous injections targeting the left and right auxiliary lymph nodes in the upper thoracic area for the first four immunisations. The final (5<sup>th</sup> immunisation) is 200ul IP injection. This was the second immunisation, no clinical signs were seen on the first.</p> <p>At dosing, #1 was removed from the nose cone and placed on the mezzanine in the cage to allow for observation of recovery. It was noted the animal was no longer breathing. Clear fluid was observed coming from the nostrils. Lungs and heart were excised and sent for pathology. The lungs were much darker than normal mouse lung tissue.</p> |
| <b>4. Have you taken advice from the Named Animal Care and Welfare Officer/Named Veterinary Surgeon/others?</b>                                                                                                                                                               | NACWO advised they were happy with the actions taken.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>5. Cause of Problem, if known</b>                                                                                                                                                                                                                                          | Mouse appears to have died while under or shortly after removal from general anesthetic.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>6. Action that has been or will be taken</b><br><i>(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)</i> | <p>Since none of the mice were affected in previous dosing timepoints nor were any other mice impacted at this time point, it would appear to be an isolated incident for this particular mouse. We have encountered this once previously on this licence with an outbred strain of mice (CD-1). This was the first observed with an inbred transgenic mouse strain we have used for many years previously. We will continue to monitor on future studies and review whether to reduce or omit the use of anaesthesia if recurring on future studies.</p>                                                                                                                                                                                                          |
| <b>7. Reported by (name)</b>                                                                                                                                                                                                                                                  | Darren Schofield                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>8. Date</b>                                                                                                                                                                                                                                                                | 14 <sup>th</sup> Feb 2024                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |

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

**Inspector's comments and recommendations:**

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|-------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Comments and recommendations</b> | <p>Thank you for submitting this notification and thereby complying with standard condition 18 of your project licence.</p> <p>The content of this SC18 report has been read by an ASRU Inspector and this matter is now CLOSED.</p> <p>Please continue to inform us of any other similar incidents should they occur.</p> |
| <b>Inspector name</b>               | Giles Paiba                                                                                                                                                                                                                                                                                                                |
| <b>Date</b>                         | 16 February 2024                                                                                                                                                                                                                                                                                                           |