



To [REDACTED]
From [REDACTED] Named Information and Compliance Support Officer
Date Friday January 26th
Time 13.00
Venue [REDACTED]
Subject [REDACTED] Mice Ear Pinna C
Pages 4
Our Ref [REDACTED]

Policy-

Compliance Assurance Meetings (CAMs) are a management tool, designed to ensure Governance outside of the Act, to protect individuals, ensure due process and systems are implemented within the division of University Biomedical Services. This process will ensure the University upholds the highest standards of animal welfare and good practice relating to animal care and use.

NOTE: A CAM meeting does not replace the investigation of an incident by the Home Office or other authority. Therefore for example, where the local inspector deems appropriate a Home Office non-compliance investigation may run in parallel or sequentially with a CAM.

Event- 3 events [C) only] incidents occurred within a short time space under PPL [REDACTED]

C) A further study (15/12/2017) under PPL [REDACTED] using study plan [REDACTED] (attached) was performed by [REDACTED] (PIL). [REDACTED] contacted [REDACTED] and [REDACTED] on 23/01/2018 after three BalbC mice were found by [REDACTED] (22/01/2018) each with a large piece of ear missing (Appendix 4, 5 and 6). [REDACTED] informed [REDACTED] that he had removed ear tissue because he had not managed to obtain sufficient blood from the tail vein of each mouse and therefore required tissue for his analysis. [REDACTED] confirmed that the ear tissue was not taken for identification purposes or genotyping. Protocol 2 does not provide authority to take tissue samples nor does the study plan indicate that this procedure would be undertaken. The procedures undertaken (excluding the ear samples) were recorded on the cage cards (Appendix 7).

Closer scrutiny of study plan [REDACTED] (attached), signed off by [REDACTED] does not appear to reflect the authorities authorised by Protocol 2.

The Home Office Inspector [REDACTED] has been informed of all developments by [REDACTED] Deputy Director.

Attachments:

Project Licence documentation



Study Plan documentation





Outcome - Event C

█████ enquired how this event happened. It was confirmed that the experiment had been undertaken under PPL █████, protocol 2 and study plan █████. There had been some confusion regarding the protocol which was why █████ sought clarity.

█████ explained that he told █████ and █████ after they discovered the mice, that he had cut the ear for tissue as he had not been able to obtain sufficient blood from the tail vein procedure. He admitted this was untrue and that he had cut pieces from the ears of these mice for the purpose of identification. He said he had been worried that the holiday period was approaching (15/12/17) and that his usual temporary pen marks on the animals tails would disappear. He therefore decided to make a permanent identification mark when the four animals were first inoculated by the subcutaneous route (one animal was subsequently culled because of an adverse reaction at the site of inoculation). This method of identification was something he had performed before, outside the EU, and thought it was the only way to make a permanent mark. He admitted he had not felt it was necessary to ask for help. █████ informed the meeting that █████ had only recently noticed these cuts on the ears and that they had healed. █████ said he thought, as with the other mice found recently, that a virus had been responsible for causing part of the ear pinna to fall off, not that an ear snip had been taken.

█████ asked for clarification about exactly how protocol 2 had been used. █████ confirmed that he had only injected viral protein by the subcutaneous route, as authorised in step 2) and that repeat immunisations were also undertaken under the authority of step 2. The cage label records that viral infection was the first step undertaken and █████ explained that this was because there was not an option on the drop down list of procedures for the administration of protein. He had therefore chosen the closest option from the list. He confirmed that steps 3 and 4 were not used even though on the protocol these are not optional steps. █████ also asked █████ to explain exactly what he did on the day the animals were first inoculated. █████ said he had injected the animals with viral protein by the subcutaneous route (step 2 of protocol 2) under general anaesthesia and confirmed he had allowed the mice to recover before he took the ear snip.

█████ said the decision to cut the ears of animals lacked judgement and was wrong; using scissors to cut off large pieces of ear for the purpose of identification was no longer acceptable in the UK or EU. He realised █████ was showing remorse and understood █████ had full knowledge and understanding he had done something wrong when mice, with missing pieces of ear, were discovered. However, █████ had made the wrong decision in the first place and by responding in the way that he had when questioned about the missing ear tissue. It was noted that █████ had also made a note on the cage card, after the event, prior to the euthanasia of the animals.

█████ in consultation with █████, had suspended █████ personal licence on the 24th January 2018. █████ explained that what █████ had done may be considered a breach of the Animal Welfare Act 2006 because it was not performed under the authority of ASPA (which, when licensed, permits painful procedures to be undertaken for an experimental purpose) and without anaesthesia. However, the identification of animals is not a licenced procedure so it is not clear how the Home Office will handle this case.



Compliance Assurance Meeting

The University takes this incident very seriously which is why, as Establishment Licence holder, [REDACTED] felt he had no option but to suspend [REDACTED] PIL and remove his access to the animal facility.

Action 1

The Home Office will receive this CAM report and is likely to undertake their own investigation.

Action 2

[REDACTED] encouraged [REDACTED] to consider surrendering his licence permanently and not undertake any work on animals until a complete investigation has been undertaken and a conclusion reached by the Home Office Inspectorate. The meeting was reminded that [REDACTED] has, on record, a previous CAM and non-compliance which the Home Office may take into consideration.

[REDACTED] said he was extremely sorry that this has happened under his PPL. He said he was aware he is responsible for the licensees working under his PPL. [REDACTED] said he had been impressed by how quickly and decisively [REDACTED] acted, and that all staff in UBS should be praised for how they managed and processed this event.

Action-

Action 1: - [REDACTED] confirmed he would continue to suspend [REDACTED] PIL and his would continue to bar his access to the animal facility.

Action 2: [REDACTED] will be sent the two CAMs reports [REDACTED] at the earliest opportunity -NCSO

Appendix 4



Appendix 5



Appendix 6



Appendix 7-Cage label to event C

GLS Balb/c				GLSC	3	♀
I.D.	D.O.B	Ear - Coat	Genotype	Comments		
M00254242		- Alb	WT	SP = [REDACTED]		
M00254243		- Alb	WT	SP = [REDACTED]		
M00254244		- Alb	WT	SP = [REDACTED]		
M00254241		- Alb	WT	Culled Experimental 16-JAN-18		

22-Jan-18	IEAE557A2 (HR)	DNA, RNA or control vehicle and adjuvant
11-Jan-18	IEAE557A2 (HR)	Blood sampling from superficial vessel
15-Dec-17	IEAE557A2 (HR)	Viral Infection





C00106192

PIL: [REDACTED] (HR)	Owner: [REDACTED]
PPL: [REDACTED]	Manager: Not Recorded

Prot: 2 [Mild] Workflow:

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Glossary of terms

AA	A procedure performed without anaesthesia
AB	A procedure performed under anaesthesia, from which the animal recovers
AWERB	Animal Welfare and Ethical Review Body
CAM	Compliance Assurance Meeting
HOI	Home Office Inspector
NVS	Named Veterinary Surgeon
NACWO	Named Animal Care and Welfare Officer
PIL	Personal Licence (Procedures Individual Licence)
PILh	Personal Licence (Procedures Individual Licence) holder
PPL	Project Licence (Procedures Project Licence)
SC	Standard Conditions (of either PIL or PPL)
UBS	University Biomedical Services