



To [REDACTED]
CC [REDACTED]
From [REDACTED] Information and Compliance Support Officer
Date 10th January 2019
Time 14.30
Venue [REDACTED]
Subject Non-Licensed Animal Use
Pages 3
Our Ref CAMs_22_AN-160119

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 [REDACTED]. This process will ensure the [REDACTED] 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 [REDACTED] or other authority. Therefore for example, where the local inspector deems appropriate a [REDACTED] non-compliance investigation may run in parallel or sequentially with a CAM.

Event-

The [REDACTED] was contacted by a researcher because they required facility support over the Christmas period. An e-mail had been sent by the [REDACTED] on November 30th informing all users of the dates when [REDACTED] were unable to provide technical support. However, because this researcher had not completed the induction process, they had not received this mail. Therefore, because documentation was not in place for induction to be complete, their access card had not been programmed. Further information is required how access use was arranged with the training supervisor.

NB: A researcher requires security clearance to commence work, whereby, the [REDACTED] facilitates the process, issuing the "User Guide" document as part of the induction.

The researcher in question had previously attended [REDACTED] and passed Licensee PIL modules and received their certificate for passing the exam. However, they had not completed the [REDACTED] application process, and therefore did not have personal licence authority in place to undertake Scientific Procedures.

NB: This researcher had received e-mail circulation from the [REDACTED] research staff entitled "Performing procedures without a licence" and attended the PIL lecture on Minor Procedures where this information is detailed.

A regulated procedure was performed without a Personal Licence on 20th December 2018, this procedure was undertaken as part of their licensee training, during this procedure, 6 mice were given a topical administration of tamoxifen. The procedure was part of an ongoing experiment and the PILH who conducted the training was [REDACTED], under [REDACTED] (training supervisor). This research also commenced without study plan completion by the biofacility [REDACTED] which must also be in place prior to any animal procedures in [REDACTED]. Further information is required regarding what steps were taken by the training supervisor to ensure PIL permissions were in place.



Whilst there appears to be no animal welfare concerns, the [REDACTED] and [REDACTED] staff are concerned that there will be animal wastage following these unlicensed procedures. The [REDACTED] has been informed, and whilst their investigation is ongoing, this [REDACTED] process will be recorded along with any advice received from the inspector.

A [REDACTED] has been selected as the most appropriate means of action to ensure governance and compliance and, setting processes in place to impress there is no repetition of this event.

Action-

The [REDACTED] as Chair of the meeting enquired what information regarding the application and use of their licence the researcher had taken from the module training course. They did not know and did not remember the information provided specifically in the Minor procedures lecture in October regarding PIL use. Following the course and exam success, a letter was sent from the [REDACTED] [REDACTED] explaining what the applicant should do following receipt of their certificate. Had the researcher read the letter, which was sent as an e-mail? Yes, but the letter shown as an example by the [REDACTED] appeared different from that received.

Action 1-Letter sent to the researchers to be reviewed by the [REDACTED] for content accuracy. Post Meeting Note: Letter has not changed for a very long time

Action2- Steps following exam pass to be reconsidered by [REDACTED] with a view to reviewing [REDACTED] contact and actions following [REDACTED] letter receipt.

The [REDACTED] asked if the researcher had attended induction training and what they understood by the [REDACTED]. The researcher admitted they did not have a thorough knowledge as they had not read the booklet completely. They volunteered that they had entered the facility, without permission, using another person's access card, as they were worried and wanted to check a cohort of experimental mice. The [REDACTED] informed the researcher that sharing swipe cards was not acceptable and the person whose card was borrowed could have the access revoked as stated in the [REDACTED].

The PhD supervisor and PPL holder was asked if they knew what checks had been made by the PIL trainer prior to initiating regulated procedures, had the trainer requested to see the researchers PIL, applying PIL Standard Condition 19. The PIL trainer was an experienced and trusted licence holder having held a PIL since 2015 but had not requested to see the researchers PIL. *Action 3- The PPL holder will speak to the PIL trainer and ensure that they aware of their Personal Licence Standard conditions and their responsibilities to perform checks prior to training PIL regulated procedures.*

The [REDACTED] requested confirmation regarding what procedures had been performed. The researcher confirmed that 6 mice had received a topical application of Tamoxifen without anaesthetic and that this was the only procedure they had done. They had not, as might be interpreted from e-mail correspondence undertaken procedures on the 7th and 11th January.

The [REDACTED] requested the PPLh ensured the accuracy of the dates entered onto study plans, as in this case they did not reflect the actual date the study began.

Action 4-PPLh to review active Study plans to ensure accuracy and amend if necessary.

The researcher was asked to explain how the experiment is continuing in the light of the group moving to Germany on Monday 14th January. The researcher informed the CAMs that the mice had



been euthanased, as there was insufficient time to complete the experiment. The researcher was then asked why the study was initiated if there was not time to complete it. Responding, the researcher said they thought the [REDACTED] staff would continue procedures over the Christmas holiday period. They had not seen the e-mail (as they had not received security clearance), sent by the [REDACTED], instructing all research staff that there would not be licensed procedure cover over the holiday period, but confirmed that the PILh had received the mail sent.

Action 5- The PILh will be contacted by [REDACTED] regarding the actions they had taken.

The [REDACTED] enquired if the [REDACTED] had spoken to the researcher on the 9th January 2019, this was confirmed and they had provided their address in Germany for further contact. The [REDACTED] reiterated, their actions had not resulted in any welfare problems, but that animals had been wasted, and this was unacceptable. The PELh will be sent this report and have contact with the [REDACTED].

The PPLh informed the meeting that they were moving their group to Germany at short notice, one PILh will remain in the UK and the PPLh will retain their PPL and travel to the UK monthly for one week to oversee their research for the duration of a year. The [REDACTED] overseeing that facility is aware of these actions and the PILs for the group will be revoked apart from those remaining in the UK.

Action 6-. New PILh should not be signed off on a regulated procedure until competency has been proven and should not embark on regulated procedures until they have received confirmation notification via [REDACTED] from [REDACTED] that a PIL is in place. The [REDACTED] and [REDACTED] will employ a route of communication to [REDACTED] to ensure they are made aware that they, and their PILh are responsible for the training and supervision of new PILh

Glossary of terms

[REDACTED]	[REDACTED]
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