UNIVERSITY OF CAMBRIDGE
University Biomedical Services

Compliance Assurance Meeting

To [redacted]

From [redacted] Named Information and Compliance Support Officer

Date 10/08/2017

Time 11.00

Venue [redacted]

Subject Rat Wound Incident

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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-

On 28th July 2017 [redacted] Named Veterinary Surgeon (NVS) was carrying out a routine vet visit to the [redacted] One of the biofacility animal technicians, [redacted] identified there was an animal with a skin lesion on its flank that they would like examined; Rat #45 under study plan [redacted] had asked the Personal licensee (PILh), [redacted] to keep the animal downstairs in the holding room rather than taking him for behavioural testing due to the skin lesion and the need for examination.

This group of animals have had a single surgical procedure to implant jugular catheters with a dorsal access port fixed overlying the caudal thoracic spinal vertebrae.

When the animal room was visited it was identified that although the rest of the group were still in the room, the individual that required examination was not there. [redacted] and [redacted] were unsure as to whether the animal had been taken for Sch1 euthanasia or for use in study so they attempted to contact [redacted]

After being unable to locate [redacted] in any of the behavioural rooms he was located in the surgical prep room with rat #45. [redacted] as asked what he was intending on doing and he stated he wanted to anaesthetise the animal to debride the lesion and suture the wound edges together. The animal had not yet received any gaseous anaesthesia or any pre-medication at this point. [redacted] discussed the ramifications of continuing with this procedure and how potentially serious it was. [redacted] also discussed how important it was to understand the difference between surgery carried out under the Animals (Scientific Procedures) Act 1986 (ASPA) for a scientific purpose and surgery carried out under the Veterinary Surgeons Act 1966 (VSA) for treatment of a lesion.

[redacted]

The lesion itself was on the left flank of the animal, approximately 1.5cm x 2cm. After discussion of ASPA, [redacted] determined the lesion was not related to the regulated procedure – it was likely caused by a superficial injury and self-trauma. [redacted] discussed the scientific plan for the animal and was informed as the procedure was relatively recent that the animal would be kept for 'a little while' but could not be given a specific date at the time.

[redacted] anaesthetised the animal with Isoflurane and performed a closer assessment of the lesion. The lesion was a partial thickness ulceration, [redacted] felt the two most appropriate treatment options were either:
1. Maintain a clean wound environment with regular cleaning and monitoring of the site or
2. Elliptical excision of the ulcerated skin and closure of the site to allow healing by primary intention.
Due to the fact the animal was going to be maintained for a long time and ulcers may frequently be very slow healing injuries [redacted] made the decision that removal followed by closure of the skin was the best option. Despite the size of the lesion there was sufficient flexibility in the skin to allow excision of the lesion with narrow margins and comfortable closure without impinging on use of the limb by the animal or interference with the intravenous port. [redacted] administered Buprenorphine and Meloxicam via subcutaneous injection for pain relief under [redacted] guidance. The animal was transferred to the right hand Sterile Experimental Procedures (SEP) room, the overall procedure took approximately 25 minutes and the animal recovered well.

Post operatively [redacted] instructed that the animal should receive 3 days of oral Metacam (for pain relief) and 5 days of oral Baytril (antibiotic) due to the risk of infection from having an open contaminated wound. [redacted] was concerned the animal may continue scratching (if it were due to self-trauma), so asked for:
1. The animal not to have any behavioural experiments for at least 3 days,
2. To be closely monitored for any ongoing scratching/reformation of an ulcer at the site and
3. Should the surgical incision break down due to interference for the animal to be euthanased.

Although there was no actual offence committed [redacted] is concerned that this was a near miss and had he not happened to intervene then this procedure would have gone ahead and there would have been a criminal offence committed under section 19 of the Veterinary Surgeons Act 1966 and possibly section 5 of the Animal Welfare Act 2006.

Following the procedure whilst awaiting for the animal to recover the licensee also questioned the [redacted] whether he was legally permitted to carry out the surgery based on a statement within the adverse effects section of [redacted] Project Licence stating 'surgical wounds may be re-sutured on one occasion', again [redacted] needed to clarify this was only relating to surgical procedures carried out as per the licence, not incidental injuries.

[redacted] Director of Health and Safety, Occupational Health and Safety Service has selected a Compliance Assurance Meeting 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-

[redacted] clarified that this near miss incident fell outside of the Animal (Scientific Procedures) Act 1986 (ASPA) and was not regarded as a non-compliance issue, the outcome aim of this meeting is to clarify who can do what to an animal. The interpretation of [redacted] actions was that he thought the lesion on the rat was of a type described in the adverse effects section of the Project

Licence (PPL) and therefore one that he could treat as a Personal Licence Holder (PIL). He said he was concerned that the animal was suffering and concerned by the speed at which the lesion appeared to be increasing in size. He said he was aware the NVS would be visiting the unit however did not expect the NVS to be in the unit until later in the day. [redacted] plan was to anaesthetise the animal before cleaning and repairing the wound.

A catheter had been inserted into the animal approximately 2 weeks previously. [redacted] said he thought the lesion was caused by scratching and the scratching was probably caused by irritation from the mesh edge of the inserted the cannula.

This type of lesion, which is not associated with a wound created by a licensee, happens infrequently. Its cause was unknown and may have been exacerbated by the compound being administered.

The delicate ethical line between treating and euthanasia was discussed. The consensus was that as this wound was not part of the original surgical wound caused by the incision to place the catheter. For this reason this wound was not covered by the authorised repair intervention described in the adverse effects in the PPL granted under the Animals (Scientific Procedures) Act 1986.

This means that the repair/treatment should only be undertaken by a Registered Veterinary Surgeon (Vet) under the Veterinary Surgeon's Act. Only a Registered Veterinary Surgeon can make the clinical assessments and repair a wound to an animal under these circumstances. Members of the public, *in vivo* researchers, human surgeons, or Vets registered as non-practicing with the Royal College of Veterinary Surgeons, (for example [redacted] would not be allowed to treat an animal.

Normally in the research context a Vet would assess the animal and advise a course of treatment in consultation with the researcher.

[redacted] was advised that UBS Vets are employed to provide a service to researchers which includes requesting urgent attention for an animal. A Vet may be paged or telephoned. The contact details and instructions on how to contact a Vet are displayed in every UBS animal unit. If the usual facility UBS Vet is otherwise occupied then one of the UBS Vet team will attend to the call. All animal users are encouraged to develop the culture of picking up the phone and calling one of the UBS Vets when they discover any problem with a research animal.

[redacted] enquired if the group required more information from UBS to support licensees to make the right decision. [redacted] was keen for a further meeting where the above information could be discussed with the whole research group. The NACWO and Vets said they recognise that the PIL and the group have good intentions and attitude about animal welfare.

In future discussions about the treatment options available (including euthanasia) when adverse events are encountered, along with considerations of all stakeholders involved (including the science, and the animal's experiences), should always include a Vet.

[redacted]

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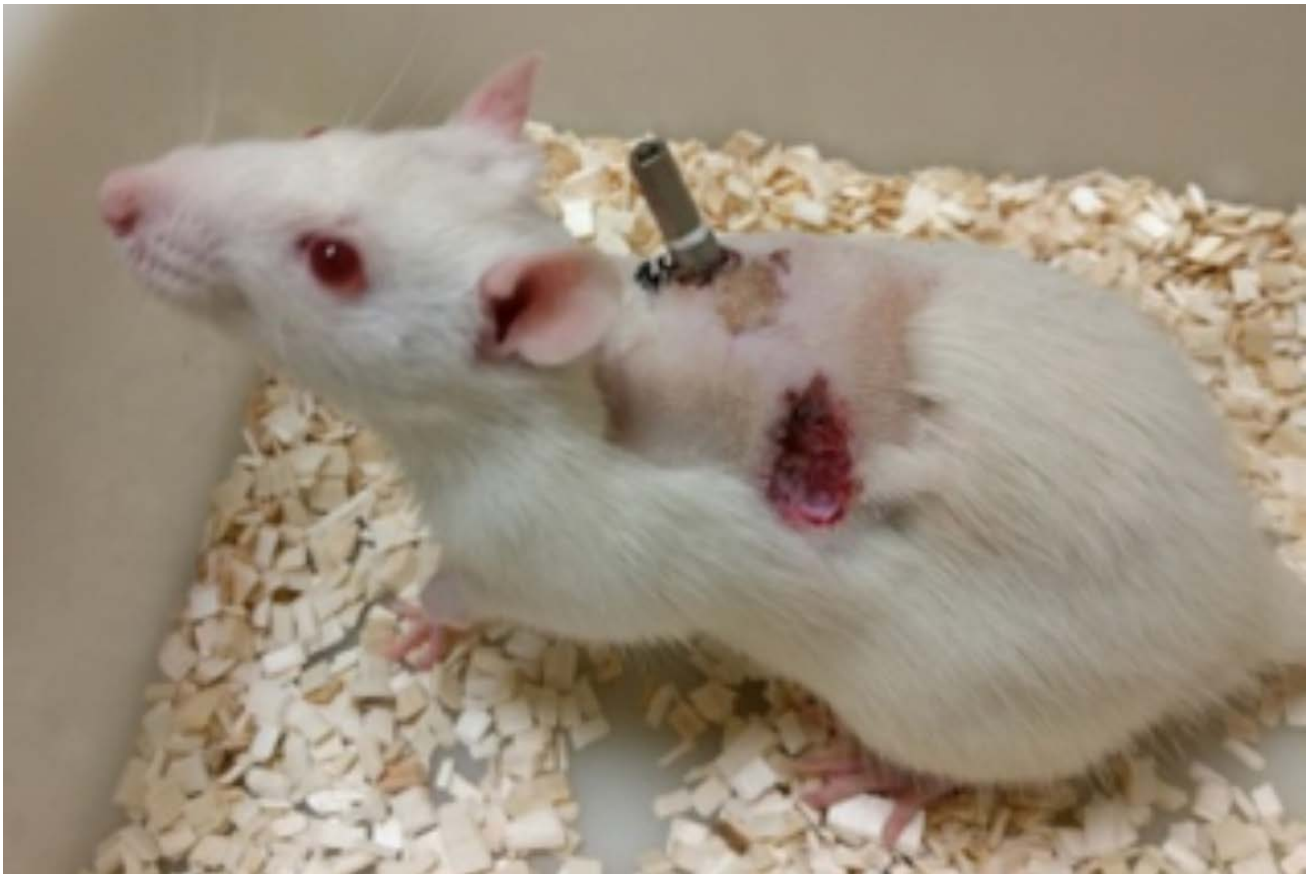
University Biomedical Services

Compliance Assurance Meeting

Appendix 1



[redacted] rat #45 photograph taken 28th July by PIL [redacted] during the examination with [redacted]

[redacted]