**IACUC Training Exercise #2 – 2021 (What to Do About a Possibly Reportable Matter)**

The following exercise is a continuation of exercise #1-2021 and may be useful in stimulating discussion regarding compliance with PHS Policy and VA Handbook 1200.07. This scenario is presented in short episodes, each followed by a question **For IACUC discussion**. To facilitate discussion, page 1 of the exercise may be distributed to the IACUC members prior to a meeting. After the IACUC discusses the first question during the meeting, a moderator can read the comments on page 2, leading to the next question **For IACUC discussion**. Following that discussion, page 3 may be distributed for the committee’s consideration.

Recall: Matt Johnson, the lead technician for Dr. Carol Wang, an investigator at the Hometown VA Medical Facility, was cleaning and treating a surgical incision of an anesthetized cat with a newly developed agent designed to improve healing where the wound is subject to movement stress. Because the procedure is short, the cat had been anesthetized with an intramuscular (i.m.) injection of a mixture of ketamine and midazolam, which typically allowed plenty of time for the entire procedure and was less stressful on the cat than mask induction with isoflurane would be. The procedure took a little longer than usual, and Matt noticed a slight increase in the cat’s respiratory rate, suggesting the cat was in a lighter plane of anesthesia, which needed to be corrected. He asked his assistant, Jerry Kim (an undergrad student volunteering in the lab to gain some research experience), to administer a small supplemental dose of the ketamine/midazolam mixture. Jerry saw that there was not enough of the mixture left, and found that the bottle of midazolam they had used to make it up was empty, so he got out a new bottle, carefully made up more of the mixture, drew up the volume that Matt had said to give, administered it i.m., and recorded the dose on the surgical notes. Matt finished the procedure without incident, and the cat recovered uneventfully. A week later, Matt was cleaning the lab and noticed that several bottles of midazolam with the same lot number, including the one that Jerry had opened during the surgery on January 14, had actually expired three days earlier, on January 11. Matt used the required procedure to dispose of the expired midazolam so it could not mistakenly be used again. Matt provided a written report about this for the IACUC. The Chair had appointed the Attending Veterinarian to investigate, and put the matter on the agenda for the next IACUC meeting.

Next: The Chair also reminded Anne Marie, the IACUC Coordinator, about preliminary notifications to ORO, OLAW, and the office of the CVMO, and asked her to give them each a call right away. Anne Marie thought it was premature to talk about communicating with anyone outside of the station, before any investigating had been done and before the IACUC had even had a chance to consider it, and she wondered whether, if it actually is necessary, it would be better to send written reports instead of just calling?

**For IACUC discussion (Question 1 of 2): What information would clarify for Anne Marie about the preliminary notifications?**

Moderator: It is to the benefit of the Hometown VA Medical Facility, to alert OLAW, ORO, and the office of the CVMO as soon as possible that there is a matter under investigation. Such an alert presumes nothing about the outcome of the investigation or the reportability of the matter, but allows OLAW, ORO, and the office of the CVMO to respond knowledgeably that an investigation is underway, if asked by the public about the matter. It also allows them to provide guidance to the station as needed, as the IACUC addresses the matter. As this communication is entirely pre-decisional, there is no requirement that it be documented in writing, and OLAW, ORO, and the office of the CVMO will accept it in any form – phone, email, FAX, etc. If the station prefers to document the alert, it’s a good idea to make it very clear (in a subject line, as a watermark, etc.) that it is a “preliminary pre-decisional notification”, and not any kind of formal report.

When the IACUC discussed the matter at their next convened meeting, one member asked whether this is even reportable, given that the cat was fine. Another member was of the opinion that the matter is reportable, but the committee should simply forward Matt’s report as the IACUC’s report to the VAMC Director, “because it is clear, concise, and beautifully to the point” – an expired drug was administered, the cat is fine, the remaining expired drug has been discarded, the matter is reportable, done. Another member questioned whether it matters that the animal involved was a cat – after all, this is a report to ORO and OLAW, which don’t distinguish between species regulated by USDA and those that are not. The Chair pointed out that any report should include a description of what the IACUC decides needs to be done to prevent recurrence, and OLAW needs to know the species in order to assess the appropriateness of the IACUC’s determinations about reportability and corrective action. The Non-Affiliated Member said, “doesn’t OLAW need to know that Jerry was the one who actually administered the expired drug, under Matt’s supervision? And doesn’t the report have to provide a description of the procedure that Matt was performing?”

**For IACUC discussion (Question 2 of 2): If the matter is reportable, what information should and should not be included in the report?**

Moderator: If the IACUC determines that the matter is reportable, a formal report is to be drafted, to follow up on the preliminary pre-decisional notification. According to NOT-OD-05-034, information needed in the formal report, to allow OLAW to assess the circumstances and actions taken to correct and prevent recurrence of the situation, includes:

* Animal Welfare Assurance number (https://grants.nih.gov/grants/olaw/assurance/300index.htm);
* relevant grant or contract number(s) if the situation is related to an activity directly supported by PHS;
* a full description of any potential or actual effect on PHS-supported activities if the situation is not directly supported by the PHS but is in a functional, programmatic, or physical area that could affect PHS-supported activities (e.g., inadequate program of veterinary care, training of technical/husbandry staff, or occupational health; inadequate sanitation due to malfunctioning cage washer; room temperature extremes due to HVAC failures); *NOTE: This applies to all VA research, because all VA research with animals is subject to PHS Policy, regardless of whether PHS funding support is involved.*
* full explanation of the situation, including what happened, when and where, the species of animal(s) involved, and the category of individuals involved (e.g., principal or co-principal investigator, technician, animal caretaker, student, veterinarian, etc.);
* description of actions taken by the institution to address the situation; and
* description of short- or long-term corrective plans and implementation schedule(s).

Note that the following are not included in the list above. The IACUC files should contain this information about each reportable matter, and the oversight entities may send follow-up requests for more details, but there is no need to include this information routinely when initial reports are submitted:

* Names of individuals involved – research staff, animal facility staff, IACUC members, etc.
* Protocol number or title – *NOTE: ORO does require these to be included in the report to ORO*
* Specific locations (room numbers) where the matter occurred
* Details of the procedures involved if they are not needed to understand the matter being reported – in this exercise, details about the pre-operative fasting, specifics about the cleaning and treatment procedure, and eventual euthanasia are not important to understanding what happened
* Any preliminary information that was found on investigation by the IACUC to be misleading or incorrect