**IACUC Training Exercise #1 – 2021 (What to Do About a Possibly Reportable Matter)**

The following exercise 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 provided, leading to the next question **For IACUC discussion**. After the last question on page 2 has been discussed, that page may be distributed for the committee’s reference.

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.

**For IACUC discussion (Question 1 of 3): What should Matt do now?**

Moderator: Matt went to the IACUC Coordinator, Anne Marie, and told her what had happened. She instructed him to write it up so it could be submitted to the IACUC within 5 days of when he realized there was a problem. When Matt went back to the lab and explained to Jerry that Matt now had to write up a report, so that the IACUC could investigate, Jerry was puzzled. The expired midazolam had been disposed of, and the cat was fine, so what was there for the IACUC to investigate? What was there for Matt to report? Besides, how could Matt write a report before any investigation was even started? And what was the rush to write something up?

**For IACUC discussion (Question 2 of 3): What is there to explain to Jerry?**

Moderator: The report that Matt was going to write was just to the IACUC, to formally let them know what had happened, and is needed because administering an expired drug to an animals is a non-compliance that is potentially reportable to VA’s Office of Research Oversight (ORO) and the Office of Laboratory Animal Welfare (OLAW). It’s the IACUC’s responsibility to look in more detail into what happened, figure out what ought to be done about it to make it less likely to happen again, and determine whether it is in fact reportable to ORO and OLAW. ORO requires that the IACUC receive the written report from anyone who notices such a potential noncompliance, within 5 days of when the person notices it.

Matt conscientiously wrote up a description of what had happened, for the IACUC to review. He knew that it is important to stick to the relevant facts and not clutter up the report with extraneous details, so he wrote:

On January 14, 2021, a mixture of ketamine and midazolam was administered to a cat during a procedure. It was discovered on January 21, 2021, that the bottle of midazolam used had expired on January 11, 2021. The procedure was completed and the cat recovered uneventfully. All expired bottles were removed and properly disposed of on January 21, 2021.

**For IACUC discussion (Question 3 of 3): What should Anne Marie do with this report?**

Moderator: Anne Marie forwarded it right away to the IACUC Chair, so that an investigative subcommittee could be appointed to look into the situation. The Chair asked the Attending Veterinarian (as an “investigative subcommittee” of one) to find out more about what had happened, and instructed Anne Marie to put it on the agenda for the next IACUC meeting, for the Attending Veterinarian to report to the IACUC on whatever had been learned by then.