IACUC 101™ Series “Scenario Shorts”

**DISCLAIMER**: With the issuing of new OLAW Guidance Notices and USDA Animal Care Policies as well as new and revised interpretations of PHS Policy and USDA Animal Welfare Regulations, answers provided in this document are subject to change. You are encouraged to remain current with relevant laws, regulations and policies.

Day 1:

1. **We just learned that our nonaffiliated member died unexpectedly. These are exceptional circumstances, and the process of identifying an individual who is willing, available and meets the criteria of community representative can take a considerable time.**
   1. **Would it be acceptable to conduct official IACUC business as long as we show evidence of trying to fill this position as quickly as possible?**
2. Yes
3. No
4. It depends
   1. **Does it matter if it is official vs. unofficial business?**
5. Yes
6. No
7. It depends

2. Our IO wants to appoint one full-voting “primary” scientist to our IACUC and two alternate scientists, either of whom (but not both) can fill in during the primary scientist's absence. The IO also wants to appoint two full-voting “primary” community members and one alternate community member who can fill-in during the absence of either (but not both) of the “primary community” members.

* 1. **Is it legal to appoint two alternates for one primary member?**
     1. Yes
     2. No
     3. Maybe
  2. **Is it legal to appoint one alternate for two primary members?**
     1. Yes
     2. No
     3. Maybe

**3. We have several collaborative or contracted animal research projects at other research facilities and CROs. Either we subgrant PHS moneys to support the work or pay for the research with our own money. We only work with institutions that have their own IACUC, PHS-Assurance and USDA registration. Our policy for collaborative research projects is that these institutions own the research animals when they are in their possession. Recently, the IACUC at a collaborator's institution suspended one of our projects because of on-going unapproved animal use. These were USDA-regulated animals on a project supported by PHS moneys from our institution.**

**3.1. Which institution must report the incident to USDA?**

* + 1. Institution that receives the money
    2. Institution that suspends the activity
    3. Both
    4. Neither

**3.2. Which institution must report the incident to OLAW?**

* + 1. Institution that receives the money
    2. Institution that suspends the activity
    3. Both
    4. Neither
    5. It depends

**3.3. Which agency must be notified?**

* + 1. USDA only
    2. OLAW only
    3. Both
    4. Neither

**3.4. Whose PHS Assurance or USDA registration is in jeopardy?**

* + 1. Receives money
    2. Owns animals
    3. Both
    4. Neither

**4. One of our PIs reported a rabbit in a PHS-funded activity experienced an unexpected mortality. Our AV, in consultation with the IACUC, asked the PI to stop any additional studies in order to reevaluate the research design. This was not a matter of noncompliance but rather what turned out to be an unexpected increase in virulence of a bacterial strain when administered to whole-animals.**

**4.1 Does the IACUC have to report this incident to OLAW and/or the USDA?**

* + 1. USDA only
    2. OLAW only
    3. Both USDA and OLAW
    4. Neither USDA or OLAW

**4.2. If the incident had been due to noncompliance, what agency(ies) would consider this a suspension?**

1. USDA only

2. OLAW only

3. Both USDA and OLAW

4. Neither USDA nor OLAW

**Day 2:**

**5. At a recent IACUC meeting, our compliance monitor stated a PI used a different surgical anesthetic in rabbits on a PHS-funded study from what he had been approved to use in his protocol. There were no animal welfare concerns prior to, during or after the surgery. During the subsequent discussion, the Chair reminded the IACUC that the drug and dose used are listed for use in rabbits in one of the IACUC-approved drug formularies. The vet went on to say that the drug and dose were also appropriate for the animals in this particular research activity; however the PI never contacted him before using the anesthetic. Since no animals were harmed, IACUC members could not decide if the change in anesthetic was acceptable in this case or a matter of noncompliance.**

**5.1 Did the change to another anesthetic constitute non-compliance?**

* + 1. Yes
    2. No

**5.2 If this is noncompliance, is the change reportable to OLAW and/or USDA?**

* + 1. USDA yes, OLAW yes
    2. USDA yes, OLAW no
    3. USDA no, OLAW yes
    4. USDA no, OLAW no

**5.3. Since the IACUC has approved a drug formulary that addresses the use of this anesthetic in this species, could the vet have given the PI a nod to the change? That is, could the significant change been administratively handled by the vet using the veterinary verification and consultation (VVC) process established by the IACUC?**

* + 1. Yes
    2. No

**6. Several of our investigators conduct non-survival surgery or acute non-surgical procedures on animals. Most of these studies are over in a couple hours while others may last all day. All end with euthanasia. Our PIs want to use (1) expired medical materials (e.g. sutures, saline, catheters, instruments, etc.), as well as (2) expired drugs including anesthetics, analgesics and euthanasia agents, and/or (3) non-pharmaceutical grade medications (even when the human or veterinary pharmaceutical-grade product is available).**

**6.1 Is it OK to use expired medical materials (e.g. sutures, saline, catheters, instruments) for acute, non-survival studies as long as their use doesn’t affect animal welfare or compromise the study?**

* + 1. Yes
    2. No

**6.2 Is it OK to use expired euthanasia, anesthesia or analgesia agents on acute, non- survival procedures as long as it does not affect animal welfare or compromise the study?**

* + 1. Yes
    2. No

**6.3 Is it OK to use non-pharmaceutical drugs on acute, non-survival studies as long as it does not affect animal welfare or compromise the study and even though there are medical grade drugs available at a much higher price?**

* + 1. Yes
    2. No

**6.4 Where must expired drugs and medical devices be stored?**

* + 1. In a segregated area
    2. In any secure area as long as well labeled
    3. Both 1 and 2
    4. In Ernie’s office

**7. We are a PHS assured and USDA registered research facility. Some of our PIs hold rats or mice or even rabbits in their labs for less than 12 hours to perform either (a.) non- invasive procedures (e.g. dosing, weighing) or (b.) surgery (non-survival or survival).**

**7.1 Does the IACUC have to inspect areas outside of the animal facility on a semi- annual basis where animals undergo only non-surgical/non-non-invasive procedures and are not housed for more than 12 hours?**

* + 1. USDA yes, OLAW yes
    2. USDA yes, OLAW no
    3. USDA no, OLAW yes
    4. USDA no, OLAW no
    5. It depends

**7.2 Does the IACUC have to inspect labs (outside the central animal facility) on a semi- annual basis where animals undergo surgery (minor or major, survival or nonsurvival) but are not housed for more than 12 hours?**

* + 1. USDA yes, OLAW yes
    2. USDA yes, OLAW no
    3. USDA no, OLAW yes
    4. USDA no, OLAW no
    5. It depends

**7.3 For USDA regulated species, who must conduct the semi-inspection of required areas?**

* + 1. At least 2 IACUC “members”
    2. At least 2 voting IACUC members (USDA)
    3. An IACUC approved, qualified consultant (PHS)
    4. 1, 2 or 3 above OK
    5. N/A

**7.4 For PHS covered species, who can conduct the semi-inspection of required areas?**

* + 1. At least 2 IACUC “members”
    2. At least 2 voting IACUC members
    3. An IACUC approved, qualified consultant
    4. 1, 2 or 3 above OK
    5. N/A

**8. The USDA regulations and PHS Policy require the conduct of both program review and facility inspection “at least once every 6 months”.**

With respect to protocol review, USDA’s new change in policy requires the IACUC shall conduct complete reviews of activities at appropriate intervals as determined by the IACUC, but not less than every 3 years. PHS Policy states that the IACUC must conduct a complete review of “each previously approved, ongoing activity” at least once every three years.

**8.1 Must the program review and facility inspections be conducted exactly every 6 months or less or is there some leeway?**

* + 1. Yes, the feds are very strict about this stuff
    2. No, the feds are reasonable-plus or minus a month (as long as there is no drift year to year)

**8.2 Is USDA’s new requirement for a complete review of protocols at least once every 3 years mean exactly 3 x 365 days or less from the previous complete review?**

* + 1. Yes, USDA is pretty inflexible about the timing of protocol review
    2. No, USDA is pretty reasonable allowing some flexibility

**8.3 Is OLAW’s requirement for a complete review of protocols at least once every 3 years mean exactly 3 x 365 days or less from the previous complete review?**

* + 1. Yes, OLAW considers the protocol to be expired at 3 years plus one day.
    2. No, OLAW is pretty reasonable-plus or minus a month