



RESEARCH RECORDS REVIEW

NEW INSPECTOR VIRTUAL TRAINING
ANIMAL WELFARE OPERATIONS

Research Facilities, Part 4

6/24/2026



RESEARCH RECORD

NEW INSPECTOR
ANIMAL WELFARE



Research Facilities, Part 4



Physical inspection of
facility and animals



Review of records

A person wearing a white long-sleeved shirt is seated at a desk, reviewing a large stack of papers. Their hands are visible, flipping through the pages. To the left, a portion of a silver laptop is visible. The background is a bright, out-of-focus window. A dark teal banner with white text is positioned at the bottom center of the image.

Review of records

Agenda

- Records to request
- IACUC meeting minutes
- Protocol selection
- Protocol review
- Specific types of protocols
- Management of facility records
- Composing citations
- Completing the inspection



Details to follow-up on after the facility inspection

- Review medical records/investigator's logs to determine that animals with painful/ distressful procedures received the proper pain/ distress relieving medication and/or care
- For APHIS approved multiple major operative procedures, verify that the stipulations in the approval letter are being met.



Required records – all research facilities

- IACUC records
- Annual Report submitted to USDA
- Contingency plan
 - Including documentation of annual review
- Program of Veterinary Care
 - Written program if AV is part time or the facility has dogs

Required records – species specific



Dogs

- Written program of veterinary care
- Exercise plan
- Medical records
- Retained dog tags



Dogs and cats

- Acquisition/disposition records
- Record of animals on hand/inventory
- Certification statement



Non-human primates

- Enrichment plan



Birds – *if covered*

- Enrichment plan



Marine mammals

- Medical records
- Necropsy records

Reviewing IACUC records

Note! If a required position is unfilled, there is not a properly constituted IACUC and the committee can not perform the required official AWA functions

1. Meeting minutes

- Attendance- required members should be at most meetings
- Discussion of any reported animal welfare concerns

2. Semi-annual program review & facility inspection

- Often done together, but not required
- Must be done every 6 months (*within the same month*)
- Written report is required
 - Must be reviewed and signed by majority
 - Differentiate significant from minor deficiencies
- Verify deficiencies have been addressed in the timeframe given



Conducting program & facility review

- OLAW checklist (*available on their website*)
 - Not **required**, but may be used
- Program and SOPs must be reviewed every 3 years
- Facility inspection
 - Animal care and use sites must be inspected by at least 2 IACUC members
 - Open to whole committee to participate
 - May also use ad-hoc invitees

I. Semiannual Program Review Checklist ⁱ

A. Institutional Policies and Responsibilities

Date:

* A = acceptable
M = minor deficiency
S = significant deficiency
C = change in program
NA = not applicable
✓ Check if repeat deficiency

1. Animal Care and Use Program

	A*	M	S	C	NA
a. Responsibility for animal well-being is assumed by all members of the program (<i>Guide, p 1</i>) [must]					
b. IO has authority to allocate needed resources (<i>Guide, p 13</i>)					
c. Resources necessary to manage program of veterinary care are provided (<i>Guide, p 14</i>) [must]					
d. Sufficient resources are available to manage the program, including training of personnel in accord with regulations and the <i>Guide</i> (<i>Guide, pp 11, 15</i>)					
e. Program needs are regularly communicated to IO by AV and/or IACUC (<i>Guide, p 13</i>)					
f. Responsibilities for daily animal care and facility management are assigned to specific individual(s) when a full-time veterinarian is not available on site (<i>Guide, p 14</i>) [must]					
g. Inter-institutional collaborations are described in formal written agreements (<i>Guide, p 15</i>)					
h. Written agreements address responsibilities, animal ownership, and IACUC oversight (<i>Guide, p 15</i>)					

2. Disaster Planning and Emergency Preparedness

	A*	M	S	C	NA
a. Disaster plans for each facility to include satellite locations are in place (<i>Guide, pp 35, 75</i>) [must]					
b. Plans include provisions for euthanasia (<i>Guide, p 35</i>) [must]					
c. Plans include triage plans to meet institutional and investigators' needs (<i>Guide, p 35</i>)					
d. Plans define actions to prevent animal injury or death due to HVAC or other failures (<i>Guide, p 35</i>)					
e. Plans describe preservation of critical or irreplaceable animals (<i>Guide, p 35</i>)					
f. Plans include essential personnel and their training (<i>Guide, p 35</i>)					
g. Animal facility plans are approved by the institution and incorporated into overall response plan (<i>Guide, p 35</i>)					
h. Law enforcement and emergency personnel are provided a copy and integration with overall plan is in place (<i>Guide, p 35</i>)					

3. IACUC

	A*	M	S	C	NA
a. Meets as necessary to fulfill responsibilities (<i>Guide, p 25</i>) [must]					
b. IACUC Members named in protocols or with conflicts recuse themselves from protocol decisions (<i>Guide, p 25</i>) [must]					
c. Continuing IACUC oversight after initial protocol approval is in place (<i>Guide, p 33</i>)					
d. IACUC evaluates the effectiveness of training programs (<i>Guide, p 15</i>)					

4. IACUC Protocol Review - Special Considerations

	A*	M	S	C	NA
a. Humane endpoints are established for studies that involve tumor models, infectious diseases, vaccine challenge, pain modeling, trauma, production of monoclonal antibodies, assessment of toxicologic effects, organ or system failure, and models of cardiovascular shock (<i>Guide, p 27</i>)					
b. For pilot studies, a system to communicate with the IACUC is in place (<i>Guide, p 28</i>)					
c. For genetically modified animals, enhanced monitoring and reporting is in place (<i>Guide, p 28</i>)					
d. Restraint devices are justified in the animal use protocols (<i>Guide, p 29</i>) [must]					

Facilities with dogs must have a written and signed Program of Veterinary Care

- Regularly scheduled AV visits to all premises where dogs are kept- **NOT LESS THAN EVERY 12 MONTHS**
- Complete physical exam of each dog- **NOT LESS THAN EVERY 12 MONTHS**
- Vaccination per schedule approved by AV
 - Must include Rabies, Parvovirus, Distemper
- Sampling and treatment for parasites and other pests per schedule approved by AV
- Preventive care plan for coats, nails, eyes, ears, skin, teeth
- Must also address requirements under §2.33

unless otherwise required by a research protocol approved by the IACUC

Medical records must be kept for dogs

- §3.13(b) also applies to research facilities
- As a reminder, records must include:
 1. Identity of the animal
 2. Routine Husbandry, including dates
 - Vaccines, preventatives, tests and exam results*
 3. Health problems, including dates
 - Descriptions, tests and exam results, treatment plans*

**3.13(a)(3) – vaccines, sampling, and treatment may be exempted for research approved by the IACUC*





Assessing the annual report

Ensure that:

- All animal facilities are reported
- Only regulated species are reported
- Animals are reported in the correct column
- IACUC-approved exceptions not provided for in AWA are reported
- IACUC-approved exemptions provided for in the AWA are not reported
- The number of animals reported is correct
- There are appropriate explanations for all Column E animals

Additional facility records

not specifically required in AWR

- Animal inventory (other than dogs and cats)
- Medical records (other than dogs and marine mammals)
- IACUC membership roster
- Husbandry records
- Cagewash temperature logs
- Drug logs
- Study Records/lab notebooks
- Surgery records
- Acquisition/disposition records for species other than dogs/cats
- Complaint review/investigation logs
- Proof of past deficiency corrections
- Training records
- Anesthesia machine maintenance
- Necropsy/death records for species other than marine mammals

Assessing staff qualifications & training

- The facility is required to assure that anyone involved in animal activities is trained and qualified
 - Training records, while not specifically required, should be available for each employee
- Specific topics to look for include:
 - Handling and care of all species they are authorized to work with
 - Pre- and post-procedural care
 - Aseptic surgical techniques
 - Methods to minimize animal use and pain/distress
 - Proper use of anesthetics & analgesics
 - Methods for reporting concerns
 - Ethical considerations and resources for related information
 - Each technical skill they are authorized to perform



Determining which study protocols to review

Legal Name: [REDACTED]

Customer Number: [REDACTED] Certificate Number: [REDACTED] Site Number: 001

Inspection Date: 10/29/19

Inspection Type: Routine ☐ Focused ☒ (list areas inspected) Paperwork- IACUC meeting minutes, letters to the IO, Semi Annual reports etc

Inspector: [REDACTED]

Reasons Protocols Were Selected for Review :	How Many Protocols Were Selected
1. Protocols identified during inspection of concern (select all)	0
2. Column E protocols (select all)	1
3. Protocols with IACUC-approved exemptions/exceptions (select all)	6
4. Protocols cited as noncompliant and not corrected during the last inspection (select all)	0
5. Additional Protocols Selected: a. If <5 remaining protocols, select all remaining: b. If >5 remaining protocols, select 5 additional protocols: 1) Protocol for each regulated species and/or, 2) Protocols involving high risk procedures (see Chapter 7, Animal Welfare Inspection Guide for guidance):	5
Total Protocols Selected and Reviewed	12

*Note: Protocol selection guidance applies to protocols which have been initially approved, or have had significant changes approved, since the last inspection. For protocols reviewed by an Animal Care Veterinary Medical Officer within the last year, professional judgment should be used in determining

- Review **ALL** of the following protocols:
 - Protocols of concern
 - Category E
 - With IACUC approved exceptions/exemptions
 - Protocols cited on previous inspection
- In addition, review:
 - Five additional protocols
(if 5 or more remain)
 - All of the remaining protocols
(if less than five remain)

AWR Required IACUC Considerations & Protocol Details

Ethics	identification of species and number of animals	§2.31[e]
	rationale for species and numbers of animals to be used	§2.31[e]
	does not unnecessarily duplicate previous experiments	§2.31[d](1)
Pain & Distress	procedures to avoid or minimize discomfort, distress, or pain	§2.31[e]
	considered alternatives to painful/distressing procedures	§2.31[d](1)
	use of appropriate sedatives, analgesics or anesthetics	§2.31[d](1)
	euthanasia when likely to experience severe or chronic pain/distress	§2.31[d](1)
	description of euthanasia method(s)	§2.31[e]
Wellbeing	living conditions appropriate for the species	§2.31[d](1)
	veterinary care provided as necessary	§2.31[d](1)
Procedures	complete description of the proposed use of the animals	§2.31[e]
	personnel are appropriately qualified and trained	§2.31[d](1)
	pre-operative and post-operative care	§2.31[d](1)
	survival surgery will be performed using aseptic procedures	§2.31[d](1)
	no more than one major operative procedure	§2.31[d](1)

Rationale for the number of animals to be used

Examples of rationale that may be used include, but are not limited to:

- Required for statistically significant results
- Based on scientific literature or past experience
- Based on results of pilot study
- Required by the Food and Drug Administration (FDA) or other Federal agency
- Required by international testing requirements
- Number of students/animal and procedures needed to learn





Complete description of proposed animal use

- Most important information used by the IACUC to assess actual care and use
- Adequate detail to provide all reviewers with the same expectations for the conduct of the study
 - Especially the number and frequency of procedures
 - Should be clear enough to be easily understood by the IACUC's non-affiliated member





Complete description of proposed animal use

- Details that should be addressed include:
 - The dose, route, and types of medications or test articles given
 - How animals are restrained
 - Whether the animal will experience pain or discomfort
 - Experimental endpoints
- May reference IACUC approved SOPs in lieu of providing details





Minimizing discomfort and distress

- Procedures must be performed with appropriate sedatives, analgesics or anesthetics, *unless withholding is justified for scientific reasons*
- Alternatives to procedures that may cause more than momentary or slight pain or distress must be considered
 - **Consideration must be documented in writing**
- Procedures involving pain or distress must include, in their planning, consultation with the attending veterinarian
- Paralytics may only be used with anesthesia
- Animals that would otherwise experience severe or chronic pain or distress that cannot be relieved will be painlessly euthanized

Alternative searches

- A “written narrative description of the methods and sources” is required
- Literature searches for alternatives
 - Keywords – procedure, not research goals
 - Sources
- Animal Welfare Information Center (National Agricultural Library)
 - Brochure

https://www.nal.usda.gov/sites/default/files/page-files/3Rs_Alternatives_Literature_Searching_Brochure_2024_508_0.pdf



Conducting Literature Searches: Considering 3Rs (Replacement, Reduction, Refinement) Alternatives

1: Identify Areas to Potentially Implement Alternatives

Find areas of the protocol that could potentially incorporate the 3Rs. Think about:

- The protocol's objective and study uniqueness
- Animal used and other animal/non-animal models
- Number of animals required
- Animal housing, care and painful/stressful procedures

2: Finding Databases and Grey Literature Resources

Search multiple databases! No database covers all journals, subject areas, or types of materials. Talk to your library to find out what databases are available at your institution. Don't forget to search non-database resources as well.

Databases Useful for Finding 3Rs Information**

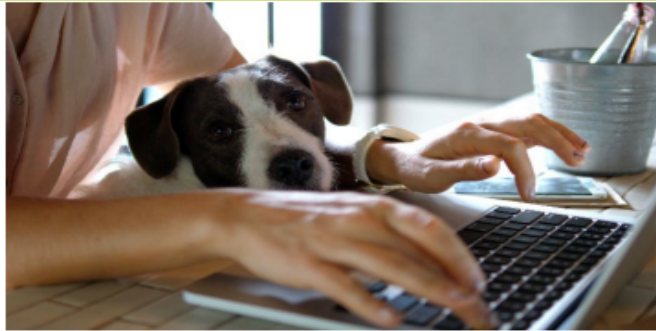
- AGRICOLA
- PubMed
- Web of Science
- Scopus
- BIOSIS
- Zoological Record
- EMBASE



3Rs Web Resources**

- AWI: <https://awionline.org/content/refinement-databases>
- JHU CAAT: <https://caat.jhsph.edu/>
- ICCVAM: <https://ntp.niehs.nih.gov/go/regaccept>
- NC3Rs: <https://www.nc3rs.org.uk/>
- NICEATM: <https://ntp.niehs.nih.gov/whatwestudy/niceatm>
- NORECOPA: <https://norecopa.no/>
- 3RsC: <https://www.3rc.org/>
- 3Rs Principles in Wildlife Research: <https://3rswildlife.info>

**Mention of commercial databases or external organizations does not constitute endorsement or imply preference by the U.S. Department of Agriculture.



3-4: Developing a Search String

The search string consists of multiple components:

- Scientific terms related to the research protocol
- Animal terms (if applicable)
- 3Rs alternatives terms relevant to the protocol
- Search logic: Boolean operators, parentheses, quotation marks, truncations, etc. (use AWIC's Database Search Operator Reference Guide for assistance: https://www.nal.usda.gov/sites/default/files/page-files/AWIC-database-cheat-sheet-revised-12-30-2022_508.pdf)

Consider synonyms, acronyms, alternate spellings and variations of the words (such as tenses).

Search String Example in Web of Science:

```
TS=((recover* OR assess* OR collect* OR analy* OR process* OR sampl* OR measur*) NEAR/5 (tissue* OR "tissue sample*" OR fluid* OR "fluid sample*" OR "blood sample*" OR "urine sample*"))
```

3Rs Keyword Examples

- analgesic or analgesia or pain medication
- anesthesia or anaesthesia or anesthetic
- housing or enclosure or caging
- welfare or well-being or wellness
- organoid or spheroid or 3D cell culture
- organs-on-chips or microfluidic device or microphysiological system
- repository or data reuse or sharing or repurposing

See our webpage for other examples

5: Modifying a Search String

Literature searching is a trial-and-error process—if you find that your initial search string brings back a lot of irrelevant information, it might be time to modify your search string. Here are some quick ways to modify a search string:

- Change what field you're searching (e.g., title vs. title/abstract)
- Limit by publication year to decrease the number of citations you are receiving
- Remove irrelevant search terms using the Boolean operator 'NOT'
- Narrow the search by replacing general terms for terms specific to the disease, method, procedure, etc., that you're studying

6: Records and Citation Management

- Save your search strings, databases searched, and years of search in a word document
- Export and save relevant citations into a citation manager (EndNote, Zotero, etc.) to help organize and quickly import citations into research papers

Tips for IACUC Members

- Ensure protocol forms clearly state what information is required from the researchers
- Inform researchers of available information resources and how to access them
- Encourage researchers to work with librarians and statisticians
- Here are some **RED FLAGS** to look out for in a literature search:
 - Only 1 database searched
 - The term "alternatives" is used alone
 - Keywords listed are not relevant to protocol
 - Keywords and search logic linked incorrectly (e.g., wrong Boolean operators)
 - Search doesn't cover adequate time period

Specific Types of Protocols

- Painful/distressful procedures
- Antibody production
- Food and/or water restriction
- Neuromuscular blockers
- Surgical procedures
- Teaching protocols
- Toxicity and vaccine studies

Activity:

- Consider each of these types of protocols
- Come up with one or two special/unique considerations to review for that protocol type
- Share your considerations with the group



Painful/distressful procedures



Painful/distressful procedures

- Written description of methods and sources used to determine that no alternatives to the painful/distressful procedure are available
- Measures used to alleviate are clearly stated, including drugs, dosages, routes, and frequency of administration
- Adequate scientific justification if pain relief is not to be used
- Attending veterinarian was consulted
- Timely humane euthanasia of animals experiencing severe or chronic pain/distress that cannot be relieved

NOTE: "As needed" frequency of administration is **not** acceptable *unless there are detailed instructions and criteria for determining administration of the drug*



Antibody production



Antibody production

- Written description of methods and sources used to determine that no alternatives to the painful/distressful procedure are available
- Justification for the number of animals to be used
 - May be based on the amount of antibody needed and the amount which can be produced by an animal
- Complete description of the procedure
 - Induction of antibody production, including adjuvants if used
 - Collection of blood/serum
 - Methods to minimize pain and distress

Food and/or water restriction



Food and/or water restriction

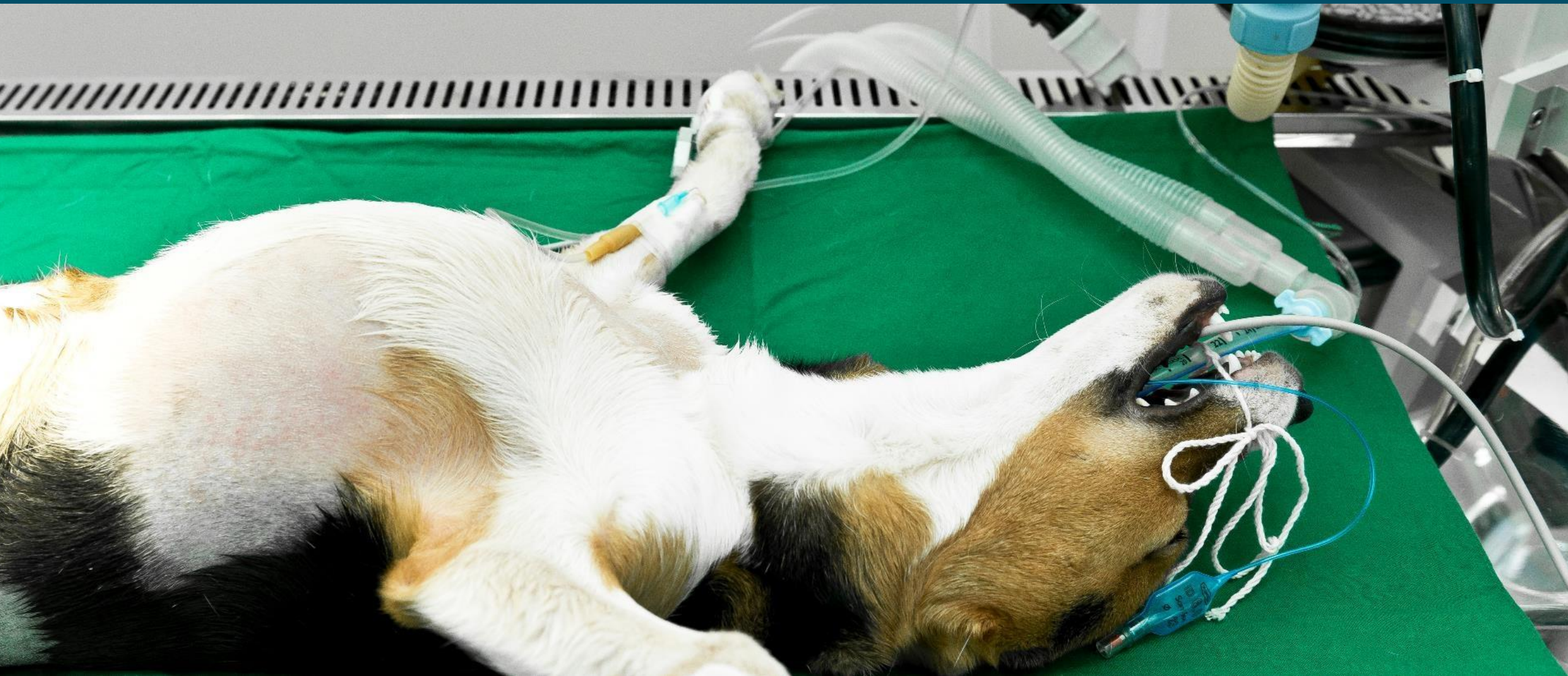
- Protocol must justify the food/water restriction
- Written description of methods and sources used to determine that no alternatives to the painful/distressful procedure are available
- Selection of animals and training are described
- Animal monitoring to minimize adverse impact is described
 - Including physiological parameters are being monitored during the study
 - Supportive care for animals showing dehydration or stress

Food and/or water restriction- continued

- Procedures used to restrict food/water are clearly described
 - How daily food and water intake was determined
 - How the animal is to receive its required daily food or water intake
- Humane endpoints have been identified



Neuromuscular blockers (NMB)



Neuromuscular blockers (NMB)

- Use of NMB is justified
- Use of NMB is adequately described in the protocol
 - Used with general anesthesia
- Proper training of all personnel
- Proper monitoring (i.e. heart rate and blood pressure)
- Supportive care, such as ventilator support, is being provided during anesthesia
- Surgical and anesthesia records contain the appropriate information
- Recovery procedures are described and appropriate
 - Use of reversal agents when available

NOTE: The pain withdrawal response is **not** an appropriate measure of the level of anesthesia since this response would be prevented by the NMB

Surgical procedures



Surgical procedures

- The pre-procedural care and surgical preparation are clearly stated
- The surgical procedure is stated clearly and in detail
- All survival surgeries are performed using aseptic technique
- Major operative survival surgeries on non-rodents are performed in a dedicated surgical facility
- No animal is being used in more than one major operative survival surgery unless appropriately approved
- Post-surgical procedures are stated clearly
- Pain/discomfort relief measures are stated clearly

Teaching protocols



Teaching protocols

- Justification/rationale for animal numbers
- Complete description of procedures
 - The number of procedures to be performed on each animal is clearly stated
 - If procedures cause more than momentary or slight pain or distress
 - Proper methods are used to alleviate the pain/distress
 - Written description of methods and sources used to determine that no alternatives to the painful/distressful procedure are available
- Teaching staff are qualified and properly trained

Toxicity and vaccine studies



Toxicity and vaccine studies

TIP The Interagency Coordinating Committee on the Validation of Alternative Methods provides a list of some alternative tests.

- Written description of methods and sources used to determine that no alternatives to the painful/distressful procedure are available
- Justification/rationale for animal numbers
- Measures used to alleviate are clearly stated, including drugs, dosages, routes, and frequency of administration
- Adequate scientific justification if pain relief is not to be used
- Proper training of staff
- Humane endpoints have been identified



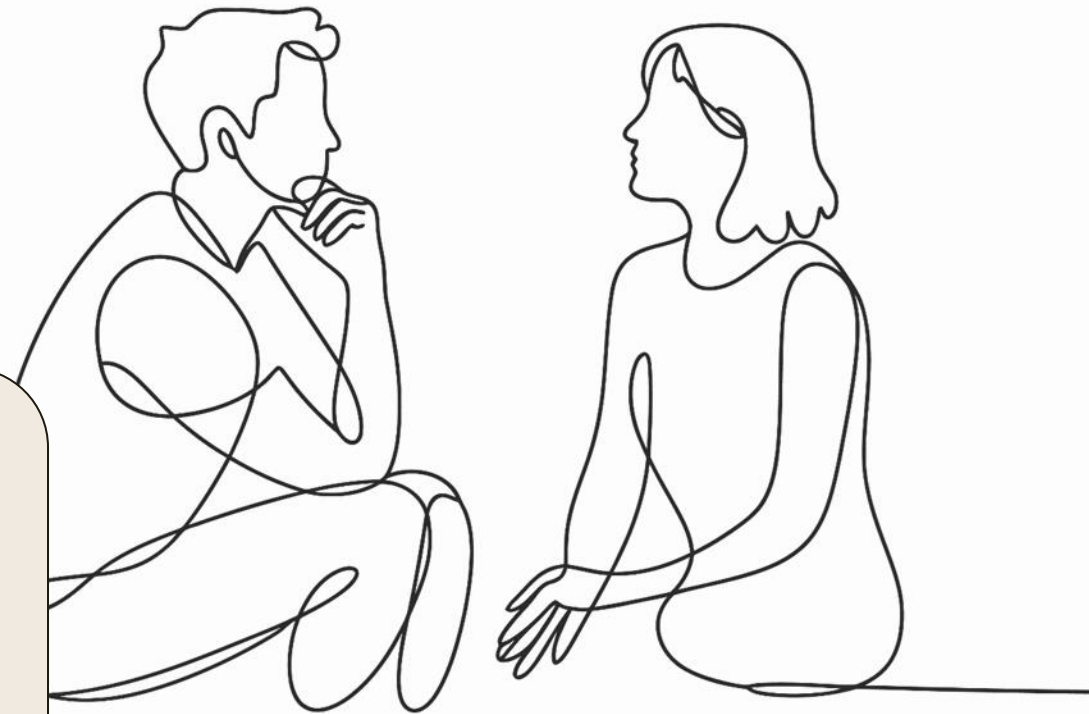
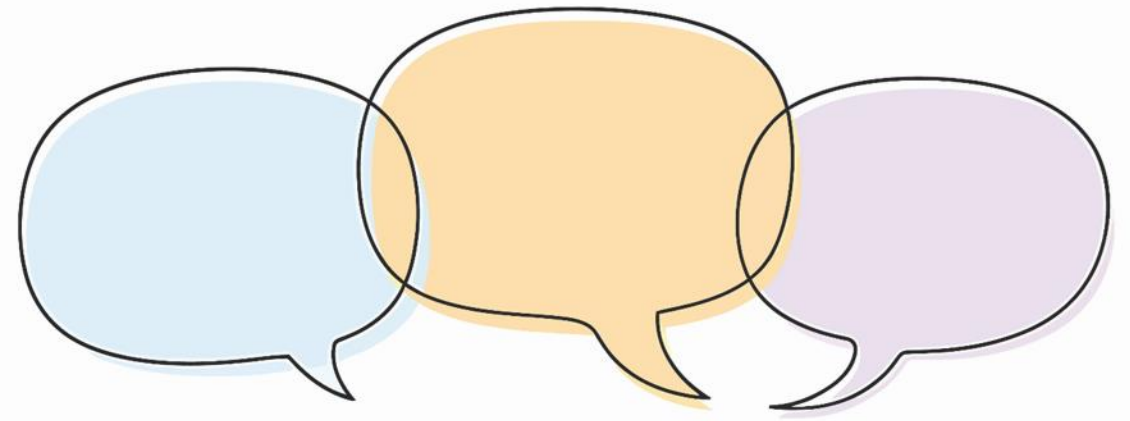
Activity: Protocol Review

The following slides offer a short segment from an IACUC approved protocol.

Assume that the rest of the protocol is compliant with 2.31(d)(1) and 2.31(e).

After reviewing each slide,
answer the following questions:

1. What relevant regulation (and subsection) is the segment addressing?
2. Is the segment, as written, compliant with that relevant regulation/subsection?
3. Why or why not?



Protocol #1: Animal model and species justification

"Based on my experience, we need to use animals.

The hamster has been a standard model used for hepatotoxicity studies and will be used so that data can be compared with literature values."



1. What relevant regulation (and subsection) is the segment addressing?
2. Is the segment, as written, compliant with that relevant regulation/subsection?
3. Why or why not?

Protocol #2: Minimizing pain and distress

“This study is an efficacy study of a new analgesic drug being evaluated in a pain model using rabbits. It contains a control group of rabbits that do not receive the test drug. These rabbits may experience unalleviated pain by necessity of study design and thus would fall into Pain Category E. The rabbit will be euthanized as soon as the pain is demonstrated and documented using the criteria set forth in FDA regulation XAD1234DKJS.”



1. What relevant regulation (and subsection) is the segment addressing?
2. Is the segment, as written, compliant with that relevant regulation/subsection?
3. Why or why not?

Protocol #3:

Major operative procedures

Procurement of animals

"The rhesus macaques used in this study will be acquired from New South Texas University after they have completed a study involving an ibutton device implanted intra-abdominally via laparotomy. The ibutton device does not cause any adverse consequences for the macaques and will not affect the outcome of this study."

Outline of Surgical Procedures

"To meet the objectives of the study at North Texas College, the rhesus macaques will undergo two surgeries. The first is a survival surgery involving a thoracotomy to implant the new device being tested. Three weeks after this surgery, the rhesus macaques will undergo a terminal surgical procedure."



1. What relevant regulation (and subsection) is the segment addressing?
2. Is the segment, as written, compliant with that relevant regulation/subsection?
3. Why or why not?



Protocol #4: Alternatives to painful procedures

Study aim

"Investigate the protective actions of silymarin against hepatotoxicity caused by different combinations of anti-tuberculosis drugs."

Experimental Design

"After baseline testing, adult Syrian hamsters will be anesthetized for jugular cannulation. Animals will be treated with intra-peritoneal and/or intra-gastric administration of the anti-TB drugs and intra-cannula administration of silymarin. Hepatoprotective effects of silymarin will be investigated by co-administration of silymarin together with the drugs. Serum biochemical tests for liver function and histopathological examination of livers will be performed."

Summary from previous slide:

Study aim

- Investigate the hepatoprotective effects of silymarin

Experimental Design

- Baseline testing
- Anesthetized for jugular cannulation
- Treated with intra-peritoneal and/or intra-gastric administration of the anti-TB drugs and intra-cannula administration of silymarin
- Serum biochemical tests for liver function and histopathological examination of livers performed



Protocol #4: Alternatives to painful procedures

1. What relevant regulation (and subsection) is the segment addressing?
2. Is the segment, as written, compliant with that relevant regulation/subsection?
3. Why or why not?

Alternative search

"A literature search was performed on 3/24/2024 using Pubmed. The time period covered was 1973-present. No alternatives were identified. Keywords used: Animal model and alternative and hepatotoxicity; hamster and hepatotoxicity and alternative; hamster and exsanguination and euthanasia"

Protocol #5:

Post-operative care

Study involves the removal of the lacrimal gland and nictitating membrane in dogs.

Post-operative Care

"All dogs will be monitored at least once every 10-15 minutes and vital signs (temperature, heart rate, respiratory rate and capillary refill time) will be assessed and recorded on the permanent anesthesia record form until the dogs can maintain themselves in voluntary sternal recumbence. Animals will be kept warm during recovery.

After their return to their housing, all dogs will be evaluated once daily for three days post-surgery. The eyes will be evaluated by an experienced research technician and ketorolac will be given as needed for pain."



Summary from previous slide:

Post-operative Care

- Vital signs monitored and recorded at least once every 10-15 minutes until the dogs can maintain themselves in voluntary sternal recumbence.
- Kept warm during recovery.
- Evaluated once daily for three days post-surgery.
- Experienced research technician will evaluate eyes and ketorolac given as needed for pain.

1. What relevant regulation (and subsection) is the segment addressing?
2. Is the segment, as written, compliant with that relevant regulation/subsection?
3. Why or why not?

Protocol #5: Post-operative care





Protocol #6:

Rationale for animal use

"Canines are a required species by the AVMA for students to have experience in during their veterinary technician education. There is a need for live animal usage so that the instruction can be a hands-on experience. Many of the clinical skills that the students need to learn can only be learned from live animals. The variation in temperament, physiology, and physical diversity gives the experience in learning that is necessary to equip these students with the skills they need."

Justify the appropriateness of the species selected

"Canines are a common animal seen in veterinary clinics and in labs"

Justify the number of animals to be used

The Program has requested 12 canines per year. The Program has a max of 24 students per class and would typically use 1 canine per 4 students each semester to teach the AVMA required procedures"



1. What relevant regulation (and subsection) is the segment addressing?
2. Is the segment, as written, compliant with that relevant regulation/subsection?
3. Why or why not?

Protocol #6: Rationale for animal use

"Canines are a required species by the AVMA for students to have experience in during their veterinary technician education. There is a need for live animal usage so that the instruction can be a hands-on experience. Many of the clinical skills that the students need to learn can only be learned from live animals. The variation in temperament, physiology, and physical diversity gives the experience in learning that is necessary to equip these students with the skills they need."

Justify the appropriateness of the species selected

"Canines are a common animal seen in veterinary clinics and in labs"

Justify the number of animals to be used

The Program has requested 12 canines per year. The Program has a max of 24 students per class and would typically use 1 canine per 4 students each semester to teach the AVMA required procedures"

Protocol #7: Number of Animals Required

"Male Syrian hamsters weighing 90-130 g will be used to form 6 study groups, each group consisting of 10 hamsters. The study will be repeated one time to confirm the results.

6 groups X 10 hamsters/group X 2 trials
= 120 hamsters total"



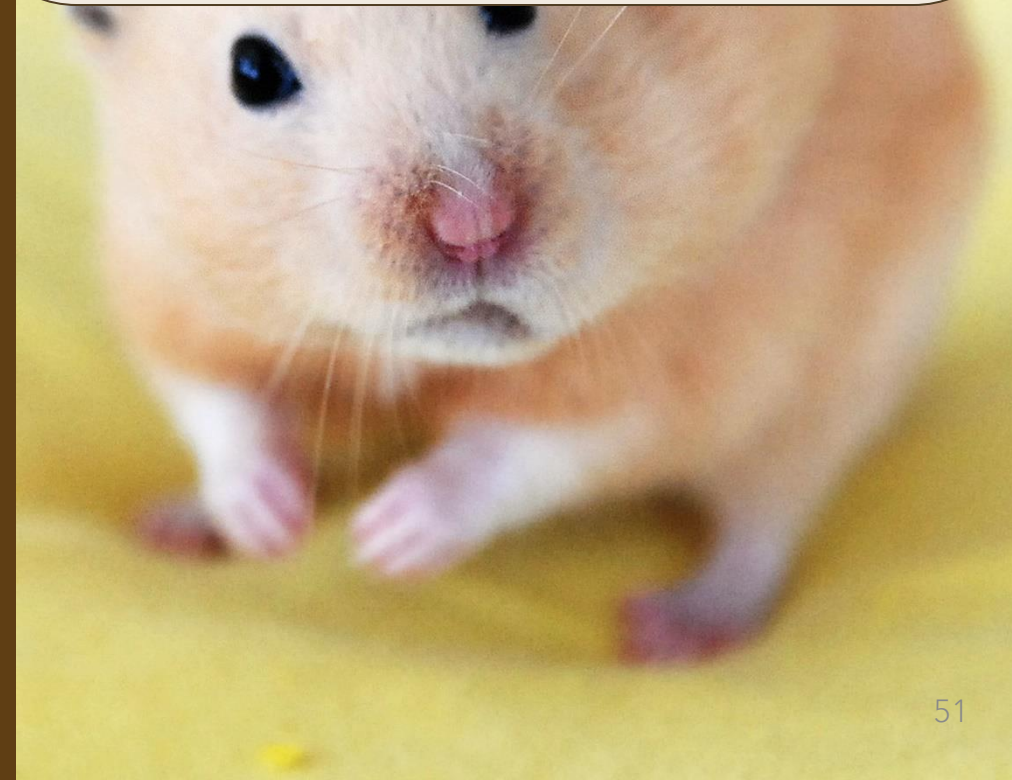
1. What relevant regulation (and subsection) is the segment addressing?
2. Is the segment, as written, compliant with that relevant regulation/subsection?
3. Why or why not?

Protocol Amendment #1:

"We have completed the non-invasive imaging study of hamsters as originally approved in this protocol. This amendment to an approved protocol will be Phase 2 of our research and adds the following procedure: the use of two compounds DDB and 4NQ designed to induce tumor growth in the hamster cheek pouches.

This amendment consists of a complete description of the use of the compounds, the effects on the animals, and the procedures designed to limit pain and distress including the euthanasia method to be used."

1. What relevant regulation (and subsection) is the segment addressing?
2. Is the segment, as written, compliant with that relevant regulation/subsection?
3. Why or why not?

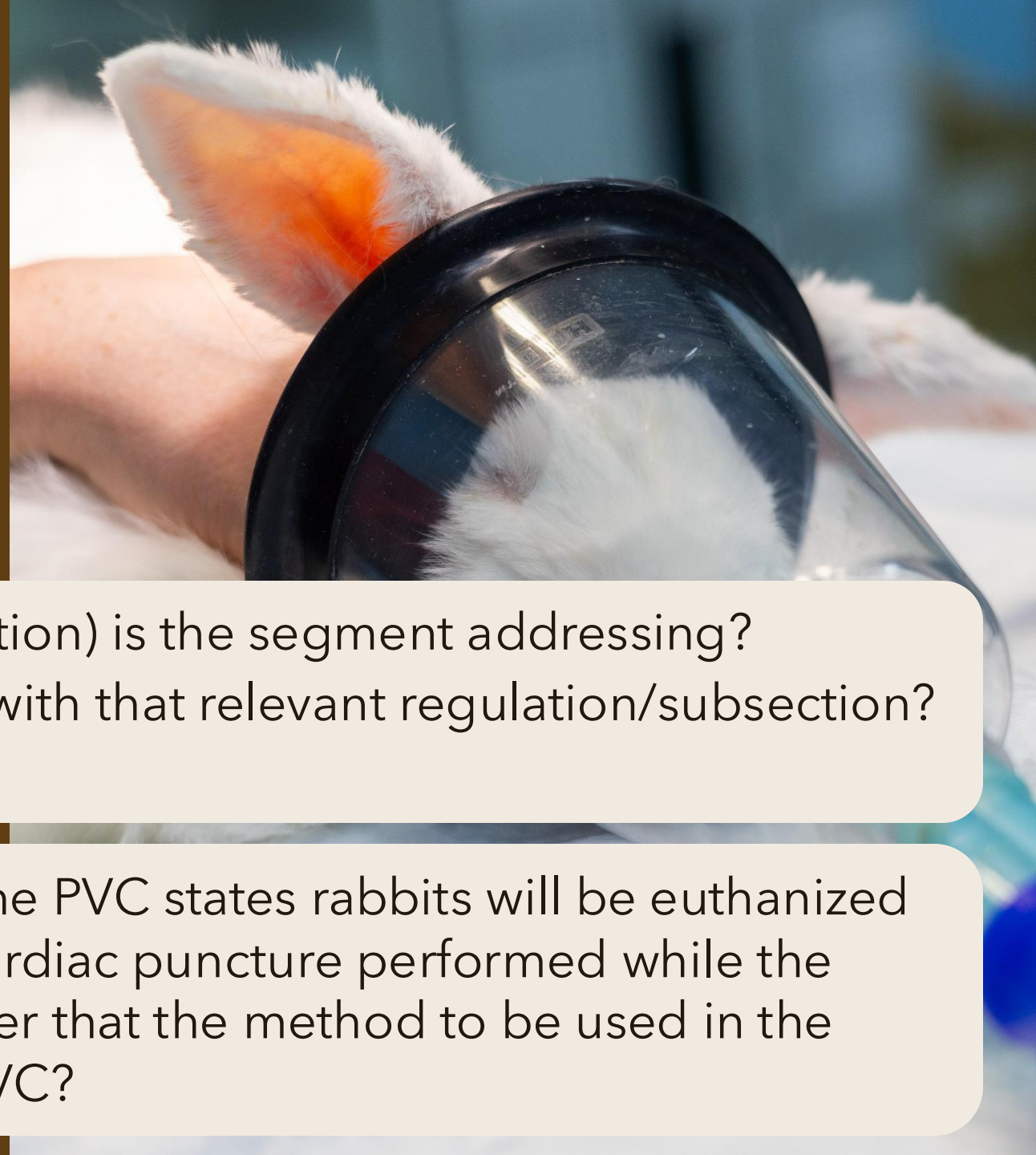


Protocol #8: Euthanasia

"The method of euthanasia for the rabbits will be exsanguination under isoflurane anesthesia."

1. What relevant regulation (and subsection) is the segment addressing?
2. Is the segment, as written, compliant with that relevant regulation/subsection?
3. Why or why not?

Additional question for this scenario: The PVC states rabbits will be euthanized with an overdose of pentobarbital via cardiac puncture performed while the animal is under anesthesia. Does it matter that the method to be used in the protocol is not the same as that in the PVC?



Time for a
break!



Contracted research

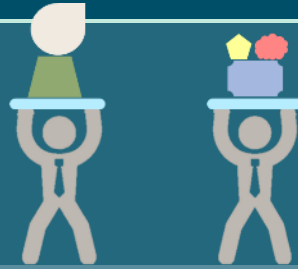
or projects that involve more than one registrant

Registrants determine responsibility for the functions of the IACUC, animal care and handling, and reporting of the animals on the Annual Report (AR)



Responsibilities shared/ not designated

- BOTH registered parties are responsible (*both would be cited for any non-compliances*)
- Animals only on one AR



Specific responsibilities are designated

- Facility is a site of both registrants
- Animals only on one AR
- Only inspect responsibilities designated to the facility being inspected



All responsibilities are designated

- Facility is only a site of the designated registrant
- Listed responsibilities are only inspected at the designated registrant



Animal Care Tech Note

Research With Free-Living Wild Animals in Their Natural Habitat and the Animal Welfare Act



The Animal Welfare Act (AWA) and regulations set standards of care and treatment for certain animals used in research, experimentation, teaching, and/or testing. While the AWA regulations cover many types of activities, they include some exceptions for field research involving wild animals in their natural habitat.

The following is quick guidance to assist Institutional Animal Care and Use Committees (IACUCs) at research facilities in determining whether an activity meets the AWA regulatory definition of “field study” and is therefore exempt from oversight or is otherwise covered under the AWA regulations. The AWA itself establishes the legal requirements and standards facilities must follow. For details, refer to the AWA (*United States Code*, Title 7, Chapter 54, Sections 2131–2159) and the Animal Welfare Regulations (*Code of Federal Regulations*, Title 9, Chapter 1, Subchapter A, Parts 1–4).



AWA Regulatory Definitions

Field study: A study conducted on free-living wild animals in their natural habitat. However, this term excludes any study that involves an invasive procedure, harms, or materially alters the behavior of an animal under study.

Wild animal: Any animal that is now or historically has been found in the wild, or in a wild state, within the boundaries of the United States, its Territories, or possessions. This term includes but is not limited to animals such as deer, skunk, opossum, raccoon, mink, armadillo, coyote, squirrel, fox, and wolf.

Major operative procedure: Any surgical intervention that penetrates and exposes a body cavity or any procedure which produces permanent impairment of physical or physiological functions.

Euthanasia: The humane destruction of an animal accomplished by a method that produces rapid unconsciousness and subsequent death without evidence of pain or distress, or a method that utilizes anesthesia produced by an agent that causes painless loss of consciousness and subsequent death.

Role of the IACUC

All research facilities must have an IACUC. Per the AWA, the IACUC is responsible for overseeing and assessing all aspects of the facility's animal program, including inspecting animal facilities and study areas, investigating complaints of inhumane animal care, and approving or suspending animal research activities. The IACUC is therefore responsible for evaluating whether an activity with wild animals is regulated under the AWA. Note: Animal areas containing free-living animals in their natural habitat need not be included in inspections.

The IACUC is to be composed of members with sufficient experience and expertise to evaluate a research facility's animal program, facilities, and procedures using animals. Ad hoc consultants may be invited to assist with the evaluations. For example, IACUC members may have sufficient expertise in-house to evaluate biomedical research activities but may need to consult outside experts to advise on field research with wild animals.

If the IACUC determines a research activity is regulated under the AWA, that activity falls under IACUC oversight and must be reviewed semiannually. If the IACUC determines an activity is not AWA-regulated, that activity is not subject to IACUC review.

Field studies

Field study means a study conducted on free-living wild animals in their natural habitat. However, this term excludes any study that involves an invasive procedure, harms, or materially alters the behavior of an animal under study.

- IACUC responsibility
- Ad-hoc consultants
- Resources, e.g., taxonomic groups

<https://www.aphis.usda.gov/sites/default/files/ac-tech-note-research-free-living-wild-animals.508.pdf>

Activity: Field Study

Determine if the animal is a
regulated animal
type yes or no in the chat box

Scenario #1

Black bears living in Great Smoky Mountains National Park are trapped and sedated in the park. Body measurements are taken and a radio collar is applied. The bears are allowed to recover where caught and return to their normal park life.



Activity: Field Study

**Determine if the animal is a
regulated animal**
type yes or no in the chat box

Scenario #2

Black bears living in Great Smoky Mountains National Park are trapped and sedated in the park. Body measurements are taken and a tooth is extracted (used to age the bear). The bears are allowed to recover where caught and return to their normal park life.



Vet schools and Vet tech schools

- Teaching
 - Farm animals
- Facility owned animals
- Spay/neuter programs
 - Records & animal identification requirements
- Pets used for teaching



TEACHING = RESEARCH

- Teaching related to basic science or biomedical research is regulated

BUT:

- Teaching related to food or fiber, or breeding, management or production efficiency is **not** regulated
- Animals under veterinarian-client-patient relationships are **not** regulated
- Animals that are faculty or student owned that are used for teaching in the presence of their owner are **not** regulated



Consult your SACS for guidance if the facility asks you to inspect non-regulated animals or facilities.

Acquisition/disposition records

- Acquisition/disposition records **must** be kept for any dogs or cats acquired by the facility
 - APHIS Forms 7005 and 7006 are **not** required but may be used
- Acquisition/disposition records are **not** required for:
 - Dogs/cats that fall under a veterinary client patient relationship
 - All regulated animals other than dogs and cats
- Records must be held for at least **3 years**
- Research facilities must individually identify dogs and cats
 - No individual identification requirements for other regulated species

Activity: Animals used in teaching

Determine if the animal is
a regulated animal
type yes or no in the chat box

Scenario #1

Ten cows from the university's
dairy herd are palpated by the
vet students during their class
on large animal reproduction



Activity:

Animals used in teaching

Determine if the animal is a regulated animal
type yes or no in the chat box

Scenario #2

A farmer wants a dairy cow checked for pregnancy. She takes it to the school to be palpated once by a vet tech student.



Activity: Animals used in teaching

Determine if the animal is a
regulated animal
type yes or no in the chat box

Scenario #3

Ten cows from the university's dairy
herd are checked for pregnancy.
They are palpated multiple times
by **agricultural students**.



Activity: Animals used in teaching

Determine if the animal is a
regulated animal
type yes or no in the chat box

Scenario #4

An owner brings in a dog for
Heartworm testing. Three blood
draws are performed so every
student has a chance to practice
the procedure.





Horses

Definitions:

- “animal” excludes horses not used for research purposes
- “farm animal” used or intended for use as food or fiber, or for improving animal nutrition, breeding, management, or production efficiency. Also includes horses when used solely as work animals.
- Federal Register – CFR 9 Part 3 – Standards for Horses and Other Farm Animals
- “Gray book” – Agricultural research, suppliers of specimens

Activity:

Horses

Determine if the animal is
a regulated animal
type yes or no in the chat box

Scenario #1

The urine of 10 pregnant
mares is collected and sold as
PMU (pregnant mare urine) for
human application



Activity: Horses

Determine if the animal is
a regulated animal
type yes or no in the chat box

Scenario #2

25 horses are used in a fertility
study to improve intra-species
breeding and soundness



Activity: Horses

Determine if the animal is a
regulated animal
type yes or no in the chat box

Scenario #3

5 horses are used to produce
tetanus antitoxin and the company
sells the product wholesale



Activity: Horses

Determine if the animal is a
regulated animal
type yes or no in the chat box

Scenario #4

2 horses are purchased at auction
by a veterinary school to be used
to teach students anatomy



Removing records from a research facility

- **Do NOT remove original records**
- Take only photos or copies of records off-site when supporting a citation *under deliberation*



Discussing retained records with the facility

- Facilities must be informed of copies of records that are retained by USDA
 - Facility is allowed 48 hours to redact protected information
- Inspectors must also review any photos taken with the facility.
 - Photos that contain protected information should be deleted or retaken
 - If the noncompliance cannot be documented without the inclusion of protected information, ensure that the photograph label states: "May contain confidential or proprietary information."





Activity: Personnel change

You are inspecting the IACUC records at one of your registered research facilities. One of the protocols you are reviewing involves chronically catheterized dogs. You remember that during your facility walk-through you noticed those dogs and stopped to talk to a knowledgeable research assistant named Mandy who explained how she cares for the dogs and the catheters. Mandy even described the data that they've been able to collect on this study.

But you don't see Mandy listed on this protocol as one of the people involved. You ask the IACUC Administrator if this protocol has been amended since the date on the version that you are reviewing. You explain that Mandy seemed very involved with these dogs but you can't find her listed as being among the trained and qualified personnel working on this study.

Activity:

Personnel change

Response #1

The IACUC Administrator explains that, although she wasn't aware that Mandy had replaced the research assistant who had been working on these dogs, Mandy is a graduate vet tech, and a very good one. The dogs are happy, the PI is happy, the IACUC is happy, ... and you were happy when you talked to Mandy yesterday.

Is this switch to a different, but clearly qualified assistant in compliance?



Activity:

Personnel change

Response #2

The IACUC Administrator shows you an Institutional Policy which classifies changes in certain personnel on studies as being "minor". Such minor additions of personnel must be reviewed, but the reviews can be done by the IACUC Administrator rather than the IACUC itself. The IACUC Administrator produces a memo which acknowledges the PI's request to add Mandy to his protocol, states that she is adequately trained and qualified, and approves her addition.

Is an institutional policy which classifies certain personnel changes to a protocol as being "minor" and allows them to only undergo administrative review instead of IACUC review in compliance with regulations?



Activity:

Personnel change

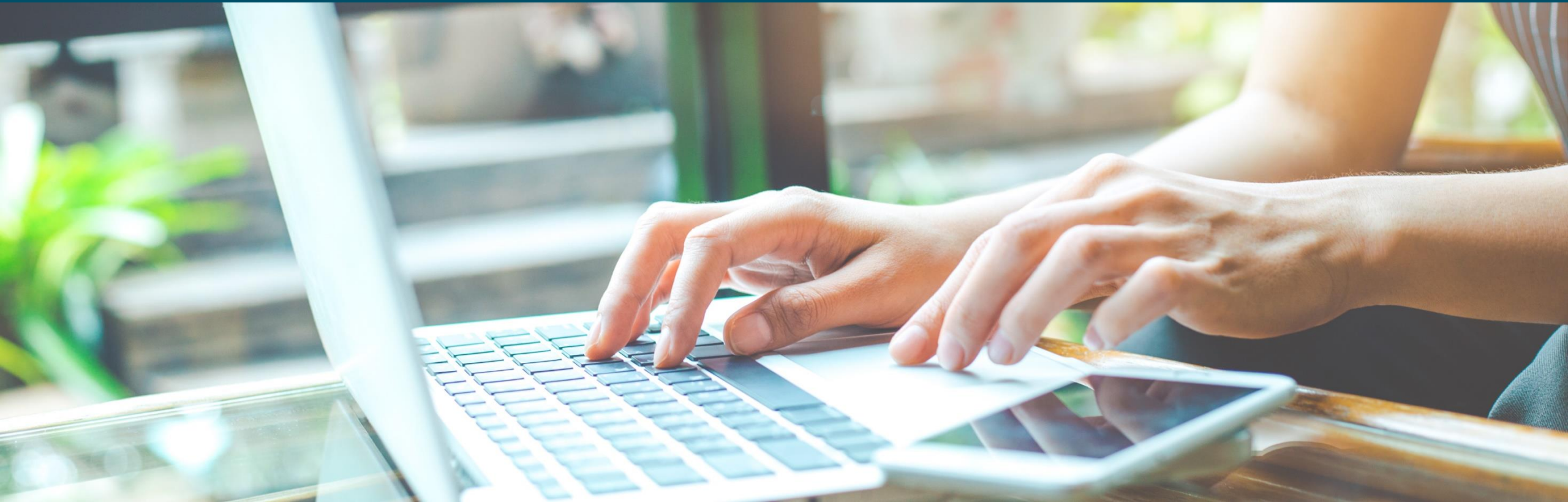
Response #3

The IACUC Administrator produces a set of IACUC minutes which indicate the PI had requested to amend his protocol by adding Mandy to it to replace another assistant. After each IACUC member was given notice of the change with no one requesting full committee review, the protocol addition was assigned by the IACUC chair to a designated reviewer who looked at Mandy's qualifications and then approved the protocol as amended. The PI was then notified that the amended protocol was approved.

Is this process for adding an additional person to the protocol in compliance?



Composing research citations



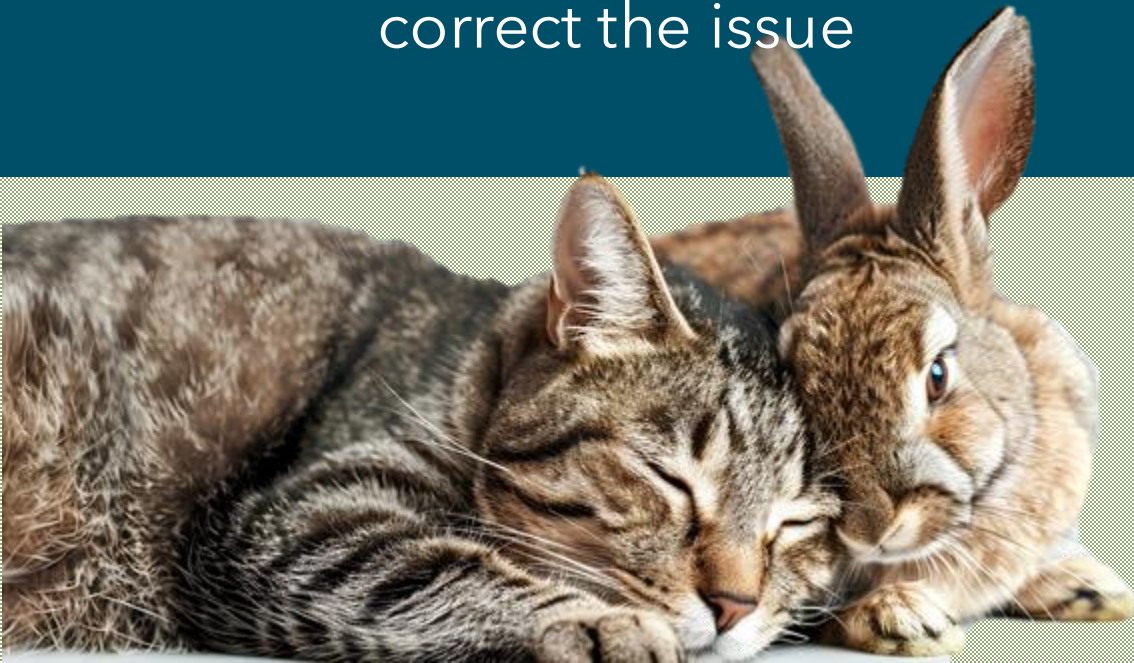
Identical to writing a citation at a licensed facility...

4 Parts of a citation narrative:

1. Regulation
2. Description of the problem
3. Why it matters
4. What needs to be done to correct the issue

4 C's of a citation narrative:

1. Clear
2. Complete
3. Compelling
4. Concise



Considerations for Research NCI

- Protect confidential/proprietary information regarding the research
- Protect the identity of researchers
- Reason why the non-compliance matters may be more difficult to write





Activity:

Citation review

Read the citation printed on the slide.
Determine whether the citation:

1. Is appropriate (i.e., meets all the elements of the regulation).
2. Contains all four parts required for a citation.
3. Is well written (meets the 4 Cs).

Citation #1

2.33(b)(2)

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

During the inspection, 4 bottles of Enlon (Edrophonium) expired 9/2024 were found being used in room SS.

The use of outdated drugs does not constitute adequate veterinary care with current established veterinary medical procedures.

Facility needs to review its monitoring procedures for drugs to ensure outdated drugs are removed in a timely manner.

Facility corrected this item at the time of inspection by removing the drugs from the area for proper disposal.



Citation #2

2.31(e)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

A protocol involving rabbits that was approved by the IACUC did not contain a complete description of the proposed use of the animals. The use of two animals in a pilot study in which a suture was placed in the eye was not clearly specified in the protocol.

Additionally, the size of the suture (6-0) to be used in the pilot study was not specified. The main study was to utilize a smaller size (10-0). Additionally all agents to be used, such as analgesics, must be specified.

A complete description of the proposed use of animals allows the IACUC members to understand all procedures so that only proposals in compliance with the Animal Welfare Act are approved. Without such a description, the IACUC cannot consider the potential impacts upon the animal care and welfare.

All protocols and subsequent amendments approved by the IACUC must contain a complete description.

Correct by: This date forward.

Citation #3

2.31(d)(1)(ii)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

Protocol 9263, a training protocol involving multiple species, is listed as USDA Pain Category C/D. The principal investigator did not provide a written narrative description of the methods and sources used to determine that alternatives were not available.

In order for the Institutional Animal Care and Use Committee (IACUC) to approve a proposed activity for procedures that may cause more than momentary or slight pain or distress to the animals including Category D studies, the principal investigator must provide such a written narrative description. Without the required description of the availability of alternatives, activities may unnecessarily cause pain or distress to the animals.

The protocol should be amended to include this required information.

Correct by: 05 August 2018 or prior to additional animal use under this protocol, whichever comes first.

Citation #4

2.31(d)(1)(viii)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE

Protocol 16083 lists only the PI under personnel carrying out procedures involving animals on the project. An email from the PI dated 6 June 2017 clearly indicates an unnamed student was conducting imaging of the hamsters. The email also states that this student was expected to have euthanized the animals at the end of the study. Any person carrying out procedures on study animals must be appropriately trained and qualified. All such persons must be listed on the protocol, along with their experience and training.

Correct from this point forward.



A row of wooden blocks spelling out 'WRAP UP' in a serif font. The blocks are light-colored with dark letters. The 'U' block is slightly offset to the right.

W R A P U P

Inspection of 'Great Research Facility'

- ✓ Previous inspection reports
- ✓ USDA Annual Report
- ✓ Facility inspection
- ✓ IACUC Records (meeting minutes, semi-annuals)
- ✓ Research Protocols
- ✓ In addition, you have completed:
- ✓ Review of PVC and species related records

What do you do next?

WRAP UP

- ❑ Determine what you are going to cite
- ❑ Write your inspection report(s)
- ❑ Conduct your exit interview
 - Show photos
 - 48 hours to redact PII from documents
- ❑ Deliver your inspection report(s)
- ❑ Complete your Protocol Selection Worksheet
- ❑ Upload documentation into eFile
 - Protocol Selection Worksheet
 - Delivered IR



Classwork



Complete Day 4 Exercises

(Records Review, Great Research Facility Citation Writing)