

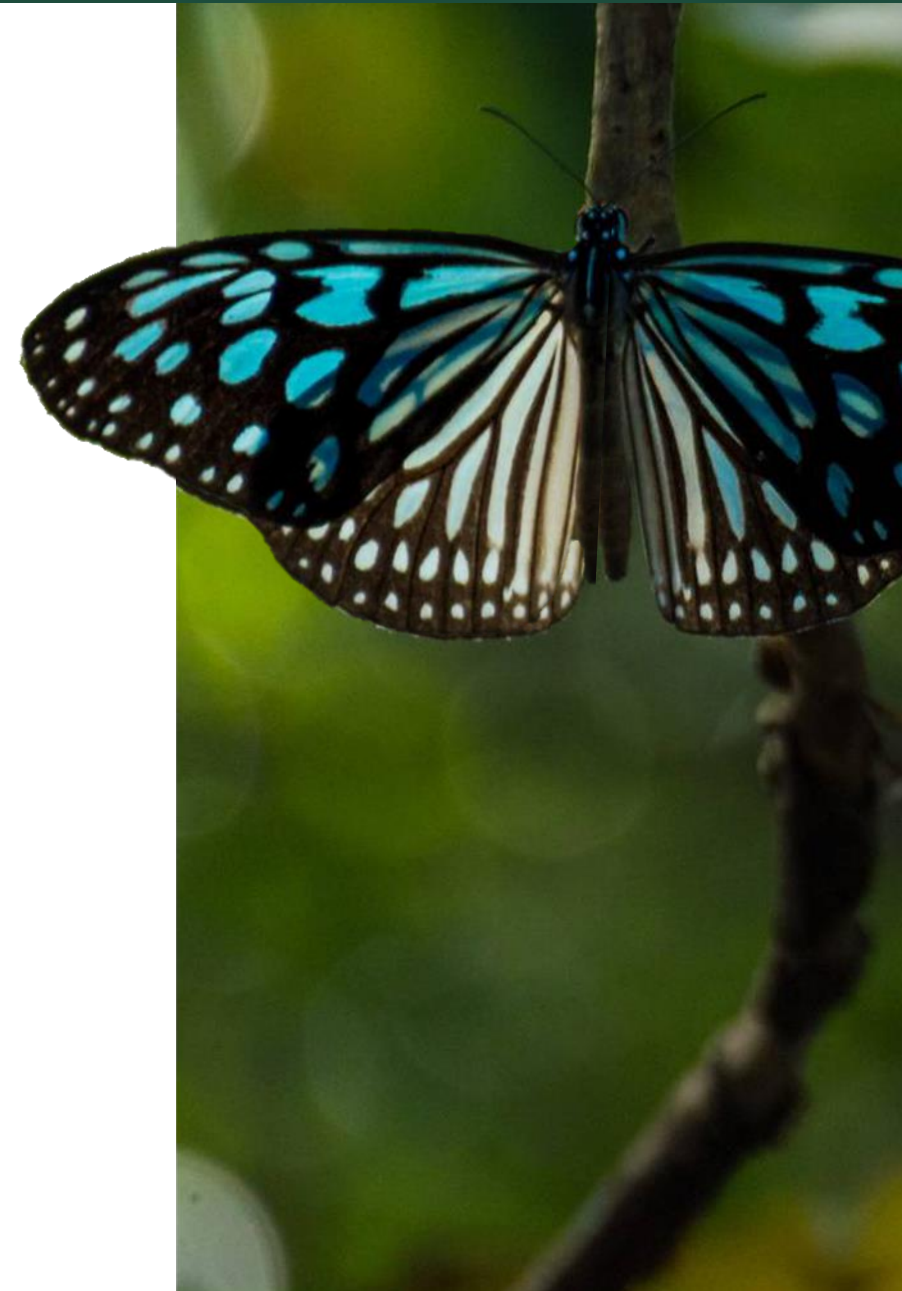


RESEARCH REGULATIONS

NEW INSPECTOR VIRTUAL TRAINING
ANIMAL WELFARE OPERATIONS

Research Facilities, Part 2

8/12/2026



RESEARCH REGULATION

NEW INSPECTOR
ANIMAL WELFARE



Research Facilities, Part 2



Note: You will want to have your Blue Book on hand and follow along.

There will be interactive exercises during this presentation.



Agenda

- §2.30 - Registration
- §2.31 - IACUC
- §2.32 - Personnel qualifications
- §2.33 - Attending veterinarian
- §2.35 - Record keeping
- §2.36 - Annual report
- §2.37 - Federal research facilities
- §2.38 - Miscellaneous





§ 2.30 - Registration

- a. Requirements and procedures
- b. Acknowledgment of regulations and standards
- c. Notification of change of operation that affects status as research facility
- d. Duration of a registration and conditions for cancellation of a registration
- e. Non-interference with APHIS officials

§ 2.31 - Institutional Animal Care and Use Committee (IACUC)





§ 2.31 - Institutional Animal Care and Use Committee (IACUC)

- a. Appointed by Chief Executive Officer to "... assess the research facility's animal program, facilities, and procedures..." to ensure animal welfare and compliance with the regulations

HOWEVER, role is not to prescribe methods or set standards for study design, performance, etc.



§ 2.31 - Institutional Animal Care and Use Committee (IACUC)

b. IACUC membership- minimum of 3 members

- Chair
- Veterinarian
- Non-affiliated member
- If >3 members, no more than 3 members from same administrative unit
- Alternates may only serve under category(s) for which they are qualified





§ 2.31(c) IACUC functions *(part 1)*

1. Review, at least once every six months, the research facility's program for humane care and use of animals
2. Inspect, at least once every six months, all of the research facility's animal facilities, including animal study areas
3. Prepare reports of its evaluations conducted. . .and submit the reports to the Institutional Official of the research facility
 - Must distinguish significant from minor deficiencies
 - Must contain a reasonable and specific plan and schedule for correcting each deficiency



IACUC Semiannual Review and Inspection

What would you expect the IACUC to look at during a Program Review?

Read the requirement under §2.31(c)(1) & (3) and discuss



What would you expect the IACUC to look at during a Facility Inspection?

Read the requirement under §2.31(c)(2) & (3) and discuss



Clarification of Requirements for Semiannual Inspections and Program Reviews

- Subcommittees of at least 2 members may conduct the inspection and program review
 - Both members must physically inspect all of the animal facilities
- The inspection and program review must be presented to a convened quorum for their review and approval



What elements need to be in the written report to the IO?

Read the requirement under
§2.31(c)(3) and discuss



What are facilities required to report to USDA?

(There are 4 specific things that must be reported)

- 
1. Failing to correct a significant deficiency by the correction date, within 15 days [[§2.31\(c\)\(3\)](#)]
 2. Change in operation, within 10 days [[§2.30\(c\)](#)]
 3. Suspension of activities involving animals [[§2.31\(d\)\(7\)](#)]
 4. Annual reporting [[§2.36](#)]



§ 2.31(c) IACUC functions *(part 2)*

4. Review, and, if warranted, investigate both internal and external concerns involving the care and use of animals at the research facility
5. Make recommendations to the Institutional Official regarding any aspect of the facility's animal program, facilities, or personnel training



§ 2.31(c) IACUC functions *(part 3)*

6. Review and approve, require modifications in, or withhold approval of those components of **proposed activities** related to the care and use of animals



IACUC review of proposed activities

"protocol review"



§ 2.31(d) IACUC review of activities involving animals

1. The IACUC shall conduct a review of those components of the activities related to the care and use of animals. . . shall determine that the proposed activities or significant changes in ongoing activities meet the following requirements:
 - i. Procedures involving animals will avoid or minimize discomfort, distress, and pain to the animals
 - ii. The principal investigator has considered alternatives to procedures that may cause more than momentary or slight pain or distress

Consideration of Alternatives,

§ 2.31(d)(1)(ii)

When proposed activities or proposed significant changes contain procedures that may cause more than momentary pain or distress, the IACUC must determine that:

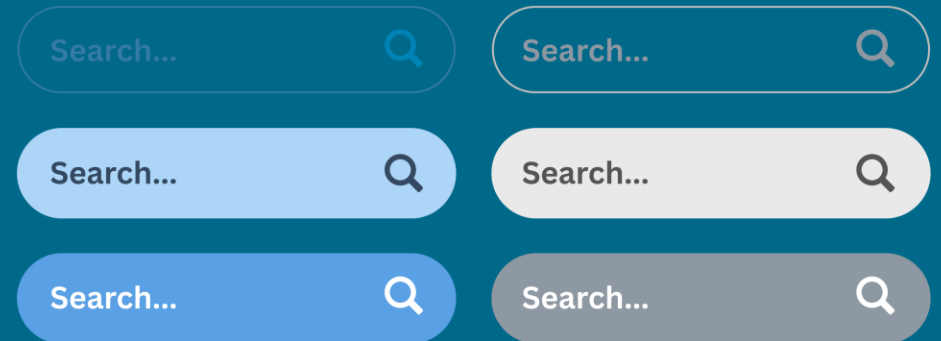
The Principal Investigator (PI) considered **alternatives** to procedures that may cause more than momentary or slight pain or distress

AND

That the PI has provided a **written narrative description of the methods and sources**, for example, the Animal Welfare Information Center, used to determine that alternatives were not available

Consideration of Alternatives

- Required for painful or distressful procedures
- Written narrative description of methods and sources
 - Database search
 - Name of database
 - Date search performed
 - Time period covered
 - Search strategy (including keywords)
 - Conferences, colloquia, subject expert consultants, or other sources
- **Must be updated if new painful or distressful procedure is added**





§ 2.31(d) IACUC review of activities involving animals *(continued)*

- iii. WRITTEN assurance that activities do not unnecessarily duplicate previous experiments
- iv. Procedures that may cause more than momentary or slight pain or distress to the animals will:
 - a. Be performed with appropriate sedatives, analgesics or anesthetics, unless withholding such agents is justified for scientific reasons, in writing, by the principal investigator
 - b. Involve, in their planning, consultation with the attending veterinarian
 - c. Not include the use of paralytics without anesthesia



§ 2.31(d) IACUC review of activities involving animals *(continued)*

- v. Animals that would otherwise experience severe or chronic pain or distress that cannot be relieved will be painlessly euthanized during or at the end of the procedure
- vi. The animals' living conditions will be appropriate for their species and contribute to their health and comfort
- vii. Medical care for animals will be available and provided as necessary by a qualified veterinarian



§ 2.31(d) IACUC review of activities involving animals *(continued)*

- viii. Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures
- ix. Activities that involve surgery include appropriate provision for pre-operative and post-operative care

All major survival surgery performed on covered animals must use aseptic procedures. . . in dedicated facilities



§ 2.31(d) IACUC review of activities involving animals *(continued)*

- x. No animal will be used in more than one major operative procedure from which it is allowed to recover, unless:
 - a. Justified for scientific reasons by the principal investigator, in writing
 - b. Required as routine veterinary procedure or to protect the health or well-being of the animal as determined by the attending veterinarian; or
 - c. In other special circumstances as determined by the Administrator on an individual basis



§ 2.31(d) IACUC review of activities involving animals *(continued)*

- xi. Methods of euthanasia used must be in accordance with the definition of the term set forth in § 1.1 of this subchapter, unless a deviation is justified for scientific reasons, in writing, by the investigator

§ 2.31(e) proposal to conduct an activity involving animals must contain the following:

1. Identification of the species and the approximate number of animals to be used
2. A rationale for involving animals, and for the appropriateness of the species and numbers of animals to be used
3. A complete description of the proposed use of the animals
4. A description of procedures designed to assure that discomfort and pain to animals will be limited to that which is unavoidable
5. A description of any euthanasia method to be used

AWR Required IACUC Considerations & Protocol Details

identification of species and number of animals	§2.31[e]
rationale for using animals, species, sex, age, and number of animals to be used	§2.31[e]
does not unnecessarily duplicate previous experiments	§2.31[d](1)
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 sedative/analgesic/anesthetic methods	§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]
living conditions appropriate for the species	§2.31[d](1)
veterinary care provided as necessary	§2.31[d](1)
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)

AWR Required IACUC Considerations & Protocol Details

Ethics	identification of species and number of animals	§2.31[e]
	rationale for using animals, species selected, and number 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)



§ 2.31(c) IACUC functions *(part 4)*

7. Review and approve, require modifications in or withhold approval of **proposed significant changes** regarding the care and use of animals in **ongoing activities**
8. Authorized to suspend an activity involving animals

What is a significant change to ongoing activities?

Significant changes include changes:

- In species
- In Principal Investigator
- In study objectives
- From nonsurvival to survival surgery
- Resulting in greater pain, distress, degree of invasiveness
- In housing or use of animals in a location that is not overseen by the IACUC
- Increase in approved animal numbers
- In anesthesia, analgesia, or experimental substances
- In euthanasia method
- Duration, frequency, type, or number of procedures performed on an animal





**The following slides outline aspects of the
Public Health Service (PHS) Policy on
Humane Care and Use of Laboratory Animals
Contact OLAW with questions**

<https://grants.nih.gov/help/central-nih-office-contacts#olaw>



Full committee review or designated member review required

PHS Policy regarding IACUC review of changes to ongoing activities

Full committee review (FCR) or designated member review (DMR) is required for the following significant changes:

- From nonsurvival to survival surgery
- resulting in greater pain, distress, or degree of invasiveness
- in housing and or use of animals in a location that is not part of the animal program overseen by the IACUC
- in species
- in study objectives
- in Principal Investigator (PI)
- that impact personnel safety.

[Click here](#) to read the PHS guidance on significant changes to animal activities



Handled according to an
IACUC approved VVC policy

PHS Policy regarding IACUC review of changes to ongoing activities

Veterinary Verification and Consultation (VVC)

Some specific significant changes to previously approved animal activities may be handled according to an IACUC-approved VVC policy that incorporates the following four required components:

1. IACUC-defined eligible significant changes, including but not limited to, changes in:
 - Anesthesia, analgesia, sedation, or experimental substances;
 - Euthanasia to any method approved in the [AVMA Guidelines for the Euthanasia of Animals](#) (approved means any acceptable method of euthanasia for a given species or, a method that is acceptable with conditions for that species provided all conditions are met); and
 - Duration, frequency, type, or number of procedures performed on an animal.



Handled according to an
IACUC approved VVC policy

PHS Policy regarding IACUC review of changes to ongoing activities

Veterinary Verification and Consultation (VVC)

Some specific significant changes to previously approved animal activities may be handled according to an IACUC-approved VVC policy that incorporates the following four required components (cont.):

2. IACUC-approved references for each VVC-eligible significant change included in the IACUC policy, to set allowable parameters
3. *IACUC-authorized veterinarian(s)* to verify, through consultation, that the requested significant change(s) are compliant with the VVC policy, and
4. A method to document the consultation and verification of the change in the protocol.

A VVC policy with these components must be approved by the IACUC before implementation.



Handled administratively with
existing IACUC approved policy

PHS Policy regarding IACUC review of changes to ongoing activities

An **increase in previously approved animal numbers** (PHS Policy IV.D.1.a.) is a significant change that may be handled administratively by an authorized individual(s), provided there is an IACUC-approved policy. The policy must:

- Specify the conditions when increases in animal numbers may be handled administratively;
- Identify the authorized individual(s) by title or name;
- Clearly define the limits of animal number increases; and
- Require that the study objectives and the rationale for using animals are unchanged by the increase. If the rationale or study objectives change, IACUC review by DMR or FCR is required.



21st Century Cures Act

- Directed NIH, USDA, and FDA to reduce duplicative administrative burden while maintaining strong protections for research animals
- Harmonized several processes that were previously not aligned between the organizations
- APHIS inspectors use the AWA as the primary authority but important for inspectors to be aware of OLAW resources and policies
- Footnote 2 of the PHS policy states “Compliance with applicable USDA regulations is an absolute requirement of this Policy”



§ 2.31(d) IACUC review of activities involving animals *(continued)*

2. Each member of the Committee shall be provided with a list of proposed activities to be reviewed and written descriptions of all proposed activities that involve the care and use of animals shall be available to all IACUC members
 - Provisions for designated review are described
3. The IACUC may invite consultants to assist in the review of complex issues



§ 2.31(d) IACUC review of activities involving animals *(continued)*

4. The IACUC shall provide written notification of its decision to approve or withhold approval of those activities related to the care and use of animals, or of modifications required to secure IACUC approval
5. The IACUC shall conduct complete reviews of activities covered by this subchapter not less than every 3 years

Includes a written description of all activities that involve the care and use of animals for review and approval at the end of the term.



§ 2.31(d) IACUC review of activities involving animals *(continued)*

6. The IACUC may suspend an activity that it previously approved if it determines that the activity is not being conducted in accordance with the description approved by the Committee
7. If the IACUC suspends an activity involving animals, . . .report that action with a full explanation to APHIS and any Federal agency funding that activity
8. Other official entities may not approve an activity involving the care and use of animals if it has not been approved by the IACUC



§ 2.32 - Personnel qualifications

- a. It shall be the responsibility of the research facility to ensure that all personnel involved in animal care, treatment, and use are qualified to perform their duties
- b. Training and instruction shall be made available, and the qualifications of personnel reviewed



§ 2.32(c)- Training and instruction of personnel must include guidance in:

1. Humane methods of animal maintenance and experimentation, including:
 - i. The basic needs of each species of animal
 - ii. Proper handling and care for the various species of animals used by the facility
 - iii. Proper pre-procedural and post-procedural care of animals
 - iv. Aseptic surgical methods and procedures



§ 2.32(c)- Training and instruction of personnel must include guidance in: *(continued)*

2. The concept, availability, and use of research or testing methods that limit the use of animals or minimize animal distress
3. Proper use of anesthetics, analgesics, and tranquilizers for any species of animals used by the facility
4. Methods whereby deficiencies in animal care and treatment are reported by any employee of the facility



§ 2.32(c)- Training and instruction of personnel must include guidance in: *(continued)*

5. Utilization of services available to provide information:
 - i. On appropriate methods of animal care and use
 - ii. On alternatives to the use of live animals in research
 - iii. That could prevent unnecessary duplication of research involving animals
 - iv. Regarding the intent and requirements of the Act

§ 2.33 - Attending veterinarian and adequate veterinary care

Research has its own AV and adequate veterinary care regulation

- Requirements are the same as § 2.40 with *one* key addition:
 - (a)(3) The attending veterinarian shall be a voting member of the IACUC
 - may appoint to the IACUC another DVM with delegated program responsibility for activities involving animals at the research facility

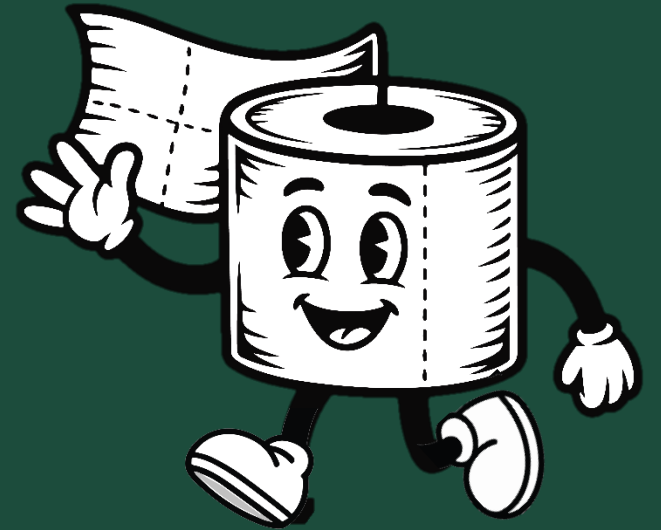
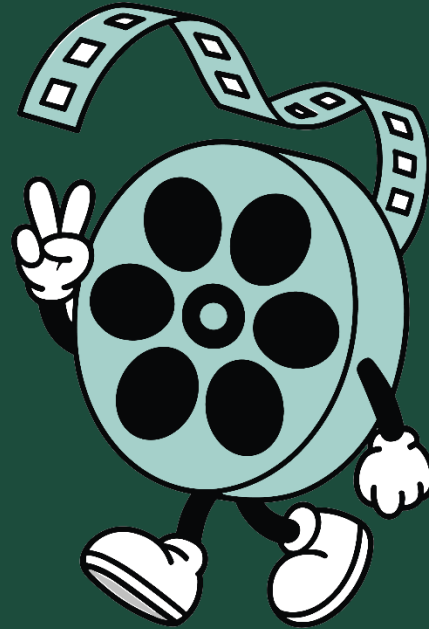


Delegated veterinary responsibility

- Most research facilities have a full-time AV
 - A written PVC is not common and is only *required* for dogs
- Delegation of AV responsibilities is common
 - Many facilities have several veterinarians on staff
 - Rotation of IACUC duties
 - Delegation of social management to a behaviorist
 - The AV can retain their full regulatory authority by developing or approving SOPs for the conduct of delegated activities



Let's take a break!





§ 2.35(a) - Recordkeeping requirements *IACUC*

1. Minutes of IACUC meetings, including records of attendance, activities of the Committee, and Committee deliberations
2. Records of proposed activities involving animals and proposed significant changes in activities involving animals, and whether IACUC approval was given or withheld
3. Records of semiannual IACUC reports and recommendations (including minority views)



§ 2.35(b) - Recordkeeping requirements

Dogs & Cats



Every research facility shall make, keep, and maintain records of the following information concerning each live dog or cat, including any offspring born:

1. The name and address of the person from whom a dog or cat was acquired
2. The USDA license or registration number of the person *if licensed or registered*
3. The vehicle license number and State, and the driver's license number and State of the person, *if not licensed or registered*



§ 2.35(b) - Recordkeeping requirements

Dogs & Cats continued

4. The date of acquisition of each dog or cat
5. The official USDA tag number or tattoo* assigned to each dog or cat
6. A description of each dog or cat which shall include:
 - i. The species and breed or type of animal
 - ii. The sex
 - iii. The date of birth or approximate age
 - iv. The color and any distinctive markings



Reminder that **microchipping is considered a tattoo**
-so microchip numbers work too!



§ 2.35(b) - Recordkeeping requirements

Dogs & Cats continued

7. Any identification number or mark assigned to each dog or cat by the research facility
8. Certification of dogs or cats are acquired from any person not licensed or registered and not a pound or shelter
 - Animals were born and raised on the person's premises
 - The person has sold fewer than 25 dogs and/or cats that year



§ 2.35(c) - Recordkeeping requirements

Dogs & Cats sold, transported, or otherwise disposed of

In addition to records required under §2.35(b)

1. The name and address of the person to whom a live dog or cat is transported, sold, or otherwise disposed of
2. The date of transportation, sale, euthanasia, or other disposition of the animal
3. The method of transportation- including the name of the initial carrier, intermediate handler, or name of owner if a privately owned vehicle



§ 2.35 - Recordkeeping requirements

- d. USDA forms **may** be used
- e. One copy accompanies animal shipments, one copy is retained by facility
- f. All records retained for **3 years** after completion of activity
 - *"All records shall be available for inspection and copying"*
 - *"APHIS inspectors will maintain the confidentiality of the information and will not remove the materials from the research facilities' premises unless" it is strictly for enforcement purposes*
 - Any records that AC has possession of are subject to FOIA



Random Source Dogs & Cats

- 2.133, (referenced in 2.38(k)(4)) describes requirements of a dealer for:
 - A 5-day holding period
 - Certification allowing for traceback to dealer and identification of dog or cat
 - All previous certifications if the animal was provided by another dealer
 - Retention of certification for at least 1 year
- National Institutes of Health (NIH) completely ended all funding for research using random source cats (in 2012) and dogs (in 2014) from Class B dealers



§ 2.36 - Annual report

- a. Must be submitted to USDA on or before December 1 of each calendar year
- b. The annual report shall:
 - 1. Assure that professionally acceptable standards governing the care, treatment, and use of animals were followed by the research facility
 - 2. Assure that each principal investigator has considered alternatives to painful procedures



§ 2.36 - Annual report *(continued)*

3. Assure that the facility is adhering to the standards and regulations under the Act
 - Any exceptions explained by the principal investigator and approved by the IACUC
 - A summary of all such exceptions - including an explanation for the exception and the species and number of animals impacted - must be attached to the facility's annual report
4. State the location of all facilities where animals were housed, used in actual research, or held for research

§ 2.36 - Annual report *(continued)*

Column

5. List common names and numbers of animals upon which activities involve no pain, distress, or use of pain-relieving drugs
6. List common names and numbers of animals upon which activities included drugs to mitigate pain or distress
7. List common name and numbers of animals upon which activities involve pain or distress to the animals and for which appropriate drugs were not provided to alleviate pain or distress
 - An explanation shall be attached to the annual report
8. List common names and numbers of animals being bred, conditioned, or held for use but not yet used

C

D

E

B

Form 7023 & Category E attachment

[illegible][illegible]

According to the Information Collection Act (1966), an agency may not conduct a survey, and a person is not required to respond to a survey or collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0579-0106. The time required to complete this information collection is estimated to average 5 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.	<table border="1"> <tr> <td data-bbox="2226 375 2461 401"> OMB APPROVED 0579-0106 </td> </tr> <tr> <td data-bbox="2226 401 2461 419"> Interagency Report Control No. 0700-0106-02 </td> </tr> <tr> <td data-bbox="2226 419 2461 442"> Fiscal year: </td> </tr> </table>	OMB APPROVED 0579-0106	Interagency Report Control No. 0700-0106-02	Fiscal year:
OMB APPROVED 0579-0106				
Interagency Report Control No. 0700-0106-02				
Fiscal year:				
UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE Annual Report of Research Facility Column E Explanation (TYPE OR PRINT)				
This information is required by law (7 U.S.C. 2143 and 9 C.F.R. §2.36). Failure to report according to the regulations can result in an order to cease and desist.				
1. REGISTRATION NUMBER	2. Research Facility Headquarters address			
3. Number of animals used in the study.	4. Species (common name) of animals used in the study.			
5. Explain the procedure producing pain and distress.				
6. Provide the scientific justification for not providing the appropriate anesthetics, analgesics, or tranquilizing drugs during procedures where the animal experienced accompanying pain or distress greater than momentary or slight.				
7. What, if any, Federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number, and the specific section number (e.g., APHIS, 9 CFR 113, 102):				
Agency	CFR			

APHIS FORM 7023B
JUL 2009

Annual Report Packets

<https://www.aphis.usda.gov/sites/default/files/fy24-annual-report-packet-ac.pdf>

Annual Report Do's and Do Not's

- **DO** submit one Annual Report per registered facility. All site locations should be consolidated into one annual report.
- **DO** include a list of all authorized personnel for the registered facility (including the authorized person who signs the report) to ensure that our contact information is up to date.
- **DO NOT** leave the form blank; if submitting all zeroes, please include those on the form.
- **DO** call (970) 494-7477 if you have any questions regarding the annual report or any information required to be included.

Tips for Categorizing Animals

- Refer to the headings on Form 7023 and 9 C.F.R. § 2.36 for information on each category.
- Useful guidance for pain and distress categorization is also available in the Animal Care Tech Note: Categorizing Pain and Distress on the Annual Report, available at: <https://www.aphis.usda.gov/sites/default/files/ac-tech-note-categorizing-animal-pain-or-distress.pdf>.
- Animals used for research, testing, teaching, or experiments at any time during the reporting year must be reported in Column C, D or E, as appropriate, whether or not they are still being held at the facility.
- For any animals that have been used and transferred to another facility during the fiscal year, the facility that used the animals in the highest pain category is required to report the animals on their annual report.
- Animals used in more than one study should be counted only once in the most painful/distressful category.
- Include animals involved in only husbandry, veterinary care, or colony management procedures in Column B.
- Euthanasia as defined in the Animal Welfare Regulations is not considered painful or distressful. Euthanasia should not be used to determine the pain category unless a method that causes pain or distress was required for scientific reasons.

Completing the APHIS Form 7023

Annual Reports are now completed and submitted electronically! The portal opens on October 4th and closes on December 31st.

Top Right: Fiscal year

- Enter the Fiscal Year (2024).

Block 1: Registration Number

- Enter the facility's registration number (also known as certificate number).

Block 2: Headquarters Research Facility

- Complete this block with the mailing information of the facility headquarters.
- Include the name of the facility and full mailing address with city, state and zip code. P.O. boxes are acceptable for the facility's mailing address.
- Include the main telephone number for the facility and the best contact email address.

Block 3: Reporting Facility/ Facility Locations

- List all facility locations, with physical addresses, where animals are being used or held. P.O. Boxes are not acceptable as addresses for site locations.
- Include phone numbers if different from the headquarters phone number.
- If more than two facilities need to be listed, use a separate sheet.

Blocks 4 through 13: Animal Usage Report

- Column A: Animals Covered by the Animal Welfare Regulations.
 - List all regulated animals by common name.
 - Do Not list any numbers under column A.
 - Do Not report laboratory rats, mice or birds bred for use in research.
 - Do Not report reptiles, amphibians, fish, or any animals not covered by the Animal Welfare Act.
 - Do Not report animals used in field studies (as defined in the Animal Welfare Regulations) or clinical trials under a veterinarian-client-patient relationship.
 - Report all birds not bred for use in research under "Birds" regardless of species.
 - Use the Other Farm Animal species and Other Animal species (Blocks 12 and 13) for species not listed on this form in Blocks 4-11.
 - Report wild and exotic rodents under Other Animals.
 - If more species need to be listed, use the APHIS 7023A- Continuation Form.
 - For assistance determining which columns the animals should be counted under (i.e., which pain category the animal falls into), consult the Tech Notes linked on page one of this guide or contact AC.AnnualReports@usda.gov.

- Column B: Animals bred, conditioned, or held but not used for regulated purposes.
 - Enter the total number of animals of each species that was bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.
 - Include animals used for breeding and their offspring if they were not used for research or teaching purposes this year.
 - Include animals still held by the facility that were used in prior years but not this year.
- Column C: Animals used for research or teaching that did not involve pain, distress, or use of pain-relieving drugs.
 - Enter the total number of animals of each species that was used and did not experience more than momentary pain or distress.
 - Report animals that experienced routine research procedures (e.g., injections, tattooing, blood sampling) in this column.
- Column D: Animals used for research or teaching that involved more than momentary pain or distress for which appropriate anesthetic, analgesics, or tranquilizing drugs were used.
 - Enter the total number of animals of each species that experienced more than momentary pain or distress that was appropriately alleviated with anesthetics, analgesics, or tranquilizers.
- Column E: Animals used for research or teaching involving accompanying pain or distress and for which the use of appropriate pain-relieving drugs would have adversely affected the activity.
 - Enter the total number of animals of each species that experienced unalleviated pain or distress to prevent an adverse effect on the procedure, results, or interpretation of the activity.
 - Include an explanation of these procedures with the report. See the Column E and Exception FAQ sheet for additional guidance.
- Column F: Total Number of Animals Used in Research
 - Total each number of animals listed under Column C, D, and E.
 - Totals will be automatically generated when using the online portal.
 - Do not include animals listed under column B.

Certification by Headquarters Research Facility Official

- Have the form signed by any authorized person at the facility. This can include, but is not limited to, the CEO, COO, President, Vice-President, Institutional Official, or Attending Veterinarian.
 - By signing the form, the facility assures it is complying with the Animal Welfare Act and Regulations and that the information provided is true, correct, and complete.

Annual Report Packets

additional tips & guidance

TIPS TO AVOID REPORTING ERRORS

General Tips:

- **DO NOT** report non-regulated animals.
 - **DO NOT** report laboratory rats and mice (genera Rattus and Mus)
 - **DO NOT** report birds bred in captivity and used in research, teaching, testing, or experimentation.
 - **DO NOT** report amphibians, reptiles, or fish.
 - **DO NOT** report horses or other farm animals used for food or fiber, or for improving animal nutrition, breeding, management, or production efficiency, or improving the quality of food or fiber.
- **DO NOT** include client-owned animals participating in clinical trials in the context of medical care under a veterinary client relationship.
- **DO NOT** include animals used in a field study as defined in the AWA Regulations. A 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." The IACUC determines whether an activity meets this definition.
- **DO NOT** report animals that a facility holds or uses outside the United States, or territories and possessions of the United States.
- **DO** report animals used or held for use at any time during the reporting period only once, in the highest pain category the animal experienced.

For teaching activities involving veterinary students or veterinary technology students:

- **DO** report facility-owned horses and other farm animals used for biomedical or non-agricultural research or teaching, including training of human or veterinary medical personnel in medical methods and procedures such as diagnostic techniques, surgery, anesthesia and analgesia
- **DO NOT** include client-owned or shelter animals at spay-neuter clinics that are used only in the context of a veterinary client patient relationship
- **DO NOT** include animals on working farms used for teaching husbandry procedures at the farm location

EXCEPTION ATTACHMENTS

Research facilities may make exceptions to the Animal Welfare Regulations and Standards when necessary to accomplish the research design. Exceptions must be specified and explained by the Principal Investigator in the research protocol and approved by the IACUC. Additionally, some exceptions also require approval by APHIS before they may be implemented. You may be required to provide exceptions along with your annual reports. This sheet provides guidance on exception attachments. Any exceptions received that are incorrect or incomplete will cause a delay in processing your annual report. Your annual report will not be considered received until all information has been received by Animal Care.



WHAT TO REPORT

Exceptions TO report on the Annual Report should be noted as IACUC-approved on the report and include:

Exceptions approved by the IACUC under 9 C.F.R. § 2.38(k) that are not provided for under the AWA regulations and standards, such as:

- + Removal of resting platforms from cat enclosures
- + Extension of interval for cleaning/sanitization of enclosures
- + Keeping animals in 24-hour dark cycle
- + Keeping animals in temperatures outside range described in the AWA standards for the relevant species

Exceptions approved by Animal Care, such as:

- + Approval for use of an animal in more than one major operative procedure from which it is allowed to recover on more than one protocol (9 C.F.R. § 2.31(d)(1)(x)(C))
- + Exception to the health certificate requirements (9 C.F.R. § 2.38(h)(2))
- + Temporary tethering of dogs used as the primary enclosure (9 C.F.R. § 3.6(c)(4))

Exception Attachment Requirements

- Ensure that attachments include a brief description of the exception, species (use common names), and the number of animals affected for the reporting year only (October 1, 2023 through September 30, 2024).
- Report approved exceptions even when no animals experienced the exception during the reporting period
- The explanation should be readily understood by a lay person
- Bullet point format is acceptable
- Basic information to include for the exception should be the same common name and/or species name as documented on form 7023, number of animals affected, what the exception is, and why the exception was required.
- Include a statement that the IACUC approved this exception
- **Check your numbers!** If the numbers of animals listed in an Exception exceed the totals used in research for that species, you will receive a letter requesting clarification.
- All Exceptions should be submitted in a format that is FOIA-ready, for questions relating to redactions please call APHIS-FOIA at: (301) 851-4102



WHAT NOT TO REPORT

Exceptions that should NOT be reported on the Annual Report include:

Exceptions approved by the IACUC that are provided for under the AWA regulations and standards, such as:

- Approval for use of an animal in more than one major operative procedure from which it is allowed to recover on one protocol (9 C.F.R. § 2.31(d)(1)(x)(A))
- Short term withholding of food and water from animals (9 C.F.R. § 2.38(f)(2)(ii))
- Exemption of an individual non-human primate from some or all the environmental enhancement plan (9 C.F.R. § 3.81(e)(2))
- Any deviation from the methods of euthanasia as defined in the AWA regulations which were justified for scientific reasons, in writing, by the investigator (9 C.F.R. § 2.31(d)(1)(xi))

Exceptions approved by a veterinarian as part of the provision of veterinary care, such as:

- Animal is fasted for surgery conducted for husbandry reasons
- Any major operative procedures for medical or colony management purposes (9 C.F.R. § 2.31(d)(1)(x)(B))
- Animals housed in an enclosure that does not meet space requirements for medical reasons while recovering from husbandry or veterinary care related surgery
- An animal that develops vomiting/diarrhea (not study-related) and veterinarian prescribes IV fluids and severely restricts food and water intake by mouth for several days

Exceptions to regulations, guidance, or policies other than the AWA Regulations and Standards

- Do not report exceptions to The Guide for the Care and Use of Laboratory Animals, PHS Policy, internal policies or procedures, etc.

QUESTIONS ON SPECIFIC SITUATIONS?

- Help is available via the Annual Report Hotline at (970) 494-7477 or by email at AnimalCare@usda.gov.

COLUMN "E" EXPLANATION ATTACHMENTS

If you have listed any animals in Column E, you are required to submit an attachment with an explanation of the procedures producing pain or distress and the reasons appropriate drugs were not used. This sheet provides useful guidance on attachments related to Column "E" explanations.

- Use Form 7023B found in your annual report packet to ensure you are addressing all regulatory requirements for reporting under the Animal Welfare Act
- Explain any procedures that caused pain or distress to the animals and reasons drugs were not used.
 - Explanations should be brief, in plain terms, and focus on what was done to the animal and what the animal experienced for example: seizures, neurologic signs, inappetence, gastrointestinal signs, etc. Do **not** include any protocols or IACUC meeting notes.
 - Include the reason(s) pain and distress could not be relieved, which should be science-based and in plain terms.
 - You may wish to include a statement that the IACUC approved the activity
 - You may wish to briefly describe procedures that were used to limit pain or distress in Column E animals for context
 - Bullet point format is acceptable
- If pain or distress could not be relieved due to regulatory requirements, list the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102). If the requirement is in accordance with a guidance document, such as an agency notice or harmonization guideline, please provide sufficient information to identify the cited document.
- **Check your numbers!** Make sure the number of animals in the attached explanations matches the numbers reported in Column E for items 4-13. If they differ, you will receive a letter requesting clarification.
- All Explanations should be submitted in a format that is FOIA-ready, for questions relating to redactions please call APHIS-FOIA at: (301) 851-4102

** Remember that reporting may be retrospective or prospective. **Retrospective** reporting involves collecting data on individual animals to put each study animal into the most appropriate category based on clinical signs of pain and distress. While more labor intensive, this method generally produces more accurate reporting. **Prospective** reporting means that all animals used for a particular activity are categorized in the highest applicable pain category based on anticipated pain and distress associated with that activity. This method is less labor intensive but may result in animals being placed in a higher category than necessary.

REMEMBER: Annual Reports are posted on the USDA website. Avoid including protocol numbers, proprietary information, personally identifiable information, and other confidential information.

QUESTIONS ON SPECIFIC SITUATIONS?

- See the [Categorizing Animal Pain or Distress in Research Facility Annual Reports Tech Note](https://www.aphis.usda.gov/sites/default/files/ac-tech-note-categorizing-animal-pain-or-distress.pdf) available at <https://www.aphis.usda.gov/sites/default/files/ac-tech-note-categorizing-animal-pain-or-distress.pdf> for assistance.
- Help is also available via the Annual Report Hotline at (970) 494-7477 or by email at AnimalCare@usda.gov.

Tech Note on Categorizing Pain & Distress

<https://www.aphis.usda.gov/sites/default/files/ac-tech-note-categorizing-animal-pain-or-distress.pdf>



Animal Care Tech Note

Categorizing Animal Pain or Distress in Research Facility Annual Reports

The Animal Welfare Act (AWA) requires research facilities to submit an annual report that states the common names and numbers of animals used in research, testing, or experimentation. The report must also categorize these animals based on procedures involving pain, distress, and/or the use of pain-relieving drugs. Research facilities may use this tech note as a reference when assigning animals to pain and distress categories.

Animal Welfare regulations define a painful procedure as "any procedure that would reasonably be expected to cause more than slight or momentary pain or distress in a human being to which that procedure is applied, that is, pain in excess of that caused by injections or other minor procedures" (9 CFR § 1.1).

Categorizing Procedures Involving Pain and/or Distress

You should evaluate only study-related procedures when categorizing animals for reporting purposes. Veterinary care or colony management procedures performed for the health of an individual animal or the colony should not be considered. For example, treating wounds acquired in fights with other animals is not study-related and should not be considered for annual reporting.

If multiple categories may apply, you should report each animal only once in the category consistent with the greatest amount of pain or distress they experienced during that period. For this reason, animals on long-term studies that span multiple reporting periods may be reported in different categories for each period.

The table on page 2 shows the pain categories listed on the annual report and examples of procedures that apply to each category. These examples are not intended to be exhaustive. You should consider the specific animal-use activity when categorizing animals.

When anesthetics, analgesics, or sedatives are used only for restraint during procedures that do not involve more than slight or momentary pain, these animals should be placed in Category C. For example, animals that are anesthetized or sedated for collecting blood samples or for imaging procedures should be assigned to Category C.

Animals exhibiting signs of pain, or distress such as weight loss, abnormal activity level, adverse reactions to touching inoculated areas, open sores/necrotic skin lesions,



abscesses, lameness, ocular pain and/or inflammation, corneal edema, and photophobia must receive appropriate and effective relief consistent with the current standard of care. Appropriate and effective relief may not necessarily require analgesics. It may also include supportive care such as ice packs, heat, soft bedding, diet alterations, and/or anti-nausea medications in addition to analgesic therapy when necessary. Animals that receive appropriate relief are listed in Category D.

You should place in Category D any animals that experience breakthrough pain after receiving appropriate anesthetic or analgesics or experience pain or distress before you detect the need for analgesics, as long as:

- The animals are appropriately monitored;
- The type, dose, and frequency of analgesics being administered are appropriate for the procedure and species; and,
- The intent is to alleviate the pain and distress as needed.

A Category D procedure may become a Category E procedure if appropriate anesthetics, analgesics, or sedatives are withheld because these agents would adversely affect the procedure, results, or interpretation of the test or research. When appropriate relief of pain or distress cannot be administered to maintain the validity of the test or research, or the nature of the activity does not allow appropriate relief, the activity must be scientifically justified in the animal activity proposal and approved by the Institutional Animal Care and Use Committee. You must report animals in this situation in Category E.

You must attach a description of the procedures producing pain and distress in Category E animals and the reasons pain-relieving drugs were not used to the annual report.

Prospective or Retrospective Reporting

You can categorize pain and distress prospectively or retrospectively. Retrospective reporting involves collecting data on individual study animals to determine the most appropriate category based on clinical signs of pain and distress the animal experienced during the reporting period. While labor intensive, this method generally produces more accurate reporting. Prospective reporting means that all animals used for a particular activity are categorized in the highest applicable pain category based on anticipated pain and distress associated with that activity. This method is

less labor intensive but may result in animals being placed in a higher category than necessary.

If animals experience pain or distress during the study due to research procedures that are in a higher pain category than originally designated, you must report the animal(s) in the higher pain category. In other words, your reporting will be retrospective to indicate the pain or distress level the animal actually experienced.

For More Information

The AWA and its regulations establish the legal requirement and standards research facilities must follow. For details, see USC Title 7, Chapter 54, Sections 2131-2159 and CFR, Title 9, Chapter 1, Subchapter A, Parts 1-4.

If you have questions, contact the U.S. Department of Agriculture (USDA) Animal Care staff at (970) 494-7478 or animalcare@usda.gov.

Pain Categories

Category	Explanation	Example
B	Animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes	• Animals on breeding protocols with no research or experimental component • Animals acquired by the facility but held in quarantine or acclimation period prior to use • Euthanizing animals on a holding protocol following current professional standards • Observing animal behavior in their home enclosures without manipulation
C	Animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs	• Observing animal behavior in the lab • Positive reward training or research • Food restriction that reduces the animal's weight by no more than 15 percent of normal age-matched controls • Manipulative procedures such as weighing, injections, palpations, skin scrapings, and radiography • Administering an anesthetic, analgesic or tranquilizing drug to an animal for restraint purposes to perform a procedure that involves no pain or distress such as imaging procedures • Exposure to mild alteration in environmental conditions with appropriate acclimation
D	Animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs were used	• Surgical manipulations (survival or terminal) in which the animals received appropriate pre-, intra-, and post-operative anesthetics and analgesics • Using Freund's complete adjuvant if alleviation of pain/distress occurs • Tumor induction or implantation if alleviation of pain/distress occurs • Induced infections or antibody production in which animals experience pain alleviated by analgesics • Exsanguination under anesthesia
E	Animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests	• Paralysis or immobilization of a conscious animal • Any Category D procedure for which needed analgesics, tranquilizers, sedatives, or anesthetics are withheld for justifiable study purposes • Toxicological, microbiological, or infectious disease research that requires continuation after clinical signs are evident without medical care or that requires death as an endpoint • Food or water restriction which reduces the animal's weight by more than 15 percent of normal age-matched controls • Certain types of forced exercise protocols that could reasonably be expected to cause distress or exhaustion • Applying noxious stimuli that the animal cannot avoid/escape • Exposure to extreme environmental conditions • Long-term restraint (days to weeks)



Sorting animals into the right pain category

prospective vs retrospective approach

- **Prospective reporting-** all animals used for a particular activity are categorized prior to conduct of the study, based on anticipated pain and distress associated with that activity
 - Less labor intensive
 - May result in animals being placed in a higher category than necessary
 - If animals experience a greater category of pain or distress than what was anticipated, they must be reported in the higher pain category
- **Retrospective reporting-** the determination is made after completion of the study, based on clinical signs of pain and distress the animal experienced during the reporting period

Activity: assigning pain/ distress category

Read the scenario on the slide.

Determine what pain category the animal should be reported in. Why?

Discuss answers as a group.



An animal experiences pain due to the research procedures, during the course of a study. The pain is recognized and treated with appropriate analgesics in a timely manner in compliance with the protocol and the analgesics prove to be substantively effective.



An animal is anticipated to experience pain due to a research procedure, but the investigator determined that analgesics, anesthetics or tranquilizers would adversely affect the study. No intervention for pain is made.



An animal is unexpectedly found dead in the cage during a study. The animal had been monitored appropriately, and there were no pre- or post-mortem sign of pain or distress. The animal had not experienced pain as part of the study prior to its death.



An animal experiences unexpected pain or distress due to the research procedures during a study. The pain is recognized, and the animal is euthanized in a timely manner in compliance with the method in the approved protocol.



An animal accidentally becomes caught in a cage and experiences pain and distress which is completely unrelated to the study. The injuries are treated, and appropriate analgesia is provided. The study, as per the approved protocol, involves no pain or distress with the only procedure being blood sampling.



Exemptions vs. exceptions vs. exclusions

An **exemption** exists when the law explicitly says the rules don't apply to a particular person, product, or situation.

Example: NHPs with an exemption to the EEP because they are individually housed

Must be in Annual Report? **NO**

An **exception** provides a departure from the standard application of a rule or regulation, usually due to unique circumstances.

Example: Decrease in cage sanitation frequency due to experimental parameters

Must be in Annual Report? **YES**
*Requires scientific justification

An **exclusion** exists when the person, product, or circumstance isn't the kind of thing the law is meant to regulate. *(The law doesn't apply because the item isn't even within the law's scope.)*

Example: Birds (all species) that are bred (hatched) in captivity for use in research

Must be in Annual Report? **NO**

Activity: exception report review

For each scenario, read the exception as reported on a facility's annual report then answer the following questions:

1. What is the applicable regulation?
2. Carefully read the regulation language. Is the scenario required to be reported as an exception on the Annual Report?
3. If it is a reportable exception, does the narrative include all the **required elements** as per 9 CFR 2.36(b)(3)?



Explanation of exception
Species affected
Number of animals affected

An exception for 34 cynomolgus macaques enrolled in studies that require restricted fluid intake for performance of complex behavioral tasks. Animals that are not fluid controlled usually will not work or will only work for periods of time so brief as to not be useful for training and recording. For some studies, this may require access to drinking water only once per day. These animals are closely monitored by veterinary staff during the study to ensure animal welfare is maintained. Duration of restricted fluid intake is limited to the minimal time needed to accomplish the task.

- 
- A photograph of a cynomolgus macaque, a species of monkey often used in biomedical research. The monkey is shown from the chest up, clinging to the vertical metal bars of a cage. Its fur is a mix of light brown and white, and its face is a reddish-pink color. The monkey's expression is somewhat somber or contemplative as it looks towards the camera. The background is dark and out of focus.
1. Reportable exception?
 2. Related regulation?
 3. Compliant narrative

Species Common name: Cat

Number of animals: Three

Exception: Lighting

Description: All animals are raised from birth to adulthood in total darkness.

Purpose and value of study: These studies examine the role of visual experience on the development of the multisensory processes by which the brain synthesizes information from different senses, like vision and hearing, to shape the way we perceive the world. By manipulating visual input during development, we learn how the nervous system compensates. This work will be translated into clinical treatments, like prosthetic devices, to improve the lives of those with congenital or early-acquired sensory deficits.

1. Reportable exception?
2. Related regulation?
3. Compliant narrative



IACUC approved exception: Physical restraint
Four Investigators were granted IACUC approval to utilize non-human primate chair restraint during experimental procedures. The animals were removed at the end of the recording sessions. The maximum length of the recording sessions was four hours. During this reporting period, thirty (30) nonhuman primates were used.

1. Reportable exception?
2. Related regulation?
3. Compliant narrative



Impacts rhesus macaques:
An exception to the 14-day sanitation frequency for rhesus macaques enrolled in studies that require dosing with a radioisotope for enhanced resolution imaging procedures. Some of the isotopes used require a 42-day period to decay to safe disposal levels. The cages are spot cleaned in place instead of a complete cage change until the isotopes have decayed to safe levels. The duration has not exceeded 42 days.

1. Reportable exception?
2. Related regulation?
3. Compliant narrative



1. Reportable exception?
2. Related regulation?
3. Compliant narrative

Impacts 65 Swine:
An exception to the every 14 day
cage change frequency for swine
in farrowing cages and piglets in
nursery pens. This lag in cage
changing is for the welfare of the
fragile animal during an important
period of their life.



Twenty Yucatan minipigs were fed a diet high in cholesterol and fat to develop atherosclerosis. This specialized diet is required for studies on coronary artery disease (CAD). When the CAD reaches an advanced level of disease, the pigs are housed in farrowing crates to limit their physical activity. They will be housed under those conditions for 48 hours before completing study.



1. Reportable exception?
2. Related regulation?
3. Compliant narrative



REMINDER



- All facilities using birds for covered research must be registered before using animals.
- All covered birds must be included on the annual report.

Bird Exclusions

- Birds (all species) that are bred (hatched) in captivity for use in research are **not covered** by the Animal Welfare Act.
 - “Bred for use in research” means an animal that is bred in captivity and used for research, teaching, testing, or experimentation purposes.
- The following activities are also **not covered**:
 - Field studies that do not materially alter the birds, such as observational studies.
 - Studies for the purpose of supporting agriculture (intended to improve the quality of food or feathers).
 - Animal, pest, and population management studies for the purposes of limiting wildlife damage and human interaction.
 - Studies involving avian patients in clinical trials under a veterinarian-client-patient relationship.
 - Use of only dead biologic specimens—no live animals.



§ 2.37 - Federal research facilities

Each Federal research facility shall establish an IACUC which shall have the same composition, duties, and responsibilities required of nonfederal research facilities, **with the following exceptions:**

- a. The Committee shall report deficiencies to the head of the Federal agency conducting the research rather than to APHIS
- b. The head of the Federal agency conducting the research shall be responsible for all corrective action to be taken at the facility and for the granting of all exceptions to inspection protocol



§ 2.38 - Miscellaneous

- a. Each research facility shall furnish to any APHIS official any information concerning the business of the research facility which the APHIS official may request in connection with the enforcement



§ 2.38 - Miscellaneous *(continued)*

- b. Access and inspection of records and property
 - 1. APHIS officials are allowed:
 - i. To enter its place of business
 - ii. To examine records required to be kept by the Act and the regulations
 - iii. To make copies of the records
 - iv. To inspect the facilities, property, and animals
 - v. To take photos of conditions and areas of noncompliance**
 - 2. The use of a room, table or other facilities necessary for the proper examination of records and shall be extended to APHIS officials by the research facility



§ 2.38 – Miscellaneous *(continued)*

- c. APHIS will publish lists of registered research facilities on its website
- d. Each research facility shall allow police or officers of other law enforcement agencies to inspect animals and records for the purpose of seeking animals that are missing
 - 1. The police or other law officer shall furnish to the research facility a written description of the missing animal and the name and address of its owner
 - 2. The police or other law officer shall abide by security measures required by the research facility



§ 2.38(e) Confiscation and destruction of animals

1. Animal is not being used to carry out research **AND** is found to be suffering as a result of the failure of the research facility to comply with any provision of the regulations
 - The APHIS official shall notify the research facility of the condition of the animal(s) and request that the condition be corrected
 - If research facility refuses to comply **AND** circumstances indicate the animal's health is in danger, the APHIS official may confiscate the animal



§ 2.38(f) – Handling

Research has its own handling regulations

1. Handling of all animals shall be done as expeditiously and carefully as possible
2.
 - i. Physical abuse shall not be used
 - ii. Deprivation of food or water shall not be used
EXCEPT the **short-term withholding of food or water from animals, when specified in an IACUC approved activity**
Must include a description of monitoring procedures



§ 2.38(g) Identification of dogs and cats

1. All live dogs and cats must be identified by
 - i. Official tag or tattoo affixed to animal when acquired
 - ii. Tag, tattoo, or collar applied by the research facility
2. Tag or tattoo numbers need to match acquisition/disposition records
3. Unweaned offspring maintained as a litter with the dam do not require individual identification
4. Tag shall be durable and circular (1 ¼" diameter) or oblong (2" x ¾")



§ 2.38(g) Identification of dogs and cats

(continued)

5. Tag shall have the following information:
 - i. "USDA"
 - ii. Numbers identifying the State and dealer, exhibitor, or research facility
 - iii. Animal ID number
6. Tags shall be serially numbered and applied in a consecutive numerical order. No tag number may be used for more than one animal or re-used within a 5 years
- 7 -12. Responsibilities to obtain, track, replace, and retain official tags.



§ 2.38(h) Health certification

1. Health certificate is required prior to delivering any dog, cat, or nonhuman primate for transport in commerce
 - i. Inspected by a licensed veterinarian within **10 days** of transport
 - ii. Appears to be free “of any infectious disease or physical abnormality which would endanger the animal(s) or other animals or endanger public health”
2. The Secretary may provide exceptions when the research facility requires animals not eligible for certification
3. Form 7001 may be used



§ 2.38(i) Holding of animals

A research facility may arrange to have another person hold animals with prior approval of the Deputy Administrator: *Provided*, that:

1. The other person agrees, in writing, to comply with the regulations and to allow inspection of the premises by an APHIS official
2. The animals remain under the total control and responsibility of the research facility
3. The other person or premises is a recognized animal site under its research facility registration (completed Form 7009)
4. The other person or premises must have a contingency plan

§ 2.38(j) Holding period

Dogs and cats obtained from sources other than dealers, exhibitors, and exempt persons shall be held for **5 full days** after acquiring the animal before they may be used by the facility.

- not including the day of acquisition
- excluding time in transit





§ 2.38 (k) Compliance with standards and prohibitions

Research facilities shall comply with the regulations and shall not obtain dogs or cats through false pretenses or acquire, use, or transport stolen animals

- 1. Exceptions may only be made when they are specified and justified in the proposal to conduct the activity ("scientific justification") and are approved by the IACUC**



§ 2.38 (I) Contingency planning

Research has its own contingency planning regulations

1. Research facilities must develop, document, and follow an appropriate plan to protect and provide care for their animals during emergencies or disasters. The plan must:
 - i. Identify potential emergency events
 - ii. Outline specific tasks to be carried out
 - iii. Identify who will be responsible for fulfilling these tasks
 - iv. Address how response and recovery will be handled



§ 2.38 (I) Contingency planning *(continued)*

2. The plan must be reviewed by the research facility annually
 - Documentation of annual reviews also required
3. Personnel must have training on their roles and responsibilities as outlined in the plan within 30 days of their start date

Substantive changes must be communicated to employees within 30 days of making the change

Homework



1. Keep working on your checklist for research facility inspections

2. Start working on Inspection Guide Chapter 7 Assessment

You will also be able to work on this assessment after each session. We go over the answers on the last day of research training

3. Complete Day 2 Exercise *We will go over the answers in our next session*

4. Self study

- Read the handouts on the Focused Annual Inspection Process (FAQ May 2019 and Internal AC communication). These documents can be found on the Animal Care SharePoint site.
- Review Inspection Guide, Ch. 7