United States Department of Agriculture

Animal and Plant Health Inspection Service

Animal Care

Fort Collins Office

2150 Centre Avenue
Building B, 3W11
Fort Collins, CO 80526
Phone: 970-494-7478

RE: ANNUAL REPORT REMINDER
Fiscal Year: 2024

September 15, 2024

Dear Registrant:

Animal Welfare Act regulations require all research registrants to file an *Annual Report of Research Facility* (APHIS Form 7023 and 7023A) with Animal Care annually, documenting their activities and animal usage for that fiscal year (October 1 through September 30). These reports are **due by December 1** of each year. Even if you did not use or hold any animals during the fiscal year, you are still **required** to complete and submit an *Annual Report*. Likewise, registrants whose registrations were canceled or terminated during the fiscal year must complete and submit an *Annual Report*. Failure to do so constitutes a violation of the Animal Welfare Act regulations which may result in enforcement action.

Annual Reports are submitted using our online reporting system. More information on submitting Annual Reports online can be found via the following link: https://www.aphis.usda.gov/aphis/ourfocus/animalwelfare/SA_Obtain_Research_Facility_Annual_Report. The Annual Reports online system will be available starting October 4th.

Please fill out all applicable fields, including the signature of an authorized individual determined by the facility. Also, please make sure that you have properly verified each total in Column F.

After you complete the form(s), please make a copy for your records. Detailed instructions are provided in the enclosed as well as reporting tips.

Thank you for your prompt attention to this matter. We appreciate your efforts in adhering to the Animal Welfare Act regulations.

If you have any questions, please contact us at 970-494-7477 or by email at AC.AnnualReports@usda.gov.

Sincerely,

Sarah Helming

Sarah Helming
Deputy Administrator
USDA, APHIS, Animal Care

ENCLOSURES

Fiscal Year 2024 Annual Report Instructions

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.

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. § 2.3 l(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 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.***

United States Department of Agriculture

Marketing and Regulatory Programs

Animal and Plant Health Inspection Service

Legislative and Public Affairs

Freedom of Information

4700 River Road
Unit 50
Riverdale, MD
20737-1232

Re: Confidential Business Information within Column E Explanation and/or IACUC Exception Attachments submitted with your Annual Report

Dear Registrant:

As you know, each year APHIS posts submitted research facility Annual Reports to its website, including any Column E Explanation and/or IACUC Exception attachments. Prior to posting the attachments, APHIS reaches out to each submitting registrant to get their input on whether the information contains any confidential business information. This year to streamline our processes, we are asking facilities to submit their input regarding confidential business information proactively at the time they submit their Annual Report.

If your research facility is submitting Column E Explanation and/or IACUC Exception attachments, please indicate at the bottom of this letter whether or not you object to the disclosure of any of the information in your records. If you do wish to object to disclosure of any of the information in the attachments, please include a written statement fully explaining all grounds upon which disclosure is opposed. Specifically, you should:

1. Highlight or list the specific information you believe should be protected;
2. Describe the nature of the information (e.g., is it a trade secret, commercial information, or financial information, and why);
3. Explain how you keep the information private or closely held;
4. If APHIS told you that it would keep the information private, provide a copy or detailed description of the assurance of confidentiality from the agency; and
5. Describe the harm that you believe may result from the release of this information, if any.

Be aware that any statements you submit in response to this notice may themselves be subject to disclosure if we receive a FOIA request for them. Please include your facility name and registration number on your response and all accompanying documents and send them by email to:

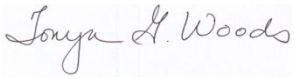
Animal and Plant Health Inspection Service
Legislative and Public Affairs—FOIA office
Attn: Andrea McNally
Email: FOIA.ACAnnualReports@usda.gov

We appreciate your support in this effort. Your assistance in providing this information proactively—regardless of whether your input indicates the presence of

confidential business information in the records—will greatly improve the efficiency of the process within the FOIA division. If we do not receive your input proactively, we will contact you in the Spring regarding these records.

If you have any questions, you may contact Andrea McNally at (202) 799-7026 or andrea.c.mcnally@usda.gov or the FOIA office at (301) 851-4102.

Sincerely,



Tonya G. Woods
Director
Freedom of Information & Privacy Act
Legislative and Public Affairs

No Objections Response

☐ We have no objections to the release of our annual report attachments and do not intend to seek judicial review to bar release of our facility's Annual Report of Research Facility Column E Explanation(s) and/or IACUC Exception(s).

Redactions for Confidential Business Information Requested

☐ We have objections to the release of our Annual Report attachments and ask that you consider the enclosed justification statement and requested redactions.

Signature	Date
Printed Name, Title	Certificate number