

TIPS ON ANNUAL REPORT ATTACHMENTS (COLUMN "E" EXPLANATIONS)

You may be required to provide explanations for certain entries in your Annual Report. You must attach these to your Annual Report. This sheet provides useful guidance on attachments related to Column "E" explanations.

ATTACHMENTS TO EXPLAIN COLUMN "E" ENTRIES

If you have listed any animals in Column E, you will be required to submit an attachment with an explanation of the procedure.

- Explain any procedures causing more than slight or momentary pain or distress.

The explanation should be brief, explained in plain terms, and focus on what the animal experienced (for example: seizures, neurologic signs, inappetence, lethargy, gastrointestinal distress, etc.). **DO NOT** include any protocols, IACUC or Meeting notes.

The reasons pain and distress could not be relieved should be science-based and described clearly in plain terms. You may wish to briefly describe procedures that limit pain or distress in Column E animals for context.

- 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.
- 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.
- Please provide all explanations in Freedom of Information Act (FOIA)-ready form or call FOIA at: (301) 851-4102. Please see the attached form and information included in this packet.
- When submitting online, you will be able to upload attachments in the system.

QUESTIONS ON SPECIFIC SITUATIONS?

- Useful guidance for Column E categories is available in chapter 7 of the Animal Welfare Inspection Guide in sections 7.5.3 (Annual Report) and 7.2.4.1 (Painful/Distressful Procedures).
- Help is also available via the Annual Report hotline at (970) 494-7477 or by email AnimalCare@usda.gov.
- The Animal Welfare Inspection Guide can be found on our website at https://www.aphis.usda.gov/animal_welfare/downloads/Animal-Care-Inspection-Guide.pdf

Tips for Attachments of Column E Explanations

1. The Annual Report is posted on the USDA website. Therefore, because protocols, proprietary information, personally identifiable information, and other confidential information is not required as a part of your Annual Report, you are highly encouraged to use form 7023B found within this packet to address the regulatory requirements of the Animal Welfare Act.
2. Explanations should be clear, brief descriptions of what the animals experienced, such as lethargy, inappetence, gastrointestinal disturbances, seizures, neurologic signs, etc.
3. Use of bullet point format is acceptable
4. It is recommended that a statement be included that the IACUC approved this Column E activity, although citing the protocol number is not recommended.
5. Please indicate if husbandry methods, humane end points, or other methods are used to minimize the pain or distress that animals experience.
6. Ensure that the same common name and/or species name is listed in your explanation and on form 7023.

TIPS TO AVOID REPORTING ERRORS

General Tips:

- **DO NOT** report the use of laboratory rats and mice (genera *Rattus* and *Mus*) bred for use in research, reptiles, or fish or other animals which are exempt from the regulation under the Animal Welfare Act (AWA).
- **DO NOT** include animal patients participating in clinical trials in the context of medical care under a veterinary client relationship.
- **DO NOT** include any birds in your Annual Report.

DO NOT REPORT NON-REGULATED ANIMALS

For teaching activities involving veterinary students or veterinary technology students:

- + **DO** 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 may be categorized in the highest applicable pain category. This method is less labor intensive but may result in over-reporting.
- **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.

- **DO NOT** include animals used in a field study as defined under the AWA regulations. A field study is defined as "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 makes the determination for the research facility of whether an activity meets this definition.
- **DO NOT** report animals that a facility holds outside the United States, or Territories or Commonwealths of the United States.

TIPS ON ANNUAL REPORT ATTACHMENTS (EXCEPTIONS)

You may be required to provide explanations along with your Annual Report. You must attach these to your Annual Report. This sheet provides useful guidance on attachments related to Exceptions.

EXCEPTION ATTACHMENTS

Review the information below on "What to Report" and "What Not to Report". If you have any Exceptions to report, follow the guidance in this checklist.

- 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, 2020 through September 30, 2021).
 - » Exceptions or exemptions to a particular AWA regulation or standard that are approved by the IACUC must be for scientific reasons and justified in writing.
 - » If a regulation or standard also provides specific parameters for an exception or exemption, those parameters must be followed.
- 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.
- Please provide all Exceptions in FOIA-ready form or call FOIA at: (301) 851-4102. *More information is included in this packet.*

QUESTIONS ON SPECIFIC SITUATIONS?

- > Useful guidance for Column E categories is available in chapter 7 of the Animal Welfare Inspection Guide in sections 7.5.3 (Annual Report) and 7.2.4.1 (Painful/Distressful Procedures).
- > Help is also available via the Annual Report hotline at (970) 494-7477 or by email at AnimalCare@usda.gov

Tips for Attachments of Column E Exceptions

- The exceptions should be a brief summary that is readily understood by a lay person.
- Use of 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.
- It is recommended that a statement be included that the IACUC approved this exception, although citing the protocol number is not recommended.



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))



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 of 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