



USDA LAUNCHES

ONLINE ANNUAL REPORTING FOR RESEARCH FACILITIES



APHIS Animal Care has a new online system for submitting Research Facility Annual Reports. Animal Care created this new system in response to requests from the research community to ease the reporting burden.

As a research facility representative, you have the opportunity to be one of the first users of this new online system. This year, if you choose to submit your organization's Annual Report using the new system and start the process by December 1, 2018, USDA will

consider your Annual Report as having been submitted on time, even if it is not fully completed by that date. If you encounter any technical issues, please report them by calling the Annual Report hotline (number on the back). We also welcome your feedback and suggestions for improvement.

If you choose to submit your report online, please follow the steps outlined below.



2018 INSTRUCTIONS FOR SUBMITTING ANNUAL REPORTS ONLINE



IF YOU ARE THE ANNUAL REPORT PREPARER

- Please make sure your business information—including the name of your current CEO/ Institutional Official (IO)—is correct. Call the Raleigh or Fort Collins Animal Care Office for help changing your business information.
- Complete the eAuthentication process outlined in the packet.
- On or after October 15, go to <https://www.aphis.usda.gov/aphis/ourfocus/animalwelfare> and click on the “USDA Launches Online Annual Reporting” banner at the top of the page. On the right hand side of the “Online Annual Reporting” page, find the “Related Links” section. Click the “Submit My Annual Report Online” link.
- Log in to the system with your eAuthentication credentials. As a one-time security measure, the online Annual Reporting system will require you to enter both your facility's Registration Number and a “Contact Number” (unique user ID number) which can be found in this packet. You will only need these numbers the first time you log in to the system.
- Click “Start Annual Report” and fill out your Annual Report online.
- Follow the instructions in the system to submit the Annual Report to your CEO/IO for e-signature. Once you have completed the Annual Report and submitted it for signature, contact your CEO/IO to let him or her know that it is ready for review.



IF YOU ARE THE CEO/IO WHO SIGNS THE ANNUAL REPORT

- Complete the eAuthentication process outlined in the packet.
- Your Report Preparer will contact you when the Annual Report is ready for your review. When contacted, go to <https://www.aphis.usda.gov/aphis/ourfocus/animalwelfare> and click on the “USDA Launches Online Annual Reporting” banner at the top of the page. On the right hand side of the “Online Annual Reporting” page, find the “Related Links” section. Click the “Submit My Annual Report Online” link. Log in to the system with your eAuthentication credentials.
- As a one-time security measure, the online Annual Reporting system will require you to enter both your facility's Registration Number and a “Contact Number” (unique user ID number) which can be found in this packet. You will only need these numbers the first time you log in to the system.
- Follow the instructions in the system to review the Annual Report and either return it to the Report Preparer for revision or use the e-signature option in the system to sign and submit your report. You may also revise the Annual Report yourself prior to signing it.

TIPS FOR COMPLETING ANNUAL REPORTS IN THE NEW SYSTEM

- » We recommend using the latest version of **Google Chrome** or **Internet Explorer** to access the online Annual Reporting system.
- » Please make sure that BOTH the Annual Report Preparer and the CEO/IO who will sign the report each know their **“Contact Number”** (user ID number) and have a copy of this document for their reference.
- » When entering numbers for each species selected, you must enter a value in each column even if that value is zero. You will not be able to navigate away from the page if any cells are blank.
- » Note that the online system does not ask you to distinguish between **“Other Farm Animals”** and **“Other Animals”**. Instead, you will enter the common names of any additional regulated animals in the category **“Other Animals”**. You will **not** see a row for **“Other Farm Animals”** on the PDF version of your online form.
- » Please remember to **save your work frequently, especially before you log out**. Clicking **“Back”** and **“Next”** on most screens will save your updates, but always click **“Save”** before logging out to prevent loss of information. Any information saved before you log out will be available the next time you log in.
- » **You will be automatically logged out after 30 minutes of inactivity**. You will receive a warning message before this happens; be sure to save your work and heed the warning message to avoid losing your data.
- » All entries will be in **“Draft”** status until the CEO/IO clicks the **“Sign and Submit Annual Report”** button and electronically signs the report. **If any changes need to be made after signing and submitting an Annual Report, we require that a paper copy of the corrected report be sent to either the Raleigh or Fort Collins Animal Care Office.**
- » If you are both the Annual Report Preparer and the Authorized Signer (CEO/IO) for your facility, the system will allow you to both prepare and sign your Annual Report online. When you log in to the system for the first time, be sure to use the **“Contact Number”** associated with your title as either CEO or IO. Once you have successfully logged-in, click the blue button on your homepage to prepare, sign, and submit an Annual Report.
- » Each attachment may not be larger than 25 megabytes, and we accept the following formats: **.doc, .docx, .pdf, .xls, .xlsx, .ppt, .pptx, .zip, .jpeg, .png, .gif**. You may upload multiple attachments if needed. If you upload a .zip file, ensure that all files within the .zip are saved as one or more of the acceptable formats above.
- » We recommend printing or saving both an electronic copy of the submitted report (you will have an option to generate a PDF version of the report) and all attachments you submit.



QUESTIONS? WE'RE HERE TO HELP!

- Questions about the eAuthentication process? Call **1-866-794-2827**.
- For questions about Annual Report content and categorizing research animals, please refer to the instructions, tips and examples included in this packet, or call the Annual Report hotline at **1-970-494-7477**.
- If you need to update your contact information and/or authorized signer (CEO/IO) information, call or send a request in writing to either:

Raleigh, NC Office USDA/APHIS/AC 920 Main Campus Dr., Ste. 200 Raleigh, NC 27606-5210 Phone: (919) 855-7100 Email: aceast@aphis.usda.gov	Fort Collins, CO Office USDA/APHIS/AC 2150 Centre Ave., Bldg. B, Mailstop 3W11 Fort Collins, CO 80526-8117 Phone: (970) 494-7478 Email: acwest@aphis.usda.gov
---	--
- For application support or other IT help, please call our APHIS Helpdesk at **877-944-8457**.
- If you would like to share feedback on the new system and/or suggestions for improvement, please email us at one of the above email addresses.



2018 GUIDANCE FOR COMPLETING ANNUAL REPORT OF RESEARCH FACILITY

This document provides guidance as you complete a Research Facility Annual Report, whether you are submitting the Annual Report by mail using APHIS Form 7023 or through our new online system. When completing your Annual Report, remember to only include information for this reporting year: October 1, 2017 to September 30, 2018.

ANNUAL REPORT INSTRUCTIONS

- ITEM 1**—Enter the registration number.
- ITEM 2**—Enter the complete name, mailing address, and telephone number of the Headquarters Research Facility, as registered with the USDA.

If the name or business information has changed, please notify the appropriate Animal Care Office in Raleigh, NC, or Fort Collins, CO, as soon as possible. Correcting this information cannot be done in the online system.

- ITEM 3**—List the location of all facilities where animals were housed or used in actual research, testing, teaching, or experimentation, or were held for these purposes (attach additional sheets if necessary). **Do not include specific buildings, laboratory names, or room numbers.**
- ITEM 4-13**—Enter the required information for each regulated animal in Columns A-F. These comprise Dogs, Cats, Guinea Pigs, Hamsters, Rabbits, Non-Human Primates, Sheep, Pigs, and Other Animals (and Other Farm Animals if using the APHIS Form 7023).

DO use common names rather than scientific names for all species. DO NOT enter numbers in Column A. If submitting by mail, include additional sheets if necessary or use APHIS Form 7023A. If submitting online, add additional rows as needed.

- COLUMN B**—Include all animals the facility physically possesses on September 30, which were:
 - » bred, conditioned, or held for research, testing, teaching, or experiments, but not used in a project, including those that died without being used for a project during this reporting year;
 - » used for research, testing, teaching, or experiments in prior years but were not used this reporting year; and
 - » used for breeding and their offspring, even if they were not used for research this reporting year, provided that such breeding colony animals are not for commercial sales.

Animals held but not used during the reporting year, and that have been moved to another facility and are not present at the facility on September 30, should only be reported by the facility in possession of them.

- COLUMN C**—Enter the type and number of animals that underwent study-related procedures that involved no more than slight or momentary pain, distress, or use of pain-relieving drugs. Routine procedures (e.g., injections, tattooing, blood sampling) should be reported here.
- COLUMN D**—Enter the type and number of animals that underwent study-related procedures that involved more than momentary pain or distress that was alleviated with anesthetics, analgesics or tranquilizers.
- COLUMN E**—Enter the type and number of animals that experienced more than slight or momentary pain or distress that could not be relieved for study-related reasons. These require attached explanations. (See next page for more.)

Note that other methods may be used to relieve more than slight or momentary pain or distress. Examples include other types of pharmacologic agents, nursing care, or other palliative methods. However, the methods used must be substantively effective (able to reduce pain and distress to that which is slight or momentary) in order to change categorization from a Column E to a Column D.

- COLUMN F**—If you are filling out the paper version of the form and submitting your report by mail, DO NOT include Column B numbers into the totals for Column F. Column F should only include Columns C + D + E totals.

DOS AND DON'TS

- + **DO** submit only one Annual Report per registered facility. Consolidate animal numbers for all sites into one report for submission. Site-specific numbers may be maintained at each site.
- + **DO** have the Annual Report signed by the Institutional Official or CEO. If submitting by mail, return the completed form with an original signature to the appropriate Animal Care Office. If submitting online, the system will walk the signer through an e-signature process.
- **DO NOT** include personally identifiable information (such as names of principle investigators and research staff) or any proprietary information.
- **DO NOT** include grants, protocols or Institutional Animal Care and Use Committee (IACUC) meeting minutes, or excerpts of these documents.

TIPS FOR CATEGORIZING ANIMALS

- + Please refer to the column headings on the Form 7023 and 9 C.F.R. § 2.36 for information on each pain category. Useful guidance for Column E categories is also available in chapter 7 of the Animal Welfare Inspection Guide in sections 7.6.3 (Annual Report) and 7.2.4.3 (Painful/Distressful Procedures). Help is also available at 970-494-7477.
- + 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, both facilities are required to report the animals according to the pain category of the work done at the facility.
- + Animals used in more than one protocol should be counted **only once**, in the most painful/distressful category.
- **DO NOT** include animals involved in husbandry, veterinary care, or colony management procedures in any pain categories. Only include those undergoing study-related procedures.
- + Please note that euthanasia performed as per the definition of euthanasia under section 1.1 Animal Welfare Act regulations is not considered painful or distressful. **Euthanasia should not be categorized in terms of pain categories unless the method of destruction deviates from the criteria listed above for scientific reasons.**

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, whether you are submitting online or by mail. 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.).

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.
- If submitting by mail, include these explanations as separate sheets mailed in with your Form 7023. If 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 7.6.3 (Annual Report) and 7.2.4.3 (Painful/Distressful Procedures).
- » Help is also available via the Annual Report hotline at 970-494-7477.

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 BIRDS

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 for certain entries in your Annual Report. You must attach these to your Annual Report, whether you are submitting online or by mail. 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, 2017 through September 30, 2018).
 - » 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.

QUESTIONS ON SPECIFIC SITUATIONS?

- » Guidance for Exceptions may be found in 9 C.F.R. § 2.36 and in the Animal Welfare Inspection Guide Section 7.2.4.12 (Exceptions/Exemptions).
- » Help is also available via the Annual Report hotline at 970-494-7477.



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

Occasionally, during the course of a research project, unforeseen events involving animals occur, and questions arise as to how best to report these animals on the Annual Report. Unexpected pain or distress and animal incidents unrelated to ongoing research should be brought to the attention of the IACUC for purposes of adequate protocol and program review but do not need to be included in the Annual Report.

The following examples are not intended to address protocol review, veterinary care, or training and qualification requirements. Animal Care is providing the following examples as guidance for Annual Reporting purposes only.

For guidance on specific situations not addressed here, please call the Annual Report Hotline at 970-494-7477.

» **EXAMPLE 1**—An animal experiences pain due to the research procedures during the course of a study. The pain is recognized, and treated in a timely manner with appropriate analgesics that prove to be substantively effective.

ANSWER: Reported in Column D.

» **EXAMPLE 2**—An animal experiences pain due to a research procedure but when the pain is recognized, the investigator determines that analgesics, anesthetics or tranquilizers would adversely affect the study.

ANSWER: Reported in Column E.

» **EXAMPLE 3**—An animal is unexpectedly found dead in its enclosure during the course of a study. The animal had been monitored appropriately and there were no pre- or post-mortem signs of pain or distress. The animal had not experienced pain as part of the study prior to its death.

ANSWER: Reported in Column C.

» **EXAMPLE 4**—An animal experiences unexpected pain or distress due to the research procedures during the course of a study. The pain is recognized and the animal is euthanized in a timely manner.

ANSWER: Reported in Column D.

» **EXAMPLE 5**—An animal becomes caught in an enclosure and experiences pain and distress that is completely unrelated to the study. The injuries are treated and appropriate analgesia is provided.

ANSWER: This animal should be reported in the pain category appropriate to its experiences in the study. The event does not affect the reporting category because it is not related to the study. If the animal did not experience any pain or distress as part of the approved study it would be reported in Column C.

» **EXAMPLE 6**—An animal develops an ear infection and experiences more than slight or momentary pain or distress entirely unrelated to the study. Analgesics, anesthetics or tranquilizers would adversely affect the study, so the animal is treated with palliative husbandry methods. Husbandry methods assist in controlling, but do not substantively mitigate, the pain.

ANSWER: Because the research activity did not cause the pain/distress (i.e., caused by an unrelated ear infection), the animal should be reported in the pain category appropriate to its experiences in the study.



**HAVE A NEW
CEO OR IO?**



If you need to update your contact information and/or authorized signer (CEO/IO) information, call or send a request in writing to either:

Raleigh, NC Office
USDA/APHIS/AC
920 Main Campus Drive Suite 200
Raleigh, NC 27606-5210
Phone: (919) 855-7100
Email: aceast@aphis.usda.gov

Fort Collins, CO Office
USDA/APHIS/AC
2150 Centre Ave.
Building B, Mailstop 3W11
Fort Collins, CO 80526-8117
Phone: (970) 494-7478
Email: acwest@aphis.usda.gov