ANNUAL REPORT	Each registered research facility, including Federal research facilities, must submit an annual report to APHIS Animal Care. [2.36, Policy #17]
Criteria	The annual report: [Policy #17] • must be submitted on APHIS Form 7023 (Annual Report of Research Facility) and APHIS Form 7023A (Continuation Sheet for Annual Report of Research Facility) (see 14.1.6 and 14.1.8) • forms will be sent to the research facility by the appropriate AC Regional Office on or before September 15th of each year The annual report must:[2.36(a)] • cover the previous Federal fiscal year (October 1st through September 30th) • be signed by the CEO or Institutional Official • be submitted by December 1st of each calendar year • be submitted to the Animal Care Regional Director for the State where the research facility is registered See "The Top Ten Tips for Completing the USDA Annual Report" on page 14.1.11.
Content	***Assurance Statements*** The annual report must contain the following assurances (as found on Form 7023) from the research facility: • professionally acceptable standards governing the care, treatment and use of the animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, were followed prior to, during, and following actual research, teaching, testing, surgery, or experimentation [2.36(b)(1)] • each principal investigator has considered alternatives to painful procedures [2.36(b)(2)] • the research facility is adhering to the standards and regulations under the AWA [2.36(b)(3)]

- the research facility has required that exceptions to the standards and regulations: [2.36(b)(3)]
  - be specified and explained by the principal investigator
  - be approved by the IACUC

  NOTE: See *Reporting Exceptions* on page 14.1.4.

Reporting Facilities

The research facility must report all locations, i.e. Sites, where animals were: [2.36(b)(4)]

- housed
- held
- used in research, teaching, testing, or experimentation

NOTE: Specific addresses are not required; location (Site) descriptions, such as Biology Department, are acceptable.

Reporting Animals - Pain Categories

The annual report must state the **common names** and the numbers of animals upon which research, teaching, testing, or experimentation was conducted involving:

- no pain, distress or need to use pain-relieving drugs (Column C) Note: Animals undergoing routine procedures, such as injections, tattooing, and blood sampling should be reported in this Category. [2.36(b)(5)]

- pain or distress to the animals for which appropriate anesthetic, analgesic or tranquilizing drugs were administered (Column D) [2.36(b)(6)]

- pain or distress to the animals for which the use of anesthetic, analgesic or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the research, teaching, testing, surgery, or experimentation (Column E) [2.36(b)(7)]
  NOTE: An explanation of the procedures producing pain or distress and the reasons pain/distress relieving drugs were not used must be attached to the annual report. (See

Optional Column E Explanation Form - page 14.1.10)

The annual report must state the **common names** and numbers of animals not used for research but being: (Column B)

- bred
- conditioned
- held

Note: Column B colony animals used for a research protocol during a fiscal year are counted as research animals, not as colony animals, that fiscal year.

Unusual Circumstances

Occasionally, unexpected pain/distress or animal incidents occur which may result in questions on how best to report these animals on the annual report. The following examples are provided for guidance:

Example 1 - An animal experiences unexpected pain due to the research procedures during a study. The pain is recognized and appropriately treated. - Column D

Example 2 - An animal experiences unexpected pain due to the research procedures during a study. The pain is recognized but the principal investigator determines that the use of analgesics, anesthetics or tranquilizers would adversely affect the study. - Column E

Example 3 - 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. - Column D

Example 4 - An animal unexpectedly dies during 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. - Column C

Example 5 - An animal incident occurs where an animal experiences pain or distress which is completely unrelated to the study. The animal is treated with appropriate analgesia. - Animal should be reported in the column appropriate to the study.

Example 6 - An animal develops a medical condition and experiences 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. - Column E (because pain relief must be withheld due to the study)

Reporting Animals - Numbers

An animal is counted:

- only once per year, even if it was used in more than one protocol
- in the most painful/distressful Category, if used in more than one protocol
- every year if it is on a multi-year protocol

Non-regulated Animals

Animals exempt from regulation under the AWA should **not** be reported on the annual report. Examples of non-regulated animals are:

- birds
- reptiles
- amphibians
- laboratory mice of the genus *Mus*
- laboratory rats of the genus *Rattus*

NOTE: Wild rodents are regulated under the AWA and must be reported.

Reporting Exceptions

A summary of the IACUC-approved exceptions must be attached to the annual report and include: [2.36(b)(3)]

- the IACUC-approved exceptions
- a brief explanation of the exceptions
- the species and number of animals affected

Examples of reportable exceptions include, but are not limited to:

- use of an animal in more than one protocol involving a
- major operative procedure from which it is allowed to recover

	• deprivation of food or water, such as:
	  ▸ inadequate nutrition
	  ▸ feeding less than once a day
	  ▸ watering less than twice a day for an hour each time
	• maintaining animals at temperatures outside the ranges specified by the standards
	• not cleaning and/or sanitizing at required frequencies
	• not providing diurnal lighting as required
	• not meeting space requirements (including innovative enclosures)
	• exceptions from the exercise plan for dogs
	• exceptions from the psychological well-being plan for primates

Inspector Verification	You (the inspector) should verify that the Research Facility's Annual Report is accurate, that is:
	• all animal facilities are reported
	• the number of animals reported is correct
	• animals are reported in the correct Column
	• IACUC-approved exceptions are reported
	• there are justifications for all Column E animals
	
	Methods of verifying the animal numbers include, but are not limited to:
	• counting the animals, if appropriate or feasible
	• asking Research Facility representative to demonstrate how the number of animals was determined for:
	  ▸ a particular species, or
	  ▸ a Column from the Annual Report
	• review of:
	  ▸ acquisition records
	  ▸ protocol medical or animal-usage records
	  ▸ animal ordering information, such as invoices or computer animal tracking systems
	  ▸ animals ordered in comparison to number of animals approved for a particular protocol
	  ▸ facility animal census records
	  ▸ internal billing records to PIs for animal housing/care

This report is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO.

FORM APPROVED
OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

FACILITY LOCATIONS *(Sites)*

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets if necessary or use APHIS FORM 7023A.)*

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used	E. Number of 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. *(An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report).*	F. TOTAL NO OF ANIMALS (Cols. C + D + E)
4. Dogs					
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits					
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

1). Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2). Each principal investigator has considered alternatives to painful procedures.

3). This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4). The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED

APHIS FORM 7023 (AUG 91) (Replaces VS FORM 18-23 (OCT 88), which is obsolete.)

PART 1 - HEADQUARTERS

INSTRUCTIONS FOR COMPLETION OF APHIS FORM 7023

(Refer to 9 CFR Part 2, Subpart C, Sections 2.33 and 2.36)

ITEM 1 - Enter registration number as assigned to the Research Facility by United States Department of Agriculture (USDA).

ITEM 2 - Enter the complete name and address of the Headquarters Research Facility as registered with USDA.

ITEM 3 - List location of each Facility or Site where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. *(Attached additional sheets if necessary.)*

ITEM 4 - 13 - DO NOT enter numbers in Column A. DO NOT add numbers entered in Column B into the total in Column F. Column F is to show total of numbers entered in Columns C + D + E. Entries in Column E must be explained on attached sheet(s).

ITEM 12 - List by common name all other farm animal species.

ITEM 13 - Other: List, by common name, all other warm-blooded animal species covered by the Regulations. *(This will include all wild or exotic species.)* Attach additional sheets if necessary or use APHIS Form 7023A.

CERTIFICATION: Must be signed by the Chief Executive Officer (C.E.O.) of the Registered Research Facility or other Institutional Official (I.O.) having authority to legally commit on behalf of the Registered Research Facility. Sign, Print or type Name and Title, and Date.

RETURN COMPLETED FORM WITH AN ORIGINAL SIGNATURE OF C.E.O. OR I.O. TO APPROPRIATE SECTOR OFFICE.

This report is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2158.

See reverse side for additional information.

Interagency Report Control No. 0188-DOA-AM

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO.

FORM APPROVED
OMB NO. 0579-0036

CONTINUATION SHEET FOR ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets if necessary or use this form.)*

A. Animals Covered By The Animal Welfare Regulations 12. &/OR 13. Other *(List by species)*	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of 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. *(An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report).*	F. TOTAL NO. OF ANIMALS (Cols. C + D + E)

ASSURANCE STATEMENTS

1). Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2). Each principal investigator has considered alternatives to painful procedures.

3). This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4). The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)
I certify that the above is true, correct, and complete (7 U.S.C. Section 2143)

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED

APHIS FORM 7023A
(AUG 91)

PART 1 - HEADQUARTERS

INSTRUCTIONS FOR COMPLETION OF APHIS FORM 7023A

(Refer to 9 CFR Part 2, Subpart C, Sections 2.33 and 2.36)

ITEM 1 - Enter registration number as assigned to the Research Facility by United States Department of Agriculture (USDA).

ITEM 2 - Enter the complete name and address of the Headquarters Research Facility as registered with USDA.

ITEM 12/13 - Other: List, by common name, all other warm-blooded animal species covered by the Regulations. *(This will include farm species used in biomedical or non-agricultural research, and all wild or exotic species.)*

DO NOT enter numbers in Column A. DO NOT add numbers entered in Column B into the total in Column F. Column F is to show total of numbers entered in Columns C + D + E. Entries in Column E must be explained on attached sheet(s).

CERTIFICATION: Must be signed by the Chief Executive Officer (C.E.O.) of the Registered Research Facility or other Institutional Official (I.O.) having authority to legally commit on behalf of the Registered Research Facility. Sign, Print or type Name and Title, and Date.

RETURN COMPLETED FORM WITH AN ORIGINAL SIGNATURE OF C.E.O. OR I.O. TO APPROPRIATE SECTOR OFFICE.

Optional Column E Explanation Form

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

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1. **Registration Number:** _____

2. **Number**_____**of animals used in this study.**

3. **Species** (common name)_____**of animals used in this study.**

4. **Explain the procedure producing pain and/or distress.**

5. **Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results.** (For Federally mandated testing, see question 6 below)

6. **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**_____

The Top Ten Tips for Completing the USDA Annual Report

Robert A. Willems, DVM and
Joseph A. Nelson

From choosing the wrong pain categories, to sloppy arithmetic, there are a number of potential pitfalls when completing and filing a USDA annual report. The authors offer clarification and guidance to make the process easier.

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Every year each research facility registered with the United States Department of Agriculture (USDA) under the Animal Welfare Act (AWA) must submit an annual report to the USDA listing the number of animals used in studies by that institution during the previous year. Here are ten suggestions to help the research community properly fill out the report and avoid some of the more common mistakes. We hope that these tips will make it easier for researchers to fulfill their annual reporting requirements.

1. If you are using the paper form of the annual report, please use the Animal and Plant Health Inspection Service (APHIS) Form 7023 provided to you. Do not submit your own version of the form. Submit the original only. Copies are not necessary.

2. If you choose to use the electronic version of the annual report from the internet, you must request a new password each year from APHIS's Animal Care (AC) staff. Passwords from previous years will not work. Either AC Regional Office in Raleigh, NC (tel: 919-855-7100) or Ft. Collins, CO (tel: 970-494-7480) can assist you with instructions on how to submit your Annual Report via the internet.

3. It is not necessary to include animals on the report that are not regulated under the AWA, such as laboratory rats and mice, birds, fish, amphibians, reptiles, farm animals used in agricultural research, or free-living wild animals involved in research meeting the definition of a field study. If you wish to include these animals voluntarily, please do so at the end of the report, and label that section "Nonregulated Animals."

4. Consolidate the numbers to be reported from the various sites operated by your registered facility on a single submitted form. Do not send in a separate form for each site at which the facility used animals in the previous year. Instead, attach to the report a statement listing the location of all facilities or sites at which animals were used during the previous year.

5. Check your arithmetic. The totals listed in column F should equal the sum of those animals listed in columns C, D, and E. Do not include the numbers from column B in these totals.

6. Enter animals into the correct columns for their pain category. For example, you should enter in column D, not column E, animals for which pain relief was provided during the study. Enter in column C animals that experienced no pain or only slight or momentary pain, as from an injection.

7. All animals listed in column E require both a description of the procedure causing the pain and/or distress and an explanation of why relief from the pain and/or distress was not provided. A description of the procedure alone is not sufficient. Attach the description and explanation to the reporting form.

8. If your Institutional Animal Care and Use Committee (IACUC) has approved any exceptions to the AWA standards during the previous year, you must attach a summary of those exceptions to the annual report. For example, if the IACUC approved the temporary housing of an animal in a cage with smaller floor space than that required by the regulations for that animal so as to meet the scientific requirements of the study, then that is an exception to the standards and you must report it.

9. The annual report should be signed and dated by the Chief Executive Officer (CEO) or Institutional Official (IO) of the institution, as listed on the institution's USDA registration form. The submitted form must bear the original signature of the IO or CEO.

10. Be sure your annual report is submitted each year to the appropriate Animal Care Regional Office by the 1 December deadline.