

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE ANNUAL REPORT OF RESEARCH FACILITY (TYPE OR PRINT)	1. CERTIFICATE NUMBER: 87-R-0001 CUSTOMER NUMBER: 12	FORM APPROVED OMB NO. 0579-0036
University Of Utah b2, b7F Telephone: (801)-581-6840		

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

FACILITY LOCATIONS (Sites) - See Attached Listing

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 animal 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 an 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 wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reaso such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs	0	22	104	0	126
5. Cats	0	1	55	0	56
6. Guinea Pigs	0	174	60	675	909
7. Hamsters	0	0	0	5	5
8. Rabbits	0	359	323	0	682
9. Non-human Primates	0	0	5	0	5
10. Sheep	0	51	48	0	99
11. Pigs	0	1	93	0	94
12. Other Farm Animals					
Calves	0	0	13	0	13
13. Other Animals					
Wood Rats	0	0	22	0	22

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 an 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)

b6, b7c

DATE SIGNED
 1-29-08

Column E Explanation

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.

1. Registration Number: 87-R-0001

2. Number 675 of animals used in this study.

3. Species (common name) GUINEA PIGS of animals used in the study.

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

The procedure performed is a skin sensitization test. The animals utilized in the test experience slight pain that is occasionally more than momentary. It consists of slight skin irritation.

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 Item 6 below)

Please refer to the attachment.

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 ISO International CFR ISO 10993-10¹ & ISO 10993-12³
Standard

NOV 25 2008

Answer to Question 5:

Pain relievers in general, are anti-inflammatory and may interfere with optimization of the potential for detection of contact sensitization in this study design. Since inflammation is a component of the sensitization response being evaluated, introduction of agents that influence an inflammation response would most likely interfere with the evaluation of the potential of the test article to elicit a sensitization response.

I have performed a literature search using MEDLINE (October 24, 2007) with the key words "drugs", "medical devices", "pharmaceuticals", "guinea pigs", "drug effects", "pain", "distress", "animal testing alternatives", "anesthesia", "analgesia", "non-animal model", "anti-inflammatory response", and "cell cultures". The years covered by this search were 1965-present. Based upon this search, I was unable to find an analgesia method which does not effect the inflammatory reaction. In addition, I have spoken to several veterinarians and veterinary pathologists, as well as a researcher from the Anesthesiology Department in the School of Medicine of the University of Utah. None of these individuals are aware of any alternatives which would not, in some way, affect the inflammatory response that we induce in this study design.

NOV 25 2008

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1. Registration Number: 87-R-0001

2. Number 5 of animals used in this study.

3. Species (common name) Hamsters of animals used in the study.

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

The intravenous injection via the saphenous vein may cause a short transient discomfort for the animal. If any animal becomes moribund, the animal will be euthanized immediately.

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 Item 6 below)

Since these animals are being used to evaluate toxicity of a new drug entity; use of analgesia, anesthesia, or tranquilizing drugs is not allowed due to the potential for confounding effects.

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 Step 4 Version-09 November 2000

↳ International Conference on Harmonization (ICH) Tripartite
Guideline: "Maintenance of the ICH Guideline on Non-Clinical
Safety Studies for the conduct of Human Clinical Trials for
Pharmaceuticals" M3 (R1).

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FACILITY LOCATIONS (SITES)

1. Comparative Medicine
2. Biology Department

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