

SH

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0579-0036. The time required to complete this information collection is estimated to average 2 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

OMB APPROVED
0579-0036

This report is required by law (7 U.S.C. 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.

Interagency Report Control
No. 0180-DQA-AN

Fiscal Year: 2009

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

REGISTRATION NUMBER: 34-R-0001

Customer Number: 109

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

University Of Michigan
1301 Catherine Street

(b)(2)High, (b)(7)f

Telephone: (734) 753 8028

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

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) 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 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 on these animals and the reasons such drugs were not used must be attached to this report.)	F. TOTAL NUMBER OF ANIMALS (Cols. C + D + E)
4. Dogs			236		236
5. Cats			9		9
6. Guinea Pigs		312	566	38	916
7. Hamsters					
8. Rabbits		151	301		452
9. Non-human Primates			12	82	94
10. Sheep		148	253	47	448
11. Pigs			319		319
12. Other Farm Animals					
Cow			9		9
13. Other Animals					
Prairie Vole		902	27		929
Bat		61			61
Wild Mice		156			156

ASSURANCE STATEMENTS

- 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.
- Each principal investigator has considered alternatives to painful procedures.
- 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.
- The attending veterinarian for this research facility has appropriate authority to ensure the provisions 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 (C.E.O.) or Legally Responsible Institutional Official (L.O.))
I certify that the above is true, correct, and complete (7 U.S.C. Section 2143)

(b)(6), (b)(7)c

DATE SIGNED

11-24-09

EG 12-3-09

NOV 25 2009

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0579-0036. The time required to complete this information collection is estimated to average 2 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.		OMB APPROVED 0579-0036
This report is required by law (7 U.S.C. 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.		Fiscal Year: 2009
Interagency Report Control No. 0180-DOA-AN		

**UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE**

**CONTINUATION SHEET FOR ANNUAL
REPORT OF RESEARCH FACILITY**
(TYPE OR PRINT)

REGISTRATION NUMBER: 34-R-0001

Customer Number: 109

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

University Of Michigan
1301 Catherine Street

(b)(2) High, (b)(7) F
Ann Arbor, MI 48106

Telephone: (734) 763 8028

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary.)					
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 on these animals and the reasons such drugs were not used must be attached to this report.)	F. TOTAL NUMBER OF ANIMALS (Cols. C + D + E)
Chipmunk		41			41
Shrew		36			36
Vole		15			15
Squirrel		1			1
Weasel		1			1
Raccoon		3			3
Degu		229			229
Wild Non-human Primates		416			416

ASSURANCE STATEMENTS

- 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.
- Each principal investigator has considered alternatives to painful procedures.
- 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.
- The attending veterinarian for this research facility has appropriate authority to ensure the provisions 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 (C.E.O.) or Legally Responsible Institutional Official (L.O.))

(b)(6), (b)(7)c

DATE SIGNED

11-24-09

NOV 25 2009

Column E Explanation

1. Registration Number: **34-R-0001**
2. Number of animals used in this study: **11**
3. Species (common name) of animals used in this study: **Baboons**
4. Explanation of procedure producing pain and/or distress.

Under anesthesia, baboons undergo vascular surgery to place indwelling catheters in the saphenous veins and are not given analgesics post-operatively.

5. Scientific justification why pain or distress could not be relieved. Methods or means used to determine that pain or distress relief would interfere with test results.

Since inflammation is a component of clot development, the use of non-steroidal anti-inflammatory agents (ketoprofen, acetaminophen, etc) would confound research results. Also, the opioid class of compounds (buprenorphine, etc) may not interfere with prostaglandin production, however we avoid these compounds because:

- A) We are giving an experimental drug and cannot discredit the potential for drug-drug interactions which could affect our results making comparisons to previously studied animals impossible.**
- B) The goal after surgery is for rapid recovery and return to normal function. The addition of an opioid to the protocol would likely prolong recovery, decrease both appetite and gut motility, and increase the risk for respiratory depression.**
- C) The animal is under general anesthesia for all tissue manipulation and suturing. The animal remains under anesthesia an additional 6 hours after the surgical procedure prior to recovery.**

Column E Explanation

1. Registration Number: **34-R-0001**
2. Number of animals used in this study: **35**
3. Species (common name) of animals used in this study: **Macaque monkeys**
4. Explanation of procedure producing pain and/or distress.

Macaque monkeys are used in self-administration studies requiring catheterization. The animals are not provided pre-emptive analgesics and could experience some low level of unrelieved pain while recovering from the surgical placement of their catheter.

5. Scientific justification why pain or distress could not be relieved. Methods or means used to determine that pain or distress relief would interfere with test results.

Many analgesics may directly interfere with the drugs being studied and are therefore not used unless an animal exhibits signs of pain. If standard analgesic drugs were administered, the ability of the laboratory to interpret data from the test compounds would be impossible.

Column E Explanation

1. Registration Number: **34-R-0001**
2. Number of animals used in this study: **36**
3. Species (common name) of animals used in this study: **Macaque monkeys**
4. Explanation of procedure producing pain and/or distress.

Macaque monkeys are used in an antinociception assay. The main aim of this study is to test compounds (i.e., analgesics) and their ability to produce analgesia. The procedure involves exposure of the monkey's tail to water of temperatures ranging from 40-55°C for a period of not more than 20 seconds. A localized compound is administered to the tail. The measure of antinociception is the latency for animals to withdraw their tails from the warm water. Either the animal or the experimenter will remove the tail at/or before the 20-second mark.

5. Scientific justification why pain or distress could not be relieved. Methods or means used to determine that pain or distress relief would interfere with test results.

If standard analgesic drugs were administered, the ability of the laboratory to interpret data from the test compounds would be impossible.

Column E Explanation

1. Registration Number: **34-R-0001**
2. Number of animals used in this study: **33**
3. Species (common name) of animals used in this study: **Sheep**
4. Explanation of procedure producing pain and/or distress.

The sheep are in column E due to the prolonged restraint. They are housed in a stanchion for up to 30 days. The animals do not appear to display any signs of discomfort and pain.

5. Scientific justification why pain or distress could not be relieved. Methods or means used to determine that pain or distress relief would interfere with test results.

The animal will be connected to an artificial lung and numerous lines for monitoring, infusion of intravenous fluids and medications, and oxygen sweep gas flow. Experience has shown that the animals can entangle their legs within these lines and tubes or gain access and chew or eat these lines. The harness will prevent the animal from turning 180 degrees within the enclosure but will allow the animal to stand and lie down freely. The animal will have continuous access to food and water.

Column E Explanation

1. Registration Number: **34-R-0001**
2. Number of animals used in this study: **14**
3. Species (common name) of animals used in this study: **Sheep**
4. Explanation of procedure producing pain and/or distress:

The sheep are in column E due to the prolonged restraint. They are housed in a stanchion for up to 30 days. The animals do not appear to display any signs of discomfort and pain.

5. Scientific justification why pain or distress could not be relieved. Methods or means used to determine that pain or distress relief would interfere with test results.

The animal will be connected to peritoneal catheters connected to the perfusion machine. Experience has shown that the animals can entangle their legs within these lines and tubes or gain access and chew or eat these lines. The harness will prevent the animal from turning 180 degrees within the enclosure but will allow the animal to stand and lie down freely. The animal will have continuous access to food and water. The sheep appear content over the course of the therapy session. The scientific justification of the need for the restraint is that the sheep would most likely pull at the catheters that have been placed for therapy delivery and could potentially cause them to come out. This could cause much more pain and discomfort to the sheep due to potential infection at the insertion site.

Column E Explanation

1. Registration Number: **34-R-0001**
2. Number of animals used in this study: **18**
3. Species (common name) of animals used in this study: **Guinea Pigs**
4. Explanation of procedure producing pain and/or distress.

Animals are placed in a harness, which allows the animal free access to a water bottle, but prevents it from twisting or shearing off the connector attached to its implant. This is conducted for 2-4 hours a day, 5 days a week.

5. Scientific justification why pain or distress could not be relieved. Methods or means used to determine that pain or distress relief would interfere with test results.

When measuring psychophysical responses to presented stimuli, it is essential for the animal to remain focused and facing forward in the test cage under the speaker and near the food reward tray. Animals are only restrained for as long as they are willing to perform the positive - reinforcement psychophysical task; once they have eaten their fill of reward pellets they are removed from the restraint device. These measurements could not be made under chemical restraint as a physical response is required from the animal to signal perception.

Column E Explanation

1. Registration Number: **34-R-0001**
2. Number of animals used in this study: **8**
3. Species (common name) of animals used in this study: **Guinea Pigs**
4. Explanation of procedure producing pain and/or distress.

The procedure involved placing the animals in a cage that is placed in a sound booth, with adequate ventilation for 2 to 4 hours. A speaker on top of the booth then emits a sound or noise at a level high enough to cause hearing loss. Animals are given free access to food and water throughout the exposure.

5. Scientific justification why pain or distress could not be relieved. Methods or means used to determine that pain or distress relief would interfere with test results.

We study the effect of noise over-exposure on the auditory epithelium and on the hearing of mammals the animals. We perform these studies in order to design ways to prevent deafness due to overstimulation and to develop ways to regenerate tissue and hearing in ears were damage was done due to noise exposure. We use a noise exposure which needs to result in hair cell loss and to mimic conditions that affect people. The noise exposure we use is similar to conditions people experience. These conditions are prevalent in military situations and in several professions such as construction, road work, and even playing in the symphony, let alone night clubs or disco dance floors. Animals do not seem to be bothered by the exposure. We cannot use sleep medication because animals sleep on their side such that one ear is covered, depriving us from the ability to have a model with symmetrical lesions.

Column E Explanation

1. Registration Number: **34-R-0001**
2. Number of animals used in this study: **12**
3. Species (common name) of animals used in this study: **Guinea Pigs**
4. Explanation of procedure producing pain and/or distress.

Animals must be restrained for vestibular testing for up to 3 hours. The animals are placed in a custom box that prevents them from easily climbing out and the head is restrained in a head holder.

5. Scientific justification why pain or distress could not be relieved. Methods or means used to determine that pain or distress relief would interfere with test results.

Investigator measures the vestibulo-ocular reflex (VOR). Our data are based on delivering precisely controlled accelerations to the vestibular receptors located in the inner ear. Both the temporal and spatial pattern of the motion stimulus is important; thus, head position must be restrained.

**Annual Report of Research Facility
University of Michigan**

List of Exceptions to the Regulations

1. Registration Number: 34-R-0001
Customer Number: 109

2. University of Michigan
1301 Catherine Street
Ann Arbor, MI 48109-5614
(734) 763-8028

Species Name	Exception to Regulation	Rationale
Cat	Housed individually	Animals are adult intact males and are socially incompatible.
Cat	Animals kept on a 24 hour light cycle.	Animals are used in sleep studies. The 24 hour light cycle encourages the animals to sleep in the darkened laboratory when needed.
Degu	Housed in same room with rats	Facility limitations. Testing chambers are all located in one room. Each animal is contained in a separate testing chamber.
Degu	Animals kept on a 24 hour light cycle	Study involves psychological effects of constant light.
Degu	Animals kept on a 24 hour dark cycle	Study involves psychological effects of constant dark.
Guinea Pig	Housed in same room with rats	Facility space limitations.
Rabbit	Housed in same room with mice and rats	Animals have radio telemetry implants and the system to record the data is located in one room.
Sheep/Calves/ Pigs	Housed in same room	Facility space limitations, moved to individual rooms when possible.
Sheep	Housed in 36" x 24" pen for up to 28 days	Animals must be prevented from turning around and damaging catheters/tubing