

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 below for additional information.

Interagency Report Control No 0180-DOA-AN

<p>UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE</p> <p style="text-align: center;">ANNUAL REPORT OF RESEARCH FACILITY (TYPE OR PRINT)</p>	<p>1. Registration No: 57-F-0004 Customer No: 947</p>	<p>FORM APPROVED OMB NO. 0579-0036</p>
<p>2. Headquarters Research Facility (Name and Address, as registered with USDA, include Zip Code):</p> <p style="text-align: center;">Centers for Disease Control and Prevention 1600 Clifton Road, NE Mailstop D-14 Atlanta, GA 30333</p>		

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 (A)

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 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	0	398	8	0	406
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	117	238	0	355
7. Hamsters	0	310	189	10	509
8. Rabbits	1	55	117	0	172
9. Non-Human Primates	0	350	231	2	583
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals	See APHIS Form 7023A				
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 the 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)

<p>Signature of C.E.O. or Institutional Official</p> <p style="text-align: center;">(b)(6), (b)(7)c</p>	<p>Name & Title of C.E.O. or Institutional Official</p>	<p>Date Signed:</p> <p style="text-align: center;">11-25-08</p>
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<p>2. Headquarters Research Facility (Name and Address, as registered with USDA, include Zip Code): Centers for Disease Control and Prevention 1600 Clifton Road NE Mailstop D-14 Atlanta, GA 30333</p>		

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	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 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)
Cow	0	1	3	0	4
Goat	0	8	2	0	10
Dormouse	0	8	5	0	13
Deer Mouse	0	633	673	0	1306
Bat	0	694	17	19	730
Ferret	0	219	450	34	703
Gambian Rat	0	13	0	0	13
Gerbil	0	27	12	0	39
Pine Vole	0	216	0	0	216
Prairie Dog	0	15	54	0	69
Raccoon	0	0	30	0	30
Skunk	0	0	80	9	89
Egyptian Fruit Bat	0	1300	602	0	1902
Sundevall's Roundleaf Bat	0	0	203	0	203
Franquet's Epauletted Fruit Bat	0	0	1	0	1

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- 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.

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Signature of C.E.O. or Institutional Official	Name & Title of C.E.O. or Institutional Official	Date Signed: 11-25-08
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Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. Registration No: 57-F-0004
Customer No: 947

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

2. Headquarters Research Facility (Name and Address, as registered with USDA, include Zip Code):
Centers for Disease Control and Prevention
1600 Clifton Road NE
Mailstop D-14
Atlanta, GA 30333

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	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 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)
Horseshoe Bat	0	0	1	0	1
Chipmunk	0	0	132	0	132
Squirrel	0	0	21	0	21
House Rat	0	0	876	0	876
Forest Rat	0	0	4	0	4
Kangaroo Rat	0	0	18	0	18
Multimatte Rat	0	0	11	0	11
Wood Rat	0	0	31	0	31
Shrew	0	0	18	0	18
Grasshopper Mouse	78	0	0	0	0
Grass Mouse	0	0	65	0	65
Brush-haired Mouse	0	0	2	0	2
White-footed Mouse	0	0	123	0	123

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 the 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.

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(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

Date Signed:

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

11-25-08

Protocol: 1394RUPSKUL

Species (common name): Skunk

Number: 4

Explanation of procedure producing pain and/or distress:

The development of clinical rabies infection is expected to occur in a subset of the infected animals. There are occasionally animals that progress to a terminal state before we are able to humanely euthanize them. However, it is critical to understand infection dynamics in this important rabies reservoir.

Justification why pain and/or distress could not be relieved:

All animals infected with rabies virus will be euthanized at first onset of clinical signs of rabies. Beginning 7 days post infection animals will be examined at least daily by rabies staff and *ad hoc* by animal care staff during routine husbandry so that euthanasia can be promptly administered. However, occasionally animals progress rapidly from apparently healthy to a terminal state. This can occasionally occur overnight or between routine check periods. The majority of animals will be euthanized at first onset and we do not expect a significant number of animals to rapidly progress as described above.

Protocol: 1405RUPBATL

Species (common name): Bat

Number: 16

Explanation of procedure producing pain and/or distress:

The development of clinical rabies infection is expected to occur in a subset of the infected animals. There are occasionally animals that progress to a terminal state before we are able to humanely euthanize them. However, it is critical to understand infection dynamics in this important rabies reservoir.

Justification why pain and/or distress could not be relieved:

All animals infected with rabies virus will be euthanized at first onset of clinical signs of rabies. Beginning 7 days post infection animals will be examined at least daily by rabies staff and *ad hoc* by animal care staff during routine husbandry so that euthanasia can be promptly administered. However, occasionally animals progress rapidly from apparently healthy to a terminal state. This can occasionally occur overnight or between routine check periods. The majority of animals will be euthanized at first onset and we do not expect a significant number of animals to rapidly progress as described above.

Protocol: 1419SANMONC

Species (common name): Rhesus macaque

Number: 2

Explanation of procedure producing pain and/or distress:

Pain due to infection with Ebola virus is predicted to be seen in all unprotected control animals and is unavoidable. Animals will be evaluated daily by a veterinarian and those that develop infection-associated Ebola hemorrhagic fever syndrome or exhibit a confluence of other clinical signs indicative of advanced disease (severe lethargy, unresponsiveness and a 15-20% reduction in body weight), will be anesthetized, terminally bled and humanely euthanized while still under general anesthesia.

Justification why pain and/or distress could not be relieved:

Nonhuman primates are the only relevant model. These experiments seek to determine the numbers of animals surviving infection as a result of immunization and treatment with drugs may affect the outcome. Certain pain relieving drugs may exacerbate the disease as clotting factors and liver functions will be affected in diseased animals.

Protocol: 1436TUMFERC**Species (common name):** Ferret**Number:** 27**Explanation of procedure producing pain and/or distress:**

Ferrets represent the best model for studying transmission and pathogenesis of highly pathogenic influenza viruses. Infection of ferrets with recombinant H1N1 viruses may cause severe morbidity and even death in some cases. Our preliminary studies suggest that a majority of viruses to be evaluated in this study will actually be attenuated for ferrets as they are in mice tested under a separate mouse protocol. Therefore, we estimate that only 20% of animals at most may experience a moribund state requiring euthanasia.

Justification why pain and/or distress could not be relieved:

Use of anesthetics, analgesics, and/or tranquilizers would have an effect on the innate immune response and alter the scientific outcome.

Protocol: 1441KLIFERC**Species (common name):** Ferret**Number:** 6**Explanation of procedure producing pain and/or distress:**

In very rare cases, ferrets infected with highly pathogenic H5N1 influenza viruses can get very ill. As soon as they are identified, these animals will be euthanized since there is no treatment available to quickly treat animals against influenza H5N1 and to relieve the pain.

Justification why pain and/or distress could not be relieved:

Ferrets represent the best model for studying transmission and pathogenesis of highly pathogenic influenza viruses. Use of anesthetics, analgesics, and/or tranquilizers would have an effect on the innate immune response and alter the scientific outcome.

Protocol: 1593FRAHAMC**Species (common name):** Hamster**Number:** 10**Explanation of procedure producing pain and/or distress:**

The development of clinical rabies infection is expected to occur in a subset of the infected animals. Based on prior experience with hamsters under similar experimental protocols we might expect up to 10% of animals that develop signs of rabies that progress to a terminal state before euthanasia can be administered.

Justification why pain and/or distress could not be relieved:

All animals infected with rabies virus will be euthanized at first onset of clinical signs of rabies. Beginning 7 days post infection animals will be examined at least twice daily by rabies staff and *ad hoc* by animal care staff during routine husbandry so that euthanasia can be promptly administered. However, occasionally animals progress rapidly from apparently healthy to a terminal state. This can occasionally occur overnight or between routine check periods. The majority of animals will be euthanized at first onset and we do not expect a significant number of animals to rapidly progress as described above.

Protocol: 1601RUPSKUL**Species (common name):** Skunk**Number:** 5**Explanation of procedure producing pain and/or distress:**

The development of clinical rabies infection is expected to occur in a subset of the infected animals. There are occasionally animals that progress to a terminal state before we are able to humanely euthanize them. However, it is critical to understand infection dynamics in this important rabies reservoir.

Justification why pain and/or distress could not be relieved:

All animals infected with rabies virus will be euthanized at first onset of clinical signs of rabies. Beginning 7 days post infection animals will be examined at least daily by rabies staff and *ad hoc* by animal care staff during routine husbandry so that euthanasia can be promptly administered. However, occasionally animals progress rapidly from apparently healthy to a terminal state. This can occasionally occur overnight or between routine check periods. The majority of animals will be euthanized at first onset and we do not expect a significant number of animals to rapidly progress as described above.

Protocol: 1618MAIFERC

Species (common name): Ferret

Number: 1

Explanation of procedure producing pain and/or distress:

Ferrets are considered to be the best model for influenza transmission and virulence studies. In the course of our studies it is necessary to evaluate the virulence and transmissibility of several highly pathogenic avian influenza viruses. The intranasal infection of ferrets with such viruses may produce a severe influenza infection with associated morbidity and mortality.

Justification why pain and/or distress could not be relieved:

Since the viral load and inflammatory response to virus replication may both play a role in the ability of a virus to cause enhanced disease and transmit from one host to another, any agent that has the potential to affect viral load or the host response to infection could interfere with the results of the experiment. Therefore, the only means to alleviate pain or distress is humane euthanasia which is performed when the animals meet the criteria described in the protocol.

Protocol: 1643RUPBATL

Species (common name): Bat

Number: 3

Explanation of procedure producing pain and/or distress:

The development of clinical rabies infection is expected to occur in a subset of the infected animals. There are occasionally animals that progress to a terminal state before we are able to humanely euthanize them. However, it is critical to understand infection dynamics in this important rabies reservoir.

Justification why pain and/or distress could not be relieved:

All animals infected with rabies virus will be euthanized at first onset of clinical signs of rabies. Beginning 7 days post infection animals will be examined at least daily by rabies staff and *ad hoc* by animal care staff during routine husbandry so that euthanasia can be promptly administered. However, occasionally animals progress rapidly from apparently healthy to a terminal state. This can occasionally occur overnight or between routine check periods. The majority of animals will be euthanized at first onset and we do not expect a significant number of animals to rapidly progress as described above.

Attachment C: Exceptions to Regulations and Standards; USDA, APHIS, Form 7023 (FY08)
Centers for Disease Control and Prevention
Registration Number: 57-F-0004
Customer Number: 947

During the reporting period, the following exceptions to the recommendations in the *Guide for the Care and Use of Laboratory Animals* were approved by the CDC – Atlanta Institutional Animal Care and Use Committee (IACUC):

1. Regarding the housing of prairie dogs assigned to research protocols, the *Guide* has recommended cage sizes for specific species of animals. However, prairie dogs are not one of the animals listed. In the *Guide*, the recommended caging requirements for our prairie dogs would fall between guinea pigs greater than 350 grams, and rabbits that are less than 2 kg. For the guinea pigs, the recommended size is greater than 101 square inches floor space and 7 inches tall. For the rabbits, 1.5 square feet of floor space and 14 inches tall. Our cages are 9 inches tall and have 216 square inches of floor space, which does fall in-between these guides. However the *Guide* also states that “at a minimum, an animal must have enough space to turn around and to express normal postural adjustments, must have ready access to food and water, and must have enough clean-bedded or unobstructed area to move and rest in”. The cages we use for the prairie dogs provide all of that, with the exception of normal vertical postural adjustment. In the wild, the animals are observed to stand on their hind legs, which they are not able to do in these cages. The reason we use these cages for the prairie dogs, is because it is the largest cage manufactured that has a HEPA filtered top. This top is very important to prevent the spread of monkeypox virus between animals since this virus is believed to be spread via large respiratory droplets, fomites and/or excrement transmission. At the inception of the study design, in collaboration with staff from the CDC Animal Resources Branch, we chose these cages because our studies are typically considered short term, with animals usually remaining in these cages for 30 days or less.
2. Regarding housing multiple species (dormice, Gambian rats, and prairie dogs) in the same room, the Attending Veterinarian of the high-containment area provided written justification for such housing and the CDC-Atlanta IACUC approved the exception in 2006. Dormice, Gambian rats, and prairie dogs are gregarious species and they are frequently held in the same room during quarantine and distribution. Currently, we house the dormice and Gambian rats in microisolator cages. Rodent disease transmission can be decreased by microisolator caging or through the use of ventilated racks. Overall, housing multiple species of rodents in one room with proper barriers and disease prevention procedures does not cause a significant concern for interspecies disease transmission. The behavioral and physiologic stress due to interspecies conflict is minimized due to the decrease in visual contact and physical separation of the species. Currently, the housing of these species is necessary until additional ABSL-3 space is cleared to allow quarantined animals into the facility. Presently, we only have one room to house these animals and neither of these species has shown aggressive tendencies toward the other species.
3. Regarding two separate surgeries for *Saimiri*, *Aotus* and macaque monkeys, the CDC-Atlanta IACUC granted the exception for two separate surgeries in three different species of monkeys. The first surgery, a splenectomy, must occur for the animal to develop parasitemia. The second surgery is for a liver biopsy to study the liver stages. These surgeries occur in this order for the investigator to replicate the disease process.