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 21

See attached form for additional information.

Interagency Report Control No.:

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 51-R-0006
CUSTOMER NUMBER: 81

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

Johns Hopkins University, The
459 S Ross Building, 720 Rutland Ave
Baltimore, MD 21205

Telephone: (410) -502-0421

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 Atached 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 ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use o 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 reas such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs	0	0	219	0	219
5. Cats	0	29	75	0	104
6. Guinea Pigs	0	1024	589	24	1637
7. Hamsters	0	76	70	0	146
8. Rabbits	3	92	545	0	640
9. Non-human Primates	291	36	350	0	385 386
10. Sheep	0	9	0	0	9
11. Pigs	0	2	854	0	856
12. Other Farm Animals					
calves	0	4	0	0	4
13. Other Animals alpaca		2	0	0	2
chinchillas	0	0	42	0	42
degus	0	10	0	0	10
ground squirrels	0	20	0	0	20

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

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anestetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese 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 ap 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 inc 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

SIGNATURE (b)(6), (b)(7)c TE SIGNED 2/20/09

APHIS FORM (AUG 9

FEB 24 2009

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: 51-R-0006

2. Number 24 of animals used in this study.

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

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

   The procedure involves anesthesia, surgical preparation, and injection of labelled beads into the brainstem and injection of tracers at various locations in the intra- and extra-thoracic trachea. In a small subset of negative control animals, recovery from surgery without additional analgesics, under close observation, is necessary.

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)

   All of the available analgesics (opioids and NSAIDs) have a modulating effect on the cough reflex and would compromise the experiments. Animals showing signs of distress such as hunching, immobility, or weight loss will be euthanized by approved methods.

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 _____

3. Reporting Facility Attachment for Research Registration No.: 51-R-006 (FY 08 Annual Report)

Facility Locations for The Johns Hopkins University

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

IACUC-approved exceptions to AWA regulations:

A. Not cleaning or sanitizing at required frequencies.

1. A number of baboon cages may be machine sanitized at 3-5 week intervals rather than the required two-week interval. These are cages in which baboons have been fitted with chronically indwelling intravenous or intragastric catheters, which are protected by a tether and harness system. The back of the cage contains an instrument panel with levers and lights that the baboon uses to produce food pellets and /or drug delivery. To sanitize the cages, the animals must be chemically restrained (e.g., ketamine hydrochloride), and the system must be dismantled. The baboon must be chemically restrained until the cage wash is complete and the system reassembled (about 30 min). (This time is used to perform a physical examination of the baboon, shave and scrub the catheter exit site, clip nails, clean teeth, obtain a body weight, etc). For some studies, the administration of a drug like ketamine and the interruption of daily experimental assessment would introduce a potentially confounding variable if an arbitrary two-week (or shorter) interval were chosen. At the request of the investigator, the IACUC approved a maximum interval of up to 5 weeks between machine sanitization. All other routine husbandry procedures, including the cleaning of cage pans, are done on schedule. In addition some cleaning of the cage bars can accomplished as needed when the baboon is in the cage to maintain the environment as clean as possible.

B. Providing space outside of that specified by the standards.

1. We occasionally house two juvenile monkeys in cages that contain a total of 6 square feet of floor space. These cages are 60 inches high, however, so they contain a total of 30 cubic feet. The veterinary medical officer felt that with the installation of additional perches these cages could be approved by the IACUC for holding two juvenile animals. As necessary and when additional perches are installed animals will be pair housed in these cages.

2. As part of a vaccine study, monkeys will be pair housed in a 4 sq ft Horsfall isolator for up to 21 days to prevent exposure of personnel to infectious agents. Monkeys will be returned to normal after confirmation that they are no longer shedding the infectious agents.

3. As part of other radioactive tracer blood distribution kinetics studies, dogs will be housed in transport cages (ranging in size from 2'X3.5' to 3'X4') for radioactive material containment for 48 hours. Feed water, waste removal will be done by radioactive-trained personnel. During this

time, dogs will also be exempt from the exercise plan. This housing is required to assure personnel safety and prevent environmental contamination.

4. The Johns Hopkins University IACUC has approved an exception to the *Guide for the Care and Use of Laboratory Animals* (National Research Council, 1996) with regard to the floor area per animal for Group 7 monkeys as defined in Table 2.2 of the *Guide*. That is, baboons greater than 30 kg were approved for housing in cages with floor area of 10 square feet rather than the 15 square feet recommended for Group 7 monkeys in the *Guide*'s Table 2.2. This exception to the *Guide* was approved due to scientific requirements of the research in that the cage serves as the experimental chamber, and has specialized equipment and computer connections.

With respect to the Animal Welfare Act (AWA) Regulations, the baboons at Johns Hopkins are housed in cages with 10 square feet of floor space, which exceeds the minimum required space for baboons (i.e., Group 5 animals) set forth in Section 3.80(b) of 9 CFR Ch.1 (1-1-05 Edition). The Veterinary Medical Officer (VMO) who inspected The Johns Hopkins University in August 2007 and August 2008 has interpreted the regulation cited above as meaning that baboons larger than 25 kg must be housed in Group 6-sized caging of 25.1 sq. ft./84 in. high rather than Group 5-sized caging of 8 sq. ft./36 in. high. Thus he asked that, where scientifically justified, the IACUC vote an exception to the regulations for >25 kg baboons housed in 10 sq. ft. cages/55.5 in. high. The Johns Hopkins University respectfully differs from the VMO on this interpretation, and initiated an appeal process, which is continuing. Thus no exception to the AWA regulation on cage size for baboons has been brought before the Johns Hopkins University IACUC.

C. Exemption from the institution's environmental enrichment program and use of alternative programs during study.

1. The investigator requested and obtained an exemption from the IACUC from the requirement for social housing and/or environmental enrichment as described in the institution's Primate Environmental Enrichment Program. Prior to behavioral training, or viral infection we routinely house compatible animals together in pairs, triples or groups, depending on their age and sex. In addition, the standard cage enrichment and novel food enrichments are made available. However, if there is a behavioral component to the study, animals must be individually housed for training on to the tasks using computerized response boards (food pellet reward), or non-computerized manual dexterity devices (raisin puzzle feeder). During this time other enrichment devices may not be used. It is important to consider, however, that the animal's use of the computerized board or manual device certainly provides enrichment. The investigators will try to pair house animals during the weekends if it does not interfere with the training. During the infections animals may or may not be pair housed. Animals will be singly housed if necessary to complete the study goals.

2. As part of a study of control of appetite, satiety and gastric motility, non human primates will be singly housed, however, they will be provided toys, remain within visual and olfactory contact with other monkeys, and will interact with humans.

3. As part of a vaccine study, monkeys will not be given environmental enrichment during the infectious period to prevent exposure of personnel to infectious agents. Monkeys will be returned to normal after confirmation that they are no longer shedding the infectious agents.

D. Exemption from normal light cycles.

1. To test the hypothesis that drug treatment with MDMA (and consequent 5-HT neurotoxicity) leads to alterations in circadian temperature and activity rhythms. This would involve housing the animals in a room under condition of constant light or a phase shifted light:dark cycle (lights on :1 AM; lights off: 3 PM), for a period of 7 days before and at least 1-week after treatment with a known neurotoxic regimen of MDMA (thereby challenging the monkeys' internal circadian rhythm system.