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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-DOA-AN

Fiscal Year: 2009

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

REGISTRATION NUMBER: 51-R-0018

Customer Number: 89

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

University Of Maryland Baltimore
10 S. Pine St. (b)(2)High, (b)(7)f
Baltimore, MD 21201

Telephone: (410) 706 3540

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

(b)(2)High, (b)(7)f 10 South Pine St., Baltimore, MD 21201

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			12	7	19
5. Cats					
6. Guinea Pigs			2204		2204
7. Hamsters					
8. Rabbits		2	67		69
9. Non-human Primates	53		215	71	286
10. Sheep			58		58
11. Pigs			9		9
12. Other Farm Animals					
13. Other Animals					
Ferrets		1			1
Gerbils			45		45

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 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).

SIGNATURE OF CEO OR LO

NAME AND TITLE OF CEO OR LO (Type or Print)

DATE SIGNED

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

11/30/09

AF
AUG 2009

DEC 01 2009

NP
12-7-09

APHIS Form 7023 Site Addendum for FY: 2009

Registration Number: 51-R-0018
Customer ID Number: 89

Facility Business Address Information:

University Of Maryland Baltimore
10 S. Pine St. (b)(2)High, (b)(7)f
Baltimore, MD 21201

Telephone: (410) 706 3540

Facilities Site(s) Address Information:

Site Code(s):

001
10 S. Pine Street
Baltimore, MD 21201
Assigned Inspector: Joel Rubin, V M D

~~002~~
(b)(2)High, (b)(7)f
Assigned Inspector: Joel Rubin, V M D

OMIT - NO COVERED SPECIES HOUSED AT THIS SITE.

DEC 01 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-0018
2. Number 7 of animals used in this study.
3. Species (common name) Canines - Beagles of animals used in the study.
4. Explain the procedure producing pain and/or distress.

Animals undergo survival surgery (cardiac arrest and various methods of resuscitation). Animals are maintained under general anesthesia and provided morphine for pain control as part of a standard intensive care protocol. Between 20-23 hours post-resuscitation animals are weaned from controlled ventilation. At 23 hours, animals are awakened for neurologic deficit scoring (NDS). Following NDS, animals are re-anesthetized for euthanasia and harvest of tissues / organs.

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)

Animals are exposed to untreated pain for five minutes during neurologic deficit scoring. This is unavoidable in light of the need to assess an accurate measurement of the clinical, neurologic outcome in an attempt to develop a human clinical trial for therapy of brain injury following resuscitation from cardiac arrest.

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 _____

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-0018
2. Number 71 of animals used in this study.
3. Species (common name) Rhesus macaques of animals used in the study.
4. Explain the procedure producing pain and/or distress.

Radiation Injury (GI acute radiation syndrome; ARS): NHP receive total body irradiation at a dose of 80cGy/min over a range of doses from 900-1400cGy (LD30, LD50 & LD70).

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)

GI toxicity induced by radiation remains a significant concern for those exposed in radiation accidents, nuclear terrorist events and oncologic therapy treatments. There are no FDA-approved drugs or biologics for treating ARS. Following model development, this model will be used to test the treatment efficacy of drugs or biologics on the GI system. Although NHP receive supportive care / medical management including the administration of pain medication; in animals receiving higher radiation doses it has been noted that bleeding, secondary to GI ulceration, has been observed. Based on clinical findings and necropsy results, the IACUC determined that the potential for unrelieved pain/distress warranted a category E classification.

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 FDA CFR Title 21, Parts 314 & 601