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UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 21-R-0081  
CUSTOMER NUMBER: 333

FORM APPROVED  
OMB NO. 0579-0036

**ANNUAL REPORT OF RESEARCH FACILITY**  
(TYPE OR PRINT)

Montefiore Medical Center  
Research & Sponsored Programs  
111 East 210th Street  
Bronx, NY 10467

Telephone: (718) -920-4151

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 reas such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS ( COLUMN C + D + E )
4. Dogs	0	0	3	3	6
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	0	0	16	2	18
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	206	0	206
12. Other Farm Animals	0	0	0	0	0
13. Other Animals	0	0	0	0	0

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 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  
( Chief Executive Officer or Legally Responsible Institutional Official )

1	OFFICIAL	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL ( Type or Print )	DATE SIGNED
(b)(6), (b)(7)c		(b)(6), (b)(7)c	11/15/08

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## Attachment 2

### Column E Explanation Form

This form is intended as an aid to completing the Column E explanation. 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.

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Registration Number: 21-R-0081 333

1. Number of animals used under Column E in this study: 3
2. Species (common name) of animals used in this study: dog
3. Explain the procedure producing pain and/or distress, including the reason(s) for species selected: This ongoing study examines the degree to which [REDACTED] injected into the [REDACTED] differentiate and populate within the [REDACTED] as a possible future treatment for people with [REDACTED]. The dog is used because of its size and the characterization of canine [REDACTED]. The procedure of injecting the [REDACTED] is done under general anesthesia with post-operative analgesics, antibiotics, and anti-inflammatory agents. Animals generally recover quickly and show no signs of pain and distress. However, complications developed in 3 of the animals in which there were no pre-monitory signs of distress, but the animals were found dead and necropsy results revealed underlying pathology that could have caused distress prior to death. 1 animal had [REDACTED], 1 [REDACTED] and 1 [REDACTED].
4. 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: Pain and/or stress relief was not withheld as part of the study (see above)
5. What if any, Federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number: NA

1. Number of animals used under Column E in this study: 2
2. Species (common name) of animals used in this study: rabbit
3. Explain the procedure producing pain and/or distress, including the reason(s) for species selected: This study examines the [REDACTED] in preventing [REDACTED] related [REDACTED] that can occur as a sequela to [REDACTED] surgery. The rabbit is used since it is the species most likely to develop [REDACTED] similar to that seen in people during the procedure of [REDACTED] surgery. The procedure is done in rabbits under general anesthesia with post-operative analgesia. While the animals recovered without incident and showed no signs of pain and distress, 2 of the animals were found dead within a few hours post surgery due to [REDACTED] related [REDACTED] disease that could have caused distress prior to death.
4. 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: Pain and/or stress relief was not withheld as part of the study (see above)
5. What if any, Federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number: NA