

AL (878) 64-R-000)

MAR 24 2006

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 211.

See attached form for additional information.

Interagency Report Comm No.

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE ANNUAL REPORT OF RESEARCH FACILITY (TYPE OR PRINT) Amended Version	1. CERTIFICATE NUMBER: 64-R-001	FORM APPROVED OMB NO. 0575-0036
	Southern Research Institute 2000 Ninth Avenue South P.O. Box 55305 Birmingham, AL 35255 Telephone: (205)-581-2000	

3. REPORTING FACILITY (List all locations where animals were housed or used in 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 animals being bred, conditioned or held for use in teaching, testing experimental research, or surgery but not 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 in these animals and the reasons such drugs were not used must be attached to this report.)	F. TOTAL NUMBER OF ANIMALS (COLUMN C+D+E)
4. Dogs		68	4	232	304
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits		22	201	4	227
9. Non-human Primates		442	29	3	474
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					
Ferrets		31	211	20	262
Cotton Rats		30	100	200	330

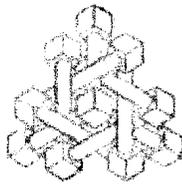
ASSURANCE STATEMENTS

- 1) Professionally accepted standards covering the care, restraint and use of animals, including appropriate use of anesthetic, analgesia, 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 reported to 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 brief explanations 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.

VERIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL (Chief Executive Officer or Legally Responsible Institutional Official)		
SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL	NAME AND TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type OR Print)	Date Signed
		23 Mar 06

[Handwritten signature]

MAR 24 2006



SOUTHERN RESEARCH

I N S T I T U T E

Affiliated with the University of Alabama at Birmingham

March 23, 2005

Reference: Registration # 64-R-0001

Attachment to Amended Annual Report of Research Facility (APHIS Form 7023)

Explanation for animals classified under Item E of Amended APHIS Form 7023:

Due to a clerical error in tabulating animals used on our research projects, the original numbers supplied on our November 23, 2005 APHIS 7023 form contained errors. A careful screening of the records revealed that tabulations were based on animals authorized for use in studies and not the actual numbers ordered and used. The following justifications contain correct and accurate placements in pain categories for all animals held or used in fiscal year 2005.

There were 200 Cotton rats and 20 ferrets noted in the "pain and distress without treatment" category because they were administered an infectious disease agent that caused pain or distress, interfered with normal functions, or caused acute progression to death. All of these animals were involved in infectious challenge studies and were used to establish the pathophysiology associated with adenoviral and coronaviral virulence. A reliable indicator of impending death or severe morbidity has now been established for these respiratory vectors and subsequent studies provide early endpoints and appropriate clinical intervention. While every effort is made to humanely euthanize animals that reach irreversible morbidity, the rapid progression of the disease combined with the non-specific nature of the developing clinical symptoms often precluded such interventions during the documentation of pathologic changes.

There were 232 dogs involved in five toxicity studies that would not allow clinical intervention until mild to moderate toxic clinical signs were elicited. These animals were not allowed to progress beyond moderate morbidity before they were removed from study through euthanasia. Clinical intervention to alleviate distress would have significantly impacted the pathology findings associated with the test articles.

MAR 24 2006

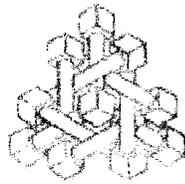
There were 4 rabbits that suffered moderate necrotic lesions at dependent sites from test article injection. Investigation required progression of the lesion to determine tolerable limits of test article administration. These animals suffered moderate pain and distress before being euthanized for harvest of the affected sites. Commonly used analgesics utilized in rabbits would have significantly interfered with the interpretation of tolerable levels of test article. The experimental animals were removed from study when progression of the lesions resulted in minimal restriction in movement or moderate clinical signs.

Three cynomolgus monkeys were used in a study to determine the virulence of a strain typed Monkeypox virus. The progression of the disease was extremely rapid and resulted in the death of the monkeys before clinical intervention was sufficiently implemented to ameliorate the effects of the virus.

The animals noted in this justification were observed for development of adverse clinical signs daily. They were under the care of a veterinarian during the entire testing period.

Submitted by:

MAR 24 2006



**SOUTHERN RESEARCH
INSTITUTE**

Affiliated with the University of Alabama at Birmingham

March 23, 2006

Locations where animals are used or held:

Site 1

**Southern Research Institute
2000 Ninth Avenue South
P.O. Box 55305
Birmingham, AL 35255**

**Skipper Building
Fruehoff Pharmacology Building
Cancer Cause and Prevention Building**

Site 2

**Southern Research Institute
431 Aviation Way
Frederick, MD 21701**

Leased space for Site 2

**Cambrex Corp.
8830 Biggs Ford Road
Walkersville, MD 21793**