

VER 02/2004

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UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. 55-F-0001 CUSTOMER NO. 962

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)

U.S. ENVIRONMENTAL PROTECTION AGENCY  
NATIONAL HEALTH & ENVIRONMENTAL  
RESEARCH LAB (MAIL DROP 51)  
RESEARCH TRIANGLE PA, NC 27711  
(919) 541-2281

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	

**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 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	None	None	None	None	0
5. Cats	"	"	"	"	0
6. Guinea Pigs	"	6	"	"	6
7. Hamsters	"	5	"	"	5
8. Rabbits	"	13	"	"	13
9. Non-Human Primates	None	None	"	"	0
10. Sheep	None	None	"	"	0
11. Pigs					
12. Other Farm Animals					
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)

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL

NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)

DATE SIGNED

*11-30-04*

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:** 55-F-0007  
**CUSTOMER NUMBER:** 955

FORM APPROVED  
OMB NO. 0579-0035

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

JOINT SPECIAL OPERATIONS MEDICAL TRAINING  
CENTER  
USAJFKSWCS  
BLDG 5-3845  
OCT 22 2004  
KEDENBURG STREET  
FORT BRAGG, NORTH CAROLINA 28310-5200  
Telephone- (910) 396-0089

OCT 22 2004

**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 )**

## **ASSURANCE STATEMENTS**

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  - 2) Each principal investigator has considered alternatives to painful procedures.
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**CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL**  
**( Chief Executive Officer or Legally Responsible Institutional Official )**

**NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)**

|DATE SIGNED  
ct2004

(is obsolete.)

NOV 26 2004

Interagency Report Control No.: *See*

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See attached form for additional information.

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 55-R-0001  
CUSTOMER NUMBER: 825

FORM APPROVED  
OMB NO. 0579-0036

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

Wake Forest University  
Medical Center Boulevard  
Winston Salem, NC 27109

Telephone: (336) -716-4548

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 )

Bowman Gray Campus (001)  
Friedberg Campus (003)

FACILITY LOCATIONS ( Sites ) - See Attached Listing

Reynolda Campus (004)  
Chestnut Campus (005)

**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  ( COLUMNS C + D + E )
4. Dogs	0	69	0	0	69
5. Cats	0	89	0	0	89
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	0	104	0	0	104
9. Non-human Primates	207	1,089	22	0	1,318
10. Sheep	77	186	0	0	263
11. Pigs	45	79	29	0	153
12. Other Farm Animals					
13. Other Animals					
Squirrels	48	0	0	0	48
Bats	36	0	0	0	36
Ferrets	129	5	0	0	134

**ASSURANCE STATEMENTS**

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- 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 an 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 explanation of the exceptions, as well as the species and number of animals affected.
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**CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL**  
( Chief Executive Officer or Legally Responsible Institutional Official )

NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL ( Type or Print )

DATE SIGNED

*1/22/04*

*L.C.W.*

*Attachment to APHIS FORM 7023***Summary of Exceptions to Regulations and Standards  
Wake Forest University 55-R-0001  
Fiscal Year 2003-2004**

1. The following is an exception to the requirements for sanitizing nonhuman primate primary enclosures at required frequencies:

Building 02 on the Friedberg Campus is used to house nonhuman primates imported directly from foreign sources (Indonesia). As required by the Centers for Disease Control (CDC), cages used in this building can not be sent through the mechanical cage washer until after the first thirty-one days (Phase I) of quarantine. Animal waste is removed from cage pans daily. After monkeys have completed Phase I quarantine, cages are sanitized at intervals in accordance with federal regulations and standards.

2. The following protocol involves an exception to the AWA regulation limiting animals to one protocol with a major survival operative procedure. The exception involves an iliac artery biopsy, performed via laparotomy, in 45 animals transferred from a previously approved protocol in which an ovariectomy had been done 4-5 years prior. The ovariectomized monkeys were uniquely suited to the current study, designed to investigate the cardiovascular health benefits of estrogen treatments in early vs late menopause, which is a question of importance to women's health. The purpose of the iliac artery biopsy was to establish the characteristics of atherosclerosis at baseline for subsequent evaluations. A written request was made to and approved by the Deputy Administrator, Animal Care, APHIS, USDA, on September 23, 2004.

*A04-105: Comparison of the Effects of Estradiol and Equol on Cardiovascular Risk Factors and Atherosclerosis of Surgically Postmenopausal Cynomolgus Monkeys*

Species Used: Female cynomolgus monkeys (*Macaca fascicularis*)  
Number Used: 45

3. All of the following protocols involve exceptions to the cage size requirements for sheep primary enclosures. Each exception was approved by the Wake Forest University (WFU) Animal Care and Use Committee (ACUC), after their determination of scientific justification. For each protocol listed, sheep (*Ovis aries*) are used in studies of pituitary-adrenal hormones, renin, and vasopressin, and are housed in metabolism carts for up to fourteen days. These studies are important to the understanding of factors relating to the health and survival of newborn infants. The Committee's justification for the exception is based on data that show movement of animals in and out of the carts on a daily basis would adversely influence the hormones measured in these experiments.

- a. *A01-079: Fetal Endocrine-Cardiovascular Relationships*  
Number Used: 50
- b. *A02-099: Vulnerability of the Fetal Brain to Hypoxia-Ischemia*  
Number Used: 12
- c. *A02-196: Prenatal and Neonatal Pituitary-Adrenal Function*  
Number Used: 42
- d. *A03-009: Local Control of the Fetal Renin-Angiotensin System*  
Number Used: 17

e. A03-148: Prenatal Glucocorticoid and Postnatal Blood Pressure

Number Used: 117

4. The following protocols involve exceptions to the requirements for watering nonhuman primates. For each protocol listed, full access to water is regulated in a manner to ensure animals are adequately motivated to perform traditional operant conditioning paradigms. Each exception was approved by the WFU ACUC, after their determination of scientific justification.

a. A03-075: Diencephalic Mechanisms of Visuomotor Integration

Access to water is regulated such that the first fluid intake of the day will occur during a training or experimental session. A well-trained animal will work to satiety during an experimental session and, in doing so, obtain its minimum daily water requirement. In the event that the animal does not obtain its minimum fluid intake during a session, fluid will be supplemented to the appropriate level when the animal is returned to its home cage. Typically, water regulation is begun on Sunday in preparation for behavioral testing on Monday. Animals participate in experiments on Monday through Friday and receive ad libitum access to water on Friday afternoon through Sunday morning. Throughout the duration of an individual animal's participation in experimental protocols, fluid intake, weight, and a variety of other physiological and behavioral measures are recorded to assure the animal's continued health and well-being. Animals are weighed daily (on the days they are tested). Health and hydration are assessed every day by both research and veterinary personnel. These studies are important to understanding the neural bases of sensory and motor control of the mechanisms of decision making in humans.

**Species Used:** Male rhesus monkeys (*Macaca mulatta*)

Number Used: 4

**b. A04-050: Cortical Implications for Rehabilitation**

Access to water is regulated such that the first fluid intake of the day will occur during a training or experimental session. A well-trained animal will work to satiety during an experimental session and, in doing so, obtain its minimum daily water requirement. In the event that the animal does not obtain its minimum fluid intake during a session, fluid will be supplemented to the appropriate level when the animal is returned to its home cage. Typically, water regulation is begun on Sunday in preparation for behavioral testing on Monday. Animals participate in experiments on Monday through Friday and receive ad libitum access to water on Friday afternoon through Sunday morning. Throughout the duration of an individual animal's participation in experimental protocols, fluid intake, weight, and a variety of other physiological and behavioral measures are recorded to assure the animal's continued health and well-being. Animals are weighed daily (on the days they are tested). Health and hydration are assessed every day by both research and veterinary personnel. Findings from this study will aid in improving rehabilitative therapy for individuals following a stroke.

**Species Used:** Male rhesus monkeys (*Macaca mulatta*)

Number Used: 4

### c. A02-135: Cross-Modal Integration in Primate Midbrain

Water regulation only occurs during periods of training and experimentation. Throughout the year animals are given ad lib access to water for variable, but often extended periods of time (months). Prior to initiation of training, each animal's *ad lib* intake of fluid is measured each day to determine its normal daily fluid consumption; generally this is between 200-250 ml. Then, during training and experiments, the animal is allowed to work to satiety during a session. If the animal will not work for that long, which can occur particularly early in the training, its fluid intake is supplemented with either pieces of fruit (apple, orange) or Gatorade. On the weekends, each animal is given access to water *ad lib* in its cage. A daily

during an experimental session and, in doing so, obtain its minimum daily water requirement (as determined by a formula based on age, size and weight of the animal). In the event that the animal does not obtain its minimum fluid intake during a session, or does not perform a session on a given day, fluid is supplemented to the appropriate level via a water bottle placed on the home cage. Typically, water regulation is begun on Sunday afternoon in preparation for behavioral testing on Monday. Animals participate in experiments on Monday through Friday and receive ad libitum access to water on Friday afternoon through Sunday afternoon. Throughout the duration of an individual animal's participation in experimental protocols, fluid intake, weight, and a variety of other physiological and behavioral measures are recorded to assure the animal's continued health and well-being. Animals are weighed on the days they are tested (or at least weekly). Health and hydration are assessed every day by both research and veterinary personnel.

One of the aims of this study is to identify those brain areas and types of cognitive behaviors most affected by brief (36-54 hour) sleep deprivation in an animal model. A monkey performs its behavioral/recording session normally during the day before sleep deprivation. That evening, before the lights go off in the housing area, the monkey is moved to a separate room in which the lights stay on all night and is kept awake by use of nonaversive stimuli (videos, music, food treats, toys, random computer sounds, interactions with technicians). Monkeys that fall asleep are reawakened within 5-10 minutes. The behavioral and electrophysiological testing of the monkey is then repeated the following afternoon. When possible, two monkeys are sleep deprived at a time, and are housed in single cages facing each other to maintain social contact throughout the night. Sleep deprivation studies are performed at minimum 10 day intervals, typically only once per 2-4 weeks per monkey. Information from these studies will aid understanding of human brain function and suggest means to combat sleep deficiencies.

**Species Used:** Male rhesus monkeys (*Macaca mulatta*)

**Number Used:** 21

6. The following protocol involves an exception to the lighting and space requirements for cats. The exceptions were approved by the WFU ACUC, after determination of scientific justification.

***A02-042: Experiential Influences on Cross-Modal Development***

This study examines the role of visual experience on the development of multisensory processes in the midbrain. From birth, kittens are raised to adulthood in total darkness. Total darkness is required to eliminate all visual experience during development in a reversible manner. Procedures such as enucleation or eyelid-suturing are inadequate because they are not reversible or allow a significant amount of light to penetrate the lids. A portion of the population is returned to full-spectrum lighting at six to twelve months of age. When in darkness, animals are cared for in accordance with all other standards and regulations. Infrared goggles are used by animal care, veterinary, and research personnel who enter the room daily to perform routine husbandry, health evaluations, and research manipulations. Criteria for monitoring the health and well-being of animals were developed, reviewed, and approved by the ACUC. All dark-reared animals have remained healthy and gain weight at rates similar to age-matched controls.

Animals in the room spend six hours per day together in an experimental pen which provides adequate space, but less than the minimum square footage per cat required by the USDA for standard housing. The size of the pen is a critical element in restricting the sensory experience of these animals, since it serves to constrain the minimum and maximum angular disparities of visual and auditory experience. Enlarging the size of the experimental pen would increase the maximal disparity beyond that which is believed to have an effect on reorganization in the nervous system. It is imperative that experimental animals are placed in the pen together to receive the same environmental manipulation. Any difference in the sensory experiences of the animals would constitute an unresolvable confound in the interpretation of the subsequently gathered data. It is important to note that animals are only in the run for six hours per

day, after which they are returned to pens that provide the minimum square footage per cat required by the USDA. Results from this work are important for the improved treatment of children with visual disorders such as blindness, amblyopia, and strabismus.

Species Used: Male and female domestic shorthair cats (*Felis domesticus*)

Number Used: 37

*Attachment to APHIS FORM 7023*  
**Explanation of Column E Procedures**  
**Wake Forest University 55-R-0001**  
**Fiscal Year 2003-2004**

The following protocols involve experiments reported in Column E. Experiments were approved by the Wake Forest University (WFU) Animal Care and Use Committee (ACUC), after their determination of scientific justification.

1. *A02-127: Neurophysiological Recording from Nonhuman Primate Brain*

Number of animals used in this study: 22

Species (common name) of animals used in the study: *Male rhesus monkeys (Macaca mulatta)*

Explain the procedure producing pain and/or distress:

*One of the aims of this study is to identify those brain areas most affected by sleep deprivation in an animal model. To that end, monkeys are kept awake for 36-54 hours by use of nonaversive stimuli (lights, videos, music, food treats, toys, random computer sounds, interactions with technicians). Behavioral, electrophysiological, and brain metabolic parameters measured after deprivation are compared to baseline parameters. Sleep deprivation studies are performed at minimum 10 day intervals, typically only once per 2-4 weeks per monkey. While the procedures used to produce sleep deprivation are not themselves considered painful, it is recognized that the lack of sleep may cause monkeys to experience unrelieved "distress" during the 36-54 hours when they are kept awake. The distress is minimized by using the nonaversive stimuli, constant interaction with technician staff with whom the monkeys are most familiar, maintenance of social interaction by working with two monkeys at a time (in single cases facing each other), and by allowing the monkey to sleep immediately following the testing.*

Provide scientific justification why pain and/or distress could not be relieved. State methods used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see next response.):

*Although humans can undergo brief periods with little to no sleep, the problems of extended sleep deprivation are vitally important. This is especially true for military pilots and personnel in combat in this Department of Defense funded study, but also for shift-workers, medical personnel, mothers with very young children, and long-distance truck drivers all of whom must continue to do their essential duties with prolonged periods of sleep loss or interruption. Despite such sleep deprivation, societal and job demands require these individuals to be attentive, remember accurately, and make appropriate decisions. Before an effective means of alleviating the effects of sleep deprivation on memory, attention, and decision-making can be developed, it is necessary to identify those cognitive functions and brain areas most affected by sleep deprivation. This ACUC approved study is necessary to characterize the effects of sleep deprivation in an animal model that is quite similar to that of a human performing a job that requires hand-eye coordination, short-term memory, and decisions based on information presented in the task. The experiment provides access to information (i.e. electrophysiological measures and testing of palliative drugs) that cannot be obtained in human studies. The procedures themselves are not painful, but the actual experience of being sleep-deprived may result in distress to the monkeys, which would be unrelieved during the 36-54 hours that they are kept awake. However, since the stress of sleep deprivation is precisely the effect being studied, it cannot be alleviated during the period of the experiment. Efforts are made to alleviate the distress as soon as the experimental measurements are completed, and sleep deprivation is not repeated for a minimum of 10 days.*

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:

*This experiment is funded by the Defense Advanced Research Projects Agency (DARPA) as part of "Preventing Sleep Deprivation" contract DAAD19-02-1-0060.*

2. A04-001: Prostanoids and Hypoxic Neonatal Pulmonary Hypertension

Number of animals used in this study: 29

Species (common name) of animals used in the study: Piglet

Explain the procedure producing pain and/or distress:

*This experiment examines the effects of low levels of oxygen (hypoxia) on tiny blood vessels from the lungs of newborn pigs. Piglets are placed in a veterinary incubator and a hypoxic atmosphere is provided by delivering 10% O<sub>2</sub> at atmospheric pressure to simulate the environment of newborns born and living at an altitude of 15,000 feet. Control piglets are housed in a similar chamber but with a room air environment. Rapid gas flow and the use of soda lime CO<sub>2</sub>absorbent is used to keep the CO<sub>2</sub>level at approximately 3-5 mm Hg. The temperature and humidity of the chamber is monitored carefully. Each chamber provides sufficient space to meet regulatory requirements. Piglets remain in the incubator under the control or hypoxic environment for 3 days. Both the control and hypoxic chamber are opened approximately 1 to 3 times a day for 30 minutes to one hour to clean the chamber and replenish food. Although animals are not expected to experience significant discomfort, piglets are monitored for difficult breathing and other signs of respiratory distress, and euthanized if such signs are observed.*

Provide scientific justification why pain and/or distress could not be relieved. State methods used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see next response.):

*Pulmonary hypertension is a well-recognized complication of human infants with a variety of cardiopulmonary disorders. Because the infants are not able to get enough oxygen, they develop structural abnormalities of the blood vessels in the lung which lead to extreme disability and sometimes death. The mechanisms involved in the initiation and maintenance of pulmonary hypertension are not well understood and currently there are few good options for treating these critically ill newborns. The goal of this project is to help understand why infants develop pulmonary hypertension and what goes on in the lungs during development of the disease. Although the procedures used in this experiment were not thought to cause significant pain or distress in animals, the ACUC felt that unavoidable discomfort might be experienced by piglets during the period of hypoxia required to induce pulmonary hypertension (3 days). Any potential discomfort was felt to be scientifically justified since maintaining the piglets in an hypoxic environment is the only known method for replicating the condition seen in human infant*

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: Not applicable

CFR: Not applicable

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

**1. CERTIFICATE NUMBER:** 55-R-0002  
**CUSTOMER NUMBER:** 861

FORM APPROVED  
OMB NO. 0579-0036

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

Research Triangle Institute  
3040 Cornwallis Rd.  
P.O. Box 12194  
Research Triangle Pa, NC 27709

Telephone: (919) -541-6182

DEC 01 2004

**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 )**

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**CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL**  
**( Chief Executive Officer or Legally Responsible Institutional Official )**

**SIGNATURE OF CEO OR INSTITUTIONAL OFFICIAL**

**NAME & TITLE OF CEO OR INSTITUTIONAL OFFICIAL** (Type or Print)

| DATE SIGNED

11/30/04

DEC 28 2004

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See reverse side for additional information

Interagency Report Control  
No. 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE		1. REGISTRATION NO. 55-R-0003	CUSTOMER NO. 863	FORM APPROVED OMB NO. 0579-0036
<b>ANNUAL REPORT OF RESEARCH FACILITY</b> (TYPE OR PRINT)		2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA, include Zip Code)  DUKE UNIVERSITY BOX 3180 DUMC DURHAM, NC 27710 (919) 681-6792		
3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attached 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)					
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4. Dogs	2	6	83		89
5. Cats		5	1		6
6. Guinea Pigs		31	280		311
7. Hamsters					
8. Rabbits		176	788		964
9. Non-Human Primates		59	3		62
10. Sheep		8	14		22
11. Pigs	10	8	681		689
12. Other Farm Animals					

Goats		3	2		5
13. Other Animals					
Ferrets		6	65		71
Monodelphis		66			66
Tree Shrew		141			141
Gerbil		1	25		26

ASSURANCE STATEMENTS

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- 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.

CERTIFICATE OF PRINCIPAL INVESTIGATOR at the above is true, correct, and complete (7 U.S.C. Section 2143)		
SIGN	NAME & TITLE OF P.I. OR INSTITUTIONAL OFFICIAL (Type or Print)	DATE SIGNED
APt	(solete)	12/1/04
PART 1 - HEADQUARTERS		

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

**1. CERTIFICATE NUMBER:** 55-R-0004  
**CUSTOMER NUMBER:** 826

FORM APPROVED  
OMB NO. 0579-0036

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

University Of North Carolina  
@ Chapel Hill  
Cb# 7115-B12 Berryhill Hall  
Div. Of Lab Animal Medicine  
Chapel Hill, NC 27599

**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 )**

## **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, 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 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 )**

**NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)**

DATE SIGNED

11-1904

), which is obsolete.)

3. Facility Locations:

- A) Mary Ellen Jones
- B) Thurston-Bowles Building
- C) Dental Research Center
- D) Beard Hall (Closed December 2003)
- E) Davie Hall
- F) Berryhill Hall
- G) Taylor Hall
- H) McGavran-Greenberg
- I) Francis Owen Blood Research Laboratory
- J) Animal Resources Center
- K) Neuroscience Research Center
- L) Molecular Biology Research Lab (Glaxo) (Closed May 2004)
- M) Kerr Building
- N) Medical Biomolecular Research Building

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 55-R-0005  
CUSTOMER NUMBER: 842

FORM APPROVED  
OMB NO. 0579-0036

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

North Carolina State University  
Box 8401  
Raleigh, NC 27695

Telephone: (919) -513-6280

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.	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 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 reason such drugs were not used must be attached to this report)	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs	10	49	54	1	134
5. Cats			127	10	137
6. Guinea Pigs		7	21		28
7. Hamsters			19		19
8. Rabbits		78	99		177
9. Non-human Primates					
10. Sheep		69	38		107
11. Pigs		633	486	180	1,249
12. Other Farm Animals <i>Pattie</i>		77	6		83
<i>Goats</i>		46	25		71
13. Other Animals					
<i>Hawks</i>	2	41	63		104
<i>Pine Vole</i>	222	287	31		318
<i>Grasshopper Mice</i>		64			64

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, 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 an 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 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)

SIGNATURE

NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)

DATE SIGNED

**UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE**

**1. REGISTRATION NO.**

**FORM APPROVED**  
**OMB NO. 0579-0036**

**CONTINUATION SHEET FOR ANNUAL REPORT  
OF RESEARCH FACILITY  
( TYPE OR PRINT)**

**2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA)**

**Include Zip Code**

North Carolina State University  
Box 8401  
Raleigh, NC 27695

**REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY** (Attach additional sheets if necessary or use this form.)

## **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 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 2142).

I certify that the above is true, correct, and complete (7 USC Section 2143)

**NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)**

SIGN

**DATE SIGNED**

11/9/14

FACILITY LOCATION FOR USDA REPORT 2004

Site A: College of Veterinary Medicine

Site A Address: Laboratory Animal Resources (LAR)

Site A City, State, Zip: Raleigh, NC

Site B: College of Veterinary Medicine

Site B Address: Veterinary Equine Research Center (VERC)

Site B City, State, Zip: Southern Pines, NC

Site C: College of Veterinary Medicine

Site C Address: Teaching Animal Unit (TAU)

Site C City, State, Zip: Raleigh, NC

Site D: College of Agriculture and Life Sciences

Site D Address: Biological Resources Facility (BRF)

Site D City, State, Zip: Raleigh, NC

Site E: College of Agriculture and Life Sciences

Site E Address: Lake Wheeler Field Laboratory - Swine

Site E City, State, Zip: Raleigh, NC

### **Column E Explanation Form**

This form is intended as an aid to completing the Column E explanation. Name, 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: **55-R-0005**

2. Number of animals listed by species (common name) used in this study.

**1 dog**

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

**Infection of splenectomized dog with Babesia canis.**

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 ( For Federally mandated testing, see question 5 below)

**Distress caused by reaction to parasites. Dog became inappetent for almost 24 hours; pain not observed.**

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 (e.g., APHIS, 9 CFR 113.102):

Agency \_\_\_\_\_ CFR \_\_\_\_\_

#### **Checklist:**

- Only the animal numbers used on this one protocol are provided
- Each animal is only counted once
- The numbers are entered in the columns, which correlate to the protocol
- The Category E explanation is completed

USDA Annual Report

Column E Explanation Form

This form is intended as an aid to completing the Column E explanation. Name, 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: **55-R-0005**

2. Number of animals listed by species (common name) used in this study. **Cats 10**

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

**Transient physical restraint for 1) collection of feces from the colon using soft plastic, lubricated loop, 2) collection of venous blood or 3) collection of urine by bladder centesis.**

**Cats were infected orally with T. foetus. This resulted in a transient diarrhea that has completely resolved. There are presently no clinical signs of T. foetus infection.**

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 ( For Federally mandated testing, see question 5 below)

**The only discomfort not relieved is that associated with the transient diarrhea. The reason for this is that there is presented no specific or symptomatic therapy capable of ameliorating diarrhea in cats infected with T. foetus.**

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 (e.g., APHIS, 9 CFR 113.102):

Agency \_\_\_\_\_ N/A \_\_\_\_\_ CFR \_\_\_\_\_ N/A \_\_\_\_\_

Checklist:

- Only the animal numbers used on this one protocol are provided
- Each animal is only counted once
- The numbers are entered in the columns, which correlate to the protocol
- The Category E explanation is completed

## **Column E Explanation Form**

This form is intended as an aid to completing the Column E explanation. Name, 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: **55-R-0005**
2. Number of animals listed by species (common name) used in this study.  
12 pigs
3. Explain the procedure producing pain and/or distress.

We orally administer *Salmonella* to pigs, then collect fecal samples over time to assess carriage and shedding. To study the effects of various mutations in *Salmonella* genes on animal carriage, we administer mutant bacteria in combination with their wild type equivalents to determine whether the mutants fail to survive in the pig intestinal tract. To study the effects of the intestinal environment itself on *Salmonella* survival, we alter the pigs' diet in ways that are likely to change the intestinal milieu, than test the survival of *Salmonella* in the intestinal tract.

Pigs are very resistant to salmonellosis. In most cases, we observe no clinical signs after infection with *Salmonella*. Some pigs do become pyrexic, can be lethargic, and can have diarrhea (occasionally with blood). These signs, when they do occur, are generally mild and resolve without treatment in 1-2 days.

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 (For Federally mandated testing, see question 5 below)

The goal of this work is expressly not to make animals sick, so that we can study the long-term asymptomatic carriage of *Salmonella*. When animals do show clinical signs of salmonellosis, there are no effective treatments that would ameliorate those signs without altering the course of the disease. Administration of antibiotics might reduce the signs, but clearly these would also affect the test results.

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 (e.g., APHIS, 9 CFR 113.102):

Agency \_\_\_\_\_ CFR \_\_\_\_\_

USDA Annual Report

**Column E Explanation Form**

This form is intended as an aid to completing the Column E explanation. Name, 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: **55-R-0005**
2. Number of animals listed by species (common name) used in this study. **10 pigs**
3. Explain the procedure producing pain and/or distress. **Animals were exposed to skin carcinogens (DMBA and MNNG) for 6 months on a weekly basis. Skin changes were observed and samples (skin punches) collected at 10 week intervals.**
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 ( For Federally mandated testing, see question 5 below) **It would not have been possible or beneficial to maintain the animals under analgesics for 6 months as the distress shown by the animals was minimal.**
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 (e.g., APHIS, 9 CFR 113.102):

Agency: **Aphis**

CFR: **9CFR, Part 2, Section 2.36**

Checklist:

- Only the animal numbers used on this one protocol are provided
- Each animal is only counted once
- The numbers are entered in the columns, which correlate to the protocol
- The Category E explanation is complete

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. CUSTOMER NO.  
55-R-0007 829

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)  
UNIVERSITY OF NORTH CAROLINA  
9201 UNIVERSITY CITY BLVD.  
CHARLOTTE, NC 28223

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)

UNC @ CHARLOTTE  
CHARLOTTE, NC 28223-0001

**REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY** (Attach additional sheets if necessary or use APHIS FORM 7023A )

A.	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 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)	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					
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits					
9. Non-Human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
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)

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)	DATE SIGNED
		11/24/2004

NOV 17 2004

See attached form for additional information.

Interagency Report Control No.: *OPA*

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 55-R-0010

FORM APPROVED  
OMB NO. 0579-0036

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

East Carolina University  
Department Of Comparative Med,  
School Of Medicine  
Greenville, NC 27858

Telephone: ~~(919) 346-2070~~ (252) 744-2420

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 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			36		36
5. Cats					
6. Guinea Pigs	23		35		58
7. Hamsters					
8. Rabbits			50		50
9. Non-human Primates			19		19
10. Sheep					
11. Pigs			147		147
12. Other Farm Animals					
13. Other Animals					
Ferret			10		10

**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  
( Executive Officer or Legally Responsible Institutional Official )

SIGNATU

NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL ( Type or Print )

DATE SIGNED

## FACILITY SITES LISTING

Licensee/Registrant Name: East Carolina University

License/Registration Number: 55-R-0010

Please list below all sites that house regulated animals under the above number. Be sure to include all requested information. If the line does not apply, please mark it N/A. If you have more than three (3) sites copy this form as many times as needed before filling in the sites.

Site No.: 1 Name/Department: School of Medicine

Address: Moye Boulevard, East Carolina University

Greenville, NC 27858

Building: Brody Medical Sciences

Floor/Room: Animal Housing on Ground and Seventh Floor; Research

Laboratories on Floors Three thru Eight

Contact Person: [REDACTED] Phone No.: [REDACTED]

Site No.: 2 Name/Department: School of Medicine

Address: Emergency Drive, East Carolina University

Greenville, NC 27858

Building: Life Sciences Building

Floor/Room: Animal Housing on First Floor; Research Laboratories

on Second Floor

Contact Person: [REDACTED] Phone No.: [REDACTED]

## FACILITY SITES LISTING

Licensee/Registrant Name: East Carolina University

License/Registration Number: 55-R-0010

Please list below all sites that house regulated animals under the above number. Be sure to include all requested information. If the line does not apply, please mark it N/A. If you have more than three (3) sites copy this form as many times as needed before filling in the sites.

Site No.: 3 Name/Department: Biology

Address: East Carolina University

Greenville, NC 27858

Building: Howell Science Complex

Floor/Room: First and Third Floors – Animal Housing Facility

Contact Person:

Phone No.:

Site No.: 4 Name/Department: Psychology

Address: East Carolina University

Greenville, NC 27858

Building: Ragsdale and Ragsdale Annex

Floor/Room: First Floor – Animal Housing Facility and Laboratories

Contact Person:

Phone No.:

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

**1. CERTIFICATE NUMBER:** 55-R-0012  
**CUSTOMER NUMBER:** 820

FORM APPROVED  
OMB NO. 0579-0036

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

**University Of North Carolina  
@ Wilmington  
601 South College Rd.  
Wilmington, NC 28403**

NOV 30 2004

Telephone: (910) -962-3810

**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 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					
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits					
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					
Prairie Vole	197	84	0	0	84

## **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, testing, surgery, or experimentation were followed by this research facility.
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**CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL**  
**( Chief Executive Officer or Legally Responsible Institutional Official )**

11A

**NAME & TITLE OF CEO OR INSTITUTIONAL OFFICIAL** (Type or Print)

| DATE SIGNED

11-2404

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 55-R-0012  
CUSTOMER NUMBER: 820

FORM APPROVED  
OMB NO. 0579-0036

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

University Of North Carolina  
@ Wilmington  
601 South College Rd.  
Wilmington, NC 28403

*DEC 02 2004*

Telephone: (910) -962-3810

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.	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 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 reason such drugs were not used must be attached to this report )	F. TOTAL NUMBER OF ANIMALS ( COLUMNS C + D + E )
4. Dogs					
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits					
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					
Prairie Vole	197	84	0	0	84

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 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 )

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL

NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)

DATE SIGNED

*Paul E. Hosier Probst*

*1 Dec 04*

NOV 24 2004

**UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE**

**1. CERTIFICATE NUMBER:** 55-R-0013  
**CUSTOMER NUMBER:** 821

FORM APPROVED  
OMB NO. 0579-0038

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

**Greer Laboratories Inc  
Albion Medical Holdings Inc  
639 Nuway Circle, N.E.  
P.O. Box 800  
Lenoir, NC 28645**

**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 )**

## **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, 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 an 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 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 )**

**NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)**

DATE SIGNED  
11-23-04

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE		1. CERTIFICATE NUMBER: 55-R-0017 CUSTOMER NUMBER: 822	FORM APPROVED OMB NO. 0579-0036
<b>ANNUAL REPORT OF RESEARCH FACILITY</b> ( TYPE OR PRINT )		Ciit Centers For Health Research 6 Davis Drive Research Triangle Pa, NC 27709  Telephone: (999)-999-9999 919-558-1200	

OCT 18 2004

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 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, 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 rea- such drugs were not used must be attached to this report )	F.  TOTAL NUMBER OF ANIMALS  ( COLUMNS C + D + E )
4. Dogs					
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits					
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					
				Only laboratory mice and rats which are exempt from regulation under the AWA were utilized during this reporting period.	

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.
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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.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL  
( Chief Executive Officer or Legally Responsible Institutional Official )

NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL ( Type or Print )	DATE SIGNED
	10/15/04

OCT 12 2004

See attached form for additional information.

Interagency Report Control No.: 98

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 55-R-0019  
CUSTOMER NUMBER: 862

FORM APPROVED  
OMB NO. 0579-0036

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

Central Carolina Community College  
1105 Kelly Drive  
Sanford, NC 27330

Telephone: (919) -775-5401

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.	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 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 appropriate anesthetic, analgesic, or tranquilizing drugs were used.	F. TOTAL NUMBER OF ANIMALS ( COLUMNS C + D + E )
4. Dogs	0	0	43	0	43
5. Cats	0	0	35	0	35
6. Guinea Pigs	0	5	0	0	5
7. Hamsters	0	0	0	0	0
8. Rabbits	0	0	12	0	12
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals	—	—	—	—	—
Cows	0	0	5	0	5
13. Other Animals	—	—	—	—	—
Horses	0	0	5	0	5

**ASSURANCE STATEMENTS**

- 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, testing, surgery, or experimentation were followed by this research facility.
- Each principal investigator has considered alternatives to painful procedures.
- 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 an 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.
- 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 )

which is obsolete.)

( AUG 91 )

DATE SIGNED  
10-5-04

OCT 12 2004



**LEE COUNTY CAMPUS**  
1105 Kelly Drive • Sanford, NC 27330  
919-775-5401 • (FAX) 919-775-1221  
SERVING CHATHAM, LEE & HARNETT COUNTIES

## Facility Locations (Sites)

1. Small animals: Central Carolina Community College Science Building (Vet. Lab)

1105 Kelly Drive  
Sanford, NC 27330

2. Large animals: Gaster's Farm  
2718 Country Way  
Sanford, NC 27330

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

**1. CERTIFICATE NUMBER:** 55-R-0021  
**CUSTOMER NUMBER:** 823

FORM APPROVED  
OMB NO. 0579-0036

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

**University Of North Carolina  
@ Greensboro  
Research Services Rm.100 Mciver Bldg  
Greensboro, NC 27402**

Telephone: (336) -334-5878

**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 )

EBERHART BUILDING - FIRST FLOOR  
STONE BUILDING - FIRST FLOOR

**FACILITY LOCATIONS ( Sites ) - See Attached Listing**

EBERHART BUILDING - SIXTH FLOOR

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY ( Attach additional sheets if necessary or use APHIS Form 7023A )

## **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, 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 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 )

**NAME & TITLE OF CEO OR INSTITUTIONAL OFFICIAL** / Title - President

| DATE SIGNED

10 / 27/04

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 55-R-0022

FORM APPROVED  
OMB NO. 0579-0036

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

North Carolina A&T State University  
Lab. Animal Resource Unit  
116 Webb Hall  
Greensboro, NC 27411

NOV 30 2004

Telephone: (336) -334-7720

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 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 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	2	1	5	0	6
5. Cats	0	1	0	0	1
6. Guinea Pigs	14	23	15	0	38
7. Hamsters	0	0	0	0	0
8. Rabbits	0	1	0	0	1
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	6	0	6
12. Other Farm Animals	-	-	-	-	-
13. Other Animals					
Gerbils	26	35	17	0	52

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.
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- 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 an 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 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 )

NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL ( Type or Print )

DATE SIGNED

11/29/04

(solete)

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!

NOV 24 2004

See attached form for additional information.

Interagency Report Control No.:

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

**1. CERTIFICATE NUMBER:** 55-R-0027  
**CUSTOMER NUMBER:** 827

FORM APPROVED  
OMB NO. 0579-0036

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

**Professional Lab & Research Services  
1251 Nc 32 North  
Corapeake, NC 27926**

Telephone: (252) -465-8686

**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 )**

## **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, testing, surgery, or experimentation were followed by this research facility.
  - 2) Each principal investigator has considered alternatives to painful procedures.
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**CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL**  
**( Chief Executive Officer or Legally Responsible Institutional Official )**

SI

AL

**NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)**

| DATE SIGNED

23 Nov 04

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 55-R-0104

FORM APPROVED  
OMB NO. 0579-0036

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

University Of North Carolina-Asheville  
Cpo #1440  
The University Of Nc At Asheville  
One University Heights  
Asheville, NC 28804

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 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 reason such drugs were not used must be attached to this report )	F.  TOTAL NUMBER OF ANIMALS ( COLUMNS C + D + E )
4. Dogs	0	0	0	0	0
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	0	0	0
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
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 research, teaching, testing, surgery, or experimentation were followed by this research facility.
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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.

**CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL**  
( Chief Executive Officer or Legally Responsible Institutional Official )

SIG:

APHI

( AUG 91 )

NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL ( Type or Print )

(T 88), which is obsolete.)

DATE SIGNED

9/30/04

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. 55-R-0107 CUSTOMER NO. 808

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)

CAROLINAS MEDICAL CENTER  
DIRECTOR COMPARATIVE MEDICINE  
P.O. BOX 32861  
CHARLOTTE, NC 28232-2861

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)

CAROLINAS MEDICAL CENTER  
CHARLOTTE, NC 28232

**REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY** (Attach additional sheets if necessary or use APHIS FORM 7023A)

A.	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 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)	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			21		21
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits			35		35
9. Non-Human Primates					
10. Sheep					
11. Pigs			88		88
12. Other Farm Animals					
13. Other Animals					
Sand Rats	54		75		75
Ferrets			4		4

**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.
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**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)

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL

NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)

DATE SIGNED

11/30/2004

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. CUSTOMER NO.  
55-R-0108 815

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)  
INTEGRATED LABORATORY SYSTEMS, INC.  
800-12 CAPITOL DR  
PO BOX 13501  
RESEARCH TRIANGLE PA, NC 27713

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)

INTEGRATED LABORATORY SYSTEMS  
DURHAM, NC 27713

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS FORM 7023A)

A.	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 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)	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					
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits					
9. Non-Human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

- 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.
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- 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.
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**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)

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)	DATE SIGNED
		11/09/2004

**APHIS Form 7023 Additional Reported Sites**

The following additional sites have been reported by the facility. The reported sites have not been verified by APHIS and have been provided by the facility solely for completeness of the APHIS Form 7023 Annual Reporting submission.

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Registration Number: 55-R-0108  
Customer Number: 815  
Facility: INTEGRATED LABORATORY SYSTEMS, INC.  
800-12 CAPITOLA DR  
PO BOX 13501  
RESEARCH TRIANGLE PA, NC 27713

---

Site B Keystone Technical Park  
Site B 601 Keystone Park Drive, Suite 100  
Site B Durham, NC 27713

NOV 16 2004

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 55-R-0109  
CUSTOMER NUMBER: 816

FORM APPROVED  
OMB NO. 0579-0036

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

Bayer Corporation, Pharmaceutical Div.  
P. O. Box 507  
Clayton, NC 27520

Telephone: (919) -553-5011

**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.)

## **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, 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 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 )**

**SIGNATURE OF C.F.O. OR INSTITUTIONAL OFFICIAL**

**NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)**

DATE SIGNED  
11/15/04

### **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: 55-R-0109
2. Number 2574 of animals used in this study.
3. Species (common name) Guinea pigs of animals used in the study.
4. Explain the procedure producing pain and/or distress.
  - a. Diphtheria potency - To determine the anti-diphtheria potency of intramuscular and intravenous products using neutralization methodology.
  - b. Tetanus potency - To quantitate the potency of Tetanus Immune Globulin (Human) by using neutralization methodology.
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)

This testing is mandated by Bayer Product License Testing Requirements. Administration of anesthetic, analgesic or tranquilizer drugs could interfere with the outcome of the testing.

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 21 CFR 640.100

**Customer ID and Site Address:**

**ID: 816**

**Telephone**

**8368 US 70 West  
Clayton, NC 27520  
County: Johnston**

**(919) 553-5011**

SEP 3 0 2004 Interagency Report Control No.: 07

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

**1. CERTIFICATE NUMBER:** 55-R-0111  
**CUSTOMER NUMBER:** 959

FORM APPROVED  
OMB NO. 0579-0036

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

Davidson College  
P.O. Box 7118  
Davidson, NC 28035

Telephone: (704) -894-2617

**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 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 tranquiliz- ing drugs would have adversely affected the procedures, res- ults or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals and the reason such drugs were not used must be attached to this report)	F.  TOTAL NUMBER OF ANIMALS ( COLUMNS C + D + E )
4. Dogs					
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits					
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					
Gerbils	64	271			

## **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, 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 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 )**

NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICER (Type or Print)

**DATE SIGNED**

9/27/2004

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 55-R-0114

FORM APPROVED  
OMB NO. 0579-0036

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

NOV 09 2004

Gaston College/Vet Tech Program  
222 Leisure Lane  
Dallas, NC 28034

Telephone: (999) -999-9999

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 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 tranquiliz- ing drugs would have adversely affected the procedures, res- ults or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals and the reason such drugs were not used must be attached to this report )	F.  TOTAL NUMBER OF ANIMALS ( COLUMNS C + D + E )
4. Dogs	--	50	104	0	154
5. Cats	--	30	54	0	84
6. Guinea Pigs	--	--	--	0	0
7. Hamsters	--	--	--	0	0
8. Rabbits	--	0	7	0	7
9. Non-human Primates	--	--	--	0	0
10. Sheep	--	--	--	0	0
11. Pigs	--	--	--	0	0
12. Other Farm Animals					
Cattle	--	5	0	0	5
13. Other Animals					
Horses	--	5	--	0	5

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 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 )

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL

NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL ( Type or Print )

DATE SIGNED

*10/30/04*

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE	1. CERTIFICATE NUMBER: 55-R-0115 CUSTOMER NUMBER: 1638	FORM APPROVED OMB NO. 0579-0036
<b>ANNUAL REPORT OF RESEARCH FACILITY</b> ( TYPE OR PRINT )		Molecular Toxicology, Inc. 157 Industrial Park Dr. Boone, NC 28607  Telephone: (828) -264-9099
<i>NOV 01 2004</i>		

**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 )

## **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, testing, surgery, or experimentation were followed by this research facility.
  - 2) Each principal investigator has considered alternatives to painful procedures.
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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.

**CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL**  
( Chief Executive Officer or Legally Responsible Institutional Official )

SIGNATURE OF CEO OR INSTITUTIONAL OFFICIAL

**NAME & TITLE OF CEO OR INSTITUTIONAL OFFICIAL** / Type or Print /

**DATE SIGNED**

10.00

~~(This is obsolete.)~~

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

**1. CERTIFICATE NUMBER:** 55-R-0117  
**CUSTOMER NUMBER:** 9721

FORM APPROVED  
OMB NO. 0579-0036

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

Icagen, Inc  
4222 Emperor Boulevard  
Suite 350  
Durham, NC 27703

NOV 2 2 2004

Telephone: (919) -941-5206

**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 )

Suite 460, same address as above. 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 )

## **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.
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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.

**CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL**  
( Chief Executive Officer or Legally Responsible Institutional Official )

SIGN.

**| NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL ( Type or Print )**

| DATE SIGNED

11/16/04

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

**1. CERTIFICATE NUMBER:** 55-R-0118  
**CUSTOMER NUMBER:** 13918

FORM APPROVED  
OMB NO. 0579-0036

# **ANNUAL REPORT OF RESEARCH FACILITY**

**( TYPE OR PRINT )**

**Biotechnics**  
310 Millstone Drive  
Hillsborough, NC 27278

Telephone: (919) -245-3114

**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 )**

## **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, testing, surgery, or experimentation were followed by this research facility.
  - 2) Each principal investigator has considered alternatives to painful procedures.
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**CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL**  
**( Chief Executive Officer or Legally Responsible Institutional Official )**

AL NAME \_\_\_\_\_ OF CEO OR INSTITUTIONAL OFFICIAL (Title if known) DATE SIGNED  
\_\_\_\_\_  
9/7/04

This report is required by law (7 USC 2143). Failure to report according to the regulations can

**See attached form for additional information**

**Interagency Report Control No.:**

<p><b>UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE</b></p> <p><b>ANNUAL REPORT OF RESEARCH FACILITY ( TYPE OR PRINT )</b></p>	<p><b>1. CERTIFICATE NUMBER:</b> 55-R-0119 <b>CUSTOMER NUMBER:</b> 16933</p>	<p><b>FORM APPROVED OMB NO. 0579-0036</b></p>
<p><b>Hybrizyme Corp. 2801 Blue Ridge Rd-Suite G70 Raleigh, NC 27607</b></p> <p><b>Telephone: (999) -999-9999</b></p>		

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

**Hybrizyme Corp.  
2801 Blue Ridge Rd-Suite G70  
Raleigh, NC 27607**

Telephone: (999) -999-9999

**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**

NA

**REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY / Attach additional sheets if necessary or use APHIS Form 7023A**

## **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 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)

1. Verify that the above is true, correct, and complete. (See Section 27.45)

	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)	DATE SIGNED
		1/23/04

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 2143.

See attached form for additional information. Interagency Report Control No. [REDACTED]

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 55-R-0120

FORM APPROVED  
OMB NO. 0579-0036

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

Dynogen Pharmaceuticals  
801 Capitola Drive Suite 12  
Durham, NC 27713

Telephone: (919) -572-1919

**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**

Same as above

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY ( Attach additional sheets if necessary or use APHIS Form 7023A )

## **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, 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 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 )**

SIGNATURE OF A D.G. OR INSTITUTIONAL OFFICIAL

**NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL** (Type or Print)

DATE SIGNED

9/5/6

## **Column E Explanation**

Date: 9/30/04

1. Registration Number: 55-R-0120
2. Number of animals used in this study: 14
3. Species (common name) of animal used in this study: cat
  
4. Explain the procedure producing pain and / or distress:  
Surgical spinal cord injury at the lumbo-sacral region leading to paralysis of the lower extremities and bladder dysfunction.
  
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.

Dynogen is a privately held, neuroscience-based pharmaceutical company focused on genitourinary (GU) and gastrointestinal (GI) disorders. One of our focuses is on developing therapeutic treatments for paraplegic and quadriplegic patients with spinal cord injury. Spinal cord injury above the lumbo-sacral level disrupts control of urination. Urination in these patients ends up being involuntary or incomplete. Because of this the bladder often becomes overfilled, which can lead to disability or death due to kidney damage. Moreover, quadriplegic or paraplegic patients with spinal cord injuries at higher levels also can exhibit a dangerous condition called autonomic dysreflexia, in which dramatic and even life threatening elevation of blood pressure can be triggered by bladder distension. Through our experiments, we expect to identify drug treatments which will prevent the rises in bladder pressure, thereby preventing involuntary urination and bladder triggered life threatening episodes of autonomic dysreflexia.

Cats are often used in this model because, cats, like humans, have a bipartite control of micturition wherein myelinated "A" delta fibers are predominately responsible for afferent signaling in the normal urination reflex. The rat uses a different pathway which is "C" fiber mediated and this has been shown to have responses of the bladder that are completely opposite of the cat and human (e.g., Kakizaki et al., Am J Physiol 280: 1407-13,2001). Due to the complex organization of the neurons within the nervous system and the distribution of various receptor types amongst those neurons, the experiments we conduct could not be replaced by computer modeling or in vitro techniques. The studies require the neurons to be interconnected exactly as they are in nature, which is only possible with an in vivo model such as we propose.

Great lengths have been taken to ensure these animals do not experience any pain and their distress level is minimal. Preoperative and postoperative analgesics are given to alleviate any pain they may experience at the site of the incision and the acute phase of the experiment which occurs 6-8 weeks post surgery, is performed under anesthesia. Long term dosing with analgesics is not indicated as the animals are not experiencing any pain and in fact would be detrimental as long term dosing has the potential for causing gastric upset and lethargy in the animal, which would impede recovery. Caging has been modified to include a padded floor and absorbant covering to ensure no bed sores develop and the animals remain clean and dry. One week post surgery these animals are let out for exercise and play time in a secured area just like the other cats in our facility. Although

they do not have control of their rear legs they do show the same exuberance to play with the enhancement toys offered, much like our other cats. Quality animal care is given to these cats, as to all our animals, seven days a week with Veterinary evaluation occurring once a week. Patient files are maintained in order to ensure the proper care is being documented and the health and the well being of the cats is monitored. In fact, once recovered from surgery these animals show so little signs of being distressed that colleagues in other institutions have this same model filed under USDA category "D".

6. What, if any, federal regulation requires 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):

Not applicable.

**NOV 17 2004** See attached form for additional information

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

**1. CERTIFICATE NUMBER:** 55-R-0121  
**CUSTOMER NUMBER:** 15523

FORM APPROVED  
OMB NO. 0579-0036

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

Ardent Pharmaceuticals, Inc  
631 United Drive  
Durham, NC 27713

Telephone: (919) -806-1806

**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 )**

## **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, testing, surgery, or experimentation were followed by this research facility.
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**CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL**  
**( Chief Executive Officer or Legally Responsible Institutional Official )**

SI

~~h is obsolete.)~~

| DATE SIGNED

W4504

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 55-R-0122  
CUSTOMER NUMBER: 22419

FORM APPROVED  
OMB NO. 0579-0036

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

Immunotherapeutics International Inc.  
730 Oakridge River Road  
Fuquay Varina, NC 27526

Telephone: (919) -539-3011

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 )

**AT ABOVE ADDRESS ONLY**

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 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 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					
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits					
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
Goats	34	16			16
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.
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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.

**CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL**  
( Chief Executive Officer or Legally Responsible Institutional Official )

SIGNATURE OF C E O OR INSTITUTIONAL OFFICIAL

NAME & TITLE OF C E O OR INSTITUTIONAL OFFICIAL ( Type or Print )

DATE SIGNED

*30 Sep 04*

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

**1. CERTIFICATE NUMBER:** 55-R-0123

FORM APPROVED  
OMB NO. 0579-0036

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

Synechor Llc  
Po Box 14865  
Research Triangle Pa, NC 27709

Telephone: (919) -541-9977

3908 Patriot Drive  
Suite 170  
Durham, NC  
27703

**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 )

## **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, 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 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 )

**SIGNATURE C**

NAME & TITLE OF CEO OR INSTITUTIONAL OFFICIAL (Title or Print)

**'DATE SIGNED**

10-12.0

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 55-R-0124  
CUSTOMER NUMBER: 15718

FORM APPROVED  
OMB NO. 0579-0036

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

Appalachian State University  
Appalachian State Univ  
Appalachian State University  
Boone, NC 28608

*NOV 26 2004*

Telephone: (704) -262-2130

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 ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted	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					
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits					
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					
<i>onychomys torridus</i>	0	77	0	0	77

**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 )

DATE SIGNED

*11-22-04*

DEC 28 2004

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 reverse side for additional information  
Interagency Report Control No. 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE		1. REGISTRATION NO. 55-R-0003	CUSTOMER NO. 863	FORM APPROVED OMB NO. 0579-0036
<b>ANNUAL REPORT OF RESEARCH FACILITY</b> (TYPE OR PRINT)		2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA, include Zip Code)  DUKE UNIVERSITY BOX 3180 DUMC DURHAM, NC 27710 (919) 681-6792		
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 animals being bred, conditioned, or held for use in teaching, testing, experiments, or research or surg. ✓ but not yet used for some purpose.	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 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 would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery or tests. (An explanation of procedures producing pain or stress 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	2	6	83		89
5. Cats		5	1		6
6. Guinea Pigs		31	280		311
7. Hamsters					
8. Rabbits		176	788		964
9. Non-Human Primates		59	3		62
10. Sheep		8	14		22
11. Pigs	10	8	681		689
12. Other Farm Animals					

Goats		3	2		5
13. Other Animals					
Ferrets		6	65		71
Monodelphis		66			66
Tree Shrew		141			141
Gerbil		1	25		26

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.

CERTIFICATE OF PRINCIPAL INVESTIGATOR

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143)

	NAME & TITLE OF PI OR INSTITUTIONAL OFFICIAL (Type or Print)	DATE SIGNED 12/1/04
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, which is obsolete)

PART 1 - HEADQUARTERS