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Summary of Studies (Animal) Listed in Column E

Title: (b)(4)

• 14 Squirrel Monkeys

Squirrel monkeys are used in drug discrimination studies for studies of (b)(4) (b)(4) In these studies, (b)(4) drugs with differing or unknown profiles of (b)(4) are evaluated. The objective is to identify and study those components of drug action that underlie potential for abuse. It should be noted that an alternative species, rats, is used for most of these studies and squirrel monkeys are involved to a lesser extent.

Squirrel monkeys are trained to discriminate between a reference drug, such as (b)(4) (b)(4) and a placebo in a trial (b)(4) Monkeys are loosely seated in a primate chair during these studies. During the training phase and as an aversive stimulus to respond during discrimination trials, a (b)(4) stimulus may be delivered to the monkey's tail after 5 seconds from the beginning of the trial. The monkeys can terminate the trial and prevent the (b)(4) by pushing on one of two levers (corresponding to the reference drug or the placebo). The monkeys quickly learn to avoid the stimulus by responding during the five seconds after the start of the trial. After the initial training session, the monkeys rarely, if ever, receive an (b)(4) stimulus. (b)(4) are never given indiscriminately or without providing the monkey the opportunity, through lever manipulation, to prevent the (b)(4)

Pain-relieving drugs are not used in these studies because any pain experienced will be transient (one second or less) and the animal can take action to avoid all pain (by pushing a lever within 5 seconds of a clear cue). Additionally, pain-relieving drugs, such as narcotics, will confound the pharmacological effects of the (b)(4) compounds studied.

Title: (b)(4)

• 3 Rhesus Monkeys

Disorders affecting (b)(4) such as (b)(4) are associated with disrupted sleep patterns and arousal. Rhesus monkeys are used in this study to investigate the cellular mechanism of these sleep disorders and how medications act and can be better used to manage them. Nonhuman primates given the (b)(4) are used as a model of

(b)(4) Induction of (b)(4) causes (b)(4)
(b)(4) This condition cannot be relieved

(b)(4) (b)(4)
(b)(4) Although the federal reporting requirements only considers the use of anesthetics, analgesics and tranquilizers to relieve pain or distress, it should be noted that (b)(4) a more specific and appropriate intervention, may be used (b)(4) (b)(4) in animals on this study.

Title: (b)(4)

• 4 Rhesus Monkeys

Human patients with a wide range of illnesses may exhibit a high rate of depression mediated by activation of the immune system and the release of (b)(4) The latter can exert effects upon the brain leading to altered behavior. For example, about 50% of humans given the (b)(4)

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(b)(4) therapeutically develop depression. In these studies, the administration of (b)(4) causes chronic immune activation and a (b)(4) similar to depression in humans. Monkeys given the (b)(4) are used to study how it disrupts brain neurochemistry and to develop treatment interventions. The (b)(4) may also be (b)(4)

(b)(4) Potentially animals may also experience heightened sensitivity to painful stimuli and other neurological abnormalities. (b)(4) immediately following surgery. (b)(4)

(b)(4)

(b)(4)

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Exceptions to Regulations and Standards

Physical Restraint and Exemptions from Social Enrichment for Nonhuman Primates: Social Isolation

There are a variety of human diseases (Parkinson's Disease, Huntington's Disease, progressive supranuclear palsy, narcolepsy, and periodic leg movements during sleep) that are associated with uncontrolled movements in sleep that compromise the health of monkeys (b)(4) Monkeys (b)(4) are kept in social isolation for periods of three days after drug administration while (b)(4) and its (b)(4) are excreted. On a scheduled basis afterwards, these animals are placed in a cage specially designed for (b)(4) and (b)(4) in a room separated from the other monkeys. Individual monkeys may be maintained in the observation and recording room for a maximum of 7 days and are then returned to their home cage in a colony with other monkeys of the same species for at least 7 days before repetition. Isolation from other monkeys is necessary in order to permit sleep undisturbed by commotion caused by other monkeys or human traffic in and out of the room. Monkeys under study are instrumented with (b)(4) which telemeter their (b)(4). This telemetric approach allows studying sleep behavior in monkeys that are unrestrained. In addition, physical restraint in a chair is done (b)(4) facilitate (b)(4)

- Title: (b)(4)
- Title: (b)(4)
- Title: (b)(4)

Physical Restraint

Monkeys in these studies are trained to do simple motor tasks such as reaching, depressing a lever, touching a target on a video screen, depressing a key to make a video target appear, or controlling a joystick to move a cursor to a target on a video screen (b)(4)

- Title: (b)(4)
- Title: (b)(4)

Physical Restraint and Exemptions from Social Enrichment for Nonhuman Primates: Single-housing In Sight and Sound of Conspecifics:

Included in this section are primates that were housed in any condition other than group or pair housing for any significant period of time. For example, study subjects discussed below include those that were housed continuously in protected-contact housing, and those housed in protected contact and/or group or pair housing for a significant portion, but not the entirety of the period covered in this report.

A. Some animals used under these conditions are in studies of normal control of movement or motion disorders induced by (b)(4). Monkeys given (b)(4) may be kept in social isolation for periods of three days after drug administration and while (b)(4) are excreted. Before and after (b)(4) administration, monkeys in these studies are trained to do

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simple motor tasks such as reaching, touching a target on a video screen, depressing a key to make a video target appear, and controlling a joystick to move a cursor to a target on a video screen. During these tasks, these monkeys are loosely restrained in a chair and typically spend (b)(4) in the laboratory. During these periods, monkeys with head appliances may also undergo short-term fixed head restraint to access the appliances for (b)(4). Additionally, the administration of the (b)(4) to induce (b)(4) causes physical impairments that put such animals at risk of plummeting in the social order and wounding and fight injury from a cage mate.

Consequently, animals given (b)(4) are generally housed singly, but in colony rooms within sight, sound and close physical proximity of other animals of the same species. Likewise, to prevent damage to expensive and sensitive surgically-implanted devices by a conspecific, monkeys may be housed singly, but otherwise within sight and sound of (b)(4).

- Title: (b)(4)
- Title: (b)(4)
- (b)(4)

B. In the study of (b)(4) (b)(4) studied following injections of (b)(4). The safety and efficacy of (b)(4) also will be evaluated. Single or protected contact housing is required after surgery for 6 to 16 weeks to evaluate behavioral (b)(4).

- (b)(4)
- (b)(4)

C. Experiments to test whether (b)(4)

(b)(4) (b)(4) involving various catheters; protected contact housing is required during this period to avoid removal of catheters by cagemates.

- Growth regulation of the neurobiology of puberty: 44 rhesus macaques

D. (b)(4)

(b)(4) (b)(4) of animals from the group for 48 hours for timed blood collections.

- (b)(4)

E. Infectious disease vaccine development studies may require single housing to prevent disease agent transmission. Some of the studies described here involve the development of a (b)(4) investigation of the role of host immune response in protecting against or contributing to the appearance of immune system damage following AIDS infection, evaluation of the function of the thymus during infection with SIV, evaluation of the development and pathogenicity of mutant viruses that develop over time in chronically infected animals, the effect of opiate dependency on the progression of AIDS, and the testing of the immunogenicity and efficacy of different AIDS vaccines and treatment regimens. Single housing is required after exposure to the virus to prevent transmission of virus from animal to animal. In addition, the animals need to be accessed frequently for blood draws. The experimental design requires that the efficacy of vaccines will be assessed after a single exposure and without the possible confound of exposure to mutant viruses. Infected animals

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in an experimental group will be housed together after approximately one month. In some experiments, animals are singly housed one month prior to inoculation to allow sufficient time for acclimatization to the new housing arrangement so that the stress of separation doesn't influence susceptibility to or course of infection.

A study testing the effects of (b)(4) requires frequent antibody infusions and blood draws during the first 3 weeks of the treatment (animals are assessed up to 4 times per week), followed by weekly blood draws for the remainder of the study, which lasts 2 months. Because these animals will be frequently handled for testing, animals are housed in protected contact housing.

(b)(4) are being done to develop a vaccine and to provide antigens for serologic and molecular studies, genomic libraries, antibody production, and gametocytes for infection of mosquitoes. Other related studies are looking at (b)(4)

(b)(4)

(b)(4) animals with malaria are housed individually in metabolism cages. This is usually required for a period of 1-2 months. It is also necessary to house the animals indoors to prevent contact with the local mosquito population. Following blood collections and treatment of the malaria infection, the animals are returned to their normal housing environment. Protected-contact housing is utilized in other malaria vaccine studies in monkeys due to the requirement of daily heel or ear sticks (as well as blood collection and immunization), as well as to avoid frequent reunions following stressful procedures. During the period to evaluate viral load and safety testing of gene therapy in a hepatitis C study, it is necessary to maintain the animals in metabolism cages. This is due to frequent blood collections and surgical interventions during the initial 4-6 weeks on study.

- Core A: Preclinical trials and pathology (Part of NCVDG Grant: DNA and protein immunogens for SIV/HIV vaccines): 77 rhesus macaques
- Core A: Nonhuman primates (Program Project Grant): 37 rhesus macaques
- New live viral vectors in candidate AIDS vaccines: animal trials core: 44 rhesus macaques
- Cellular immune responses and AIDS pathogenesis: 22 rhesus macaques and 16 mangabeys
- Induction of P vivax, P ovale, P malariae and other plasmodium infections in chimpanzees to obtain large volumes of parasites for malaria vaccine studies: 7 chimpanzees
- Molecular evolution of multiply deleted SIV in vitro: 24 rhesus macaques
- Core C: Primate Studies: 88 rhesus macaques
- Infant immunoprophylaxis against a primate lentivirus: 30 rhesus macaques
- Mechanism of oral SIV transmission: 5 rhesus macaques
- Analysis of thymic function during SIV infection: 6 mangabey, 1 rhesus macaque
- T cell turnover in normal and SIV infected sooty mangabeys: 3 mangabeys
- SHIV macaque model of oral immunization against sexually transmitted HIV: 4 rhesus macaques and 8 pigtail macaques
- Replication defective HIV vaccine: 6 rhesus macaques
- Role of virus specific immunity in primate AIDS: 3 mangabeys, 20 rhesus macaques
- Molecular analysis of antigenic variation in malaria: 17 rhesus macaques
- Malaria, pregnancy and immunopathology: 1 rhesus macaque

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- In vivo evaluation of candidate drugs: 11 rhesus macaques
- AIDS & opiates: a monkey model: 20 rhesus macaques
- Combination DNA and attenuated virus vaccine for SIV : 14 rhesus macaques
- Immune modulation of neurotropin in SIV infection: 23 rhesus macaques
- Experimental Inoculations of Macaques with Rotavirus: 6 rhesus macaques, 12 pigtail macaques
- Face Processing in Chimps Using PET: 4 chimpanzees
- Environmental Enrichment of Yerkes Primate Center Animal Colony: 2 rhesus macaques
- Colony Management Support: 131 rhesus macaques (Recently received animals in quarantine)
- Project 3: attenuated listeria vectors as an AIDS vaccine in macaques: 28 rhesus macaques
- Pox virus immunity and DNA/MVA HIP vaccines: 16 rhesus macaques
- Therapeutic vaccine for HIV: 9 rhesus macaques
- Immune modulation of neurotropin in SIV infections: 17 rhesus macaques
- Safety testing of AAV vectors in the liver of hepatitis C virus infected chimpanzees: 4 chimpanzees

F. Studies of dose and delivery vehicle in non-human primates have become a critical step to prepare for human clinical trials in human subjects. (b)(4)

(b)(4) Then (b)(4) housing to prevent possible trauma to the surgical wound.

- Use of osteoinductive factors to enhance spine fusion: 10 rhesus macaques
- Use of osteoinductive factors (BMP2)—spine fusion: 3 rhesus macaques

G. (b)(4)

(b)(4) joints and frequent blood, urine collections, and liver biopsies, as well as physical exams necessitate single cage housing for 45 days.

- Safety evaluation of anti-APO-1/Fas antibody in the chimpanzee: 10 chimpanzees

H. The integration of functional MRI (fMRI) technology with proven utility will significantly advance research efforts in biomedical and behavioral sciences. One proposal is directed towards brain activation studies during cognitive tasks. (b)(4)

(b)(4) In studies on (b)(4) animals will be used for pharmacological and neurochemistry experiments involving the placement of an indwelling venous catheter for drug delivery during daily sessions lasting 1-2 hours. Some animals also have indwelling guide cannulae. The catheters and guide cannulae must be protected from contact by other animals. If contact is allowed, the preparations can be compromised with the risk of physical injury and infection. Protected contact housing reduces the risk since both animals can control proximity to others. The animals may require single housing if they persistently place themselves at risk to damage their indwelling venous catheters or guide cannulae, or that demonstrate a proclivity to damage another animal's catheter.

Determining the relationship between prefrontal cortical circuitry and components of dopaminergic neurotransmission is the focus of one research study that will enhance

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understanding of the cognitive processes subserved by the prefrontal cortex. This will hopefully shed light on human disease states, notably schizophrenia. In order to identify particular neural connections in the prefrontal cortex of macaques, axonal tracers will be injected intracerebrally. Following stereotaxic surgery, craniotomies will be made over the prefrontal cortex. Subjects must be in protected contact housing to protect craniotomy sites and sutures.

Assessment of specific roles of separate neuronal structures are performed on monkeys to evaluate the brain's response to damage at different sites. (b)(4)

(b)(4)

Animals are required for post-surgical events until healing has occurred.

Implants may require single cage housing to prevent damage to implants in incompatible animals.

- Transition states of drug addiction in nonhuman primates: 12 rhesus macaques
 - Development of functional magnetic resonance imaging (MRI) for behavioral studies in nonhuman primates: 8 Rhesus Macaques
 - Cocaine use and pharmacotherapy effectiveness in monkeys: 5 Rhesus macaques
 - PET neuroimaging and cocaine neuropharmacology in monkeys: 26 Rhesus macaques
 - Cocaine use and monoamine function in nonhuman primates: 39 squirrel monkeys
 - Cortical circuitry related to neurotransmission proteins: 2 rhesus macaques
 - Analysis of the neuronal microcircuitry basal ganglia: 1 squirrel monkey
 - Orbitofrontal limbic ontogeny and early dysfunction: 12 rhesus macaques
 - Development of reversible inactivation technique: 2 rhesus macaques
 - Development of medial temporal lobe function: 6 rhesus macaques
- I. Visual, vestibular and oculomotor systems must work together for normal visual function. Various disease processes or injuries can compromise the normal interaction of these systems. Research in this area will provide a basic science foundation for understanding eye movement control in humans. Primates are used since they exhibit the same set of eye movements as humans. To facilitate the research, scleral search-coils are implanted to precisely measure eye movement. In addition, head movements need to be restricted during visual testing to allow accurate tracking of visual targets. Therefore, a stainless-steel receptacle is implanted. It is sometimes necessary to house animals in protected housing when they have surgical implants. This is to protect the animal from any injury due to aggressive behavior of other animals. Animals also sometimes wear goggles which may be removed during paired housing.
- Neural control of visual vestibular behavior: 2 rhesus macaques
 - Visual Processing and Smooth Eye Movement: 11 rhesus macaques
 - Binocular coordination of eye movements in monkeys: 6 rhesus macaques
- J. Studies of pancreas, kidney, and bone marrow transplants as well as arterial grafts are investigating the ability of costimulation blockade to protect the organs from rejection. For experiments involving bone marrow transplantation, single housing is required for the first 75-100 days following the transplant due to the potential complications including immunosuppression, anemia, leukopenia and thrombocytopenia. After that time, the animals may be paired with same sex and age animals. In the pancreatic islet cell transplant model, daily monitoring of urine and stool output are necessary to diagnose steatorrhea, polyuria and ketoacidosis. In addition, pancreatic enzyme replacement and Rapamycin are administered orally in a treat and it is essential that the amount consumed by each animal is recorded.

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Following renal transplantation, animals will require protected housing so that an accurate assessment of daily food/water intake and urine/feces production be accounted. Prior to surgery, animals may be pair-housed. With immunosuppressive therapy, healing can be delayed.

- Non-human primate pancreatic islet cell transplantation: 16 rhesus macaques, 8 baboons
- The effect of dosing strategy for LEA29Y on renal allograft survival in rhesus macaques: 23 rhesus macaques
- Activation, apathy, anergy, and apoptosis in transplantation: 6 rhesus
- Transplant Tolerance Project 2: 11 rhesus macaques
- Transplant Tolerance in Non-Human Primates: Costimulation, chimerism and tolerance in transplantation (Project 3): 52 rhesus macaques

K. In this study to evaluate replacement of arteries with vascular grafts, subjects will have aortiliac graft implants. Animals are singly housed to permit healing following this major surgery and evaluation of complications. Animals remain on study 1 month following surgery.

- Evaluation of small vessel prostheses: 20 baboons

Physical Restraint, Exemptions from Social Housing, and Food or Water Restriction of Nonhuman Primates

Nonhuman primates used under these conditions are in motion disorder studies or studies of brain function. Most of the animals are used to research the cause and treatment of Parkinson's Disease (PD) because of the great similarity of brain function and that (b)(4)

(b)(4) Monkeys in these studies are given (b)(4) by intracarotid injection, so that only one side of the brain is affected. These monkeys have only slight deficits in precise control of movements on one side of the body and have no substantial movement problems. In general, isolation housing is only done for a 3 day period immediately after administration of (b)(4) during the time of excretion of the neurotoxin in the feces and urine. Otherwise, monkeys in these studies are housed within sight and sound of other animals of the species and permitting physical contact with a compatible conspecific.

Monkeys in studies requiring food or water restriction are provided *ad libitum* food and water on weekends according to standard husbandry practices. During weekdays, food or water is restricted overnight and in the morning (12-15 hours total) and then food or water is provided to satiety during morning or afternoon test sessions as an inducement to perform video-based tasks. Single housing is necessary to facilitate food or water restriction – otherwise a conspecific would be subjected to unnecessary restriction or food sharing might occur. Monkeys are trained using food or water as an inducement to perform simple motor tasks such as reaching, touching a target on a video screen, depressing a key to make a video target appear, and controlling a joystick to move a cursor to a target on a video screen. These monkeys, except as indicated, are loosely restrained in a chair and typically spend 4-6 hours per daily session in the laboratory. During these periods, the monkeys with head appliances may also undergo short-term fixed head restraint to access the appliances for neurophysiologic recording and microdialysis. Water or food is provided during and immediately after the testing session to meet the daily ration. The total intake of the restricted material, food or water, is recorded daily and the animal's body weight is checked and recorded at least twice weekly to ensure that they are being well maintained.

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1. Food restricted, but provided during and after laboratory testing sessions:
 - Title: Basal ganglia discharge patterns in Parkinsonism: 5 rhesus monkeys
 - Title: Influence of subthalamic nucleus on striatal dopamine: 4 rhesus monkeys
 - Title: Pathophysiology of the basal ganglia in Parkinsonism: 5 rhesus monkeys
 - Title: Deep brain stimulation in the Parkinsonian monkey: 6 rhesus monkeys
 - Title: Cortical mechanisms of motor processing: 4 rhesus monkeys
 - Title: Development of gaze-holding abilities: 6 rhesus macaques

2. Short-term physical restraint only:
 - Title: Transition states of drug addiction in nonhuman primates: 12 rhesus macaques
 - Title: Glutamate in Parkinson's disease: 6 rhesus macaques
 - Title: PET neuroimaging and cocaine neuropharmacology in monkeys: 26 rhesus macaques
 - Title: Cocaine use and pharmacotherapy effectiveness in monkeys: 5 Rhesus macaques
 - Title: Cocaine use and monoamine function in nonhuman primates: 39 squirrel monkeys
 - Title: The error signal for postnatal eye growth in the primate: 3 rhesus macaques
 - Title: Emotional and Endocrine Covariates of Macaca mulatto: 48 rhesus macaques
 - Title: Orbitofrontal limbic ontogeny and early dysfunction: 12 rhesus macaques
 - Title: Development of reversible inactivation technique: 2 rhesus macaques
 - Title: Development of medial temporal lobe function: 6 rhesus macaques

Exemptions from Exercise for Dogs

Dogs with an inherited motoneuron disease may be restricted from exercise for 3-4 days while acutely recovering from surgery.

- Title: Functional studies in motoneuron disease: 14 dogs.

Food or Water Restriction of Swine

Swine to undergo survival bowel surgery are restricted from solid food and given an all-liquid diet for 2-3 days prior to surgery in order to fully cleanse the gastrointestinal tract including the lengthy spiral colon.

- Title: Laparoscopic ureteral replacement with reconfigured colon: 1 pig.

This report is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 211.

JAN 03 2005 See attached form for additional information.

Interagency Report Control No.:

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE ANNUAL REPORT OF RESEARCH FACILITY (TYPE OR PRINT)	1. CERTIFICATE NUMBER: 57-R-0003 CUSTOMER NUMBER: 896	FORM APPROVED OMB NO. 0379-0038
	Emory University Whitehead Biomedical Research Bldg 615 Michael Street Suite G02 Atlanta, GA 30322 Telephone: (404)-727-7428	

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 in 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	6	15	100	0	115
5. Cats	0	0	64	0	64
6. Guinea Pigs	0	0	34	0	34
7. Hamsters	0	0	0	0	0
8. Rabbits	0	189	44	0	233
9. Non-human Primates	2000	762	1541	21	2324
10. Sheep	0	7	26	0	33
11. Pigs	0	0	379	0	379
12. Other Farm Animals					
VOLES	0	462	908		1370
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 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
 (as Executive Officer or Legally Responsible Institutional Official)

 (which is obsolete.)

NAW

DATE SIGNED

1/04/05

RAN

**Annual Report to USDA
Facility Locations**

Peavine Creek Kennels, Emory University
O. Wayne Rollins Research Center, Emory University
Woodruff Memorial Research Building, Emory University
Wesley Woods, Emory University
Dental Building, Emory University
South Clinics (Winship Cancer Center and Eye Center), Emory University
Briarcliff Campus Building, Emory University
Cardiothoracic Research Labs at Crawford Long Hospital, Atlanta, GA
Yerkes National Primate Research Center, Emory University
Yerkes Field Station, Lawrenceville, GA
Whitehead Memorial Research Building, Emory University