

## **Animal Welfare Assurance for Domestic Institutions**

I, Peter Marks, as named Institutional Official for animal care and use for the White Oak Consolidated (WOC) Animal Program at the Food and Drug Administration, provide assurance that this Institution will comply with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals.

### **I. Applicability of Assurance**

This Assurance applies whenever this Institution conducts the following activities: all research, research training, experimentation, biological testing, and related activities involving live vertebrate animals supported by the PHS. This Assurance covers only those facilities and components listed below.

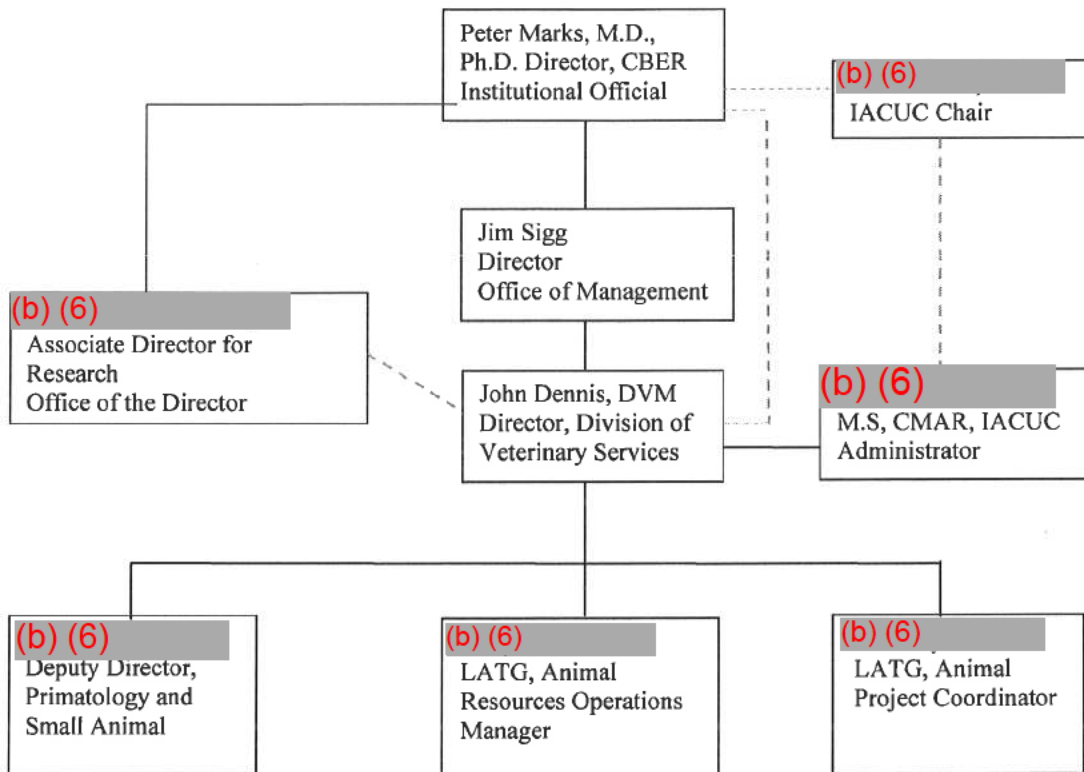
- A. The following are branches and components over which this Institution has legal authority:
  - FDA Center for Biologics Evaluation and Research (CBER):  
Office of Cellular Tissues and Gene Therapies, Office of Blood Research and Review, Office of Vaccines Research and Review, Office of Compliance and Biologics Quality, Office of Management (Division of Veterinary Services);
  - FDA Center for Drug Evaluation and Research (CDER): Office of Pharmaceutical Sciences,  
Office of Biotechnology Products, Office of Translational Science;
  - FDA Center for Devices and Radiological Health (CDRH) Office of Science and Engineering Laboratories;
  - FDA Center for Tobacco Products (CTP) Office of Science.

### **II. Institutional Commitment**

- A. This Institution will comply with all applicable provisions of the Animal Welfare Act and other Federal statutes and regulations relating to animals.
- B. This Institution is guided by the "U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training."
- C. This Institution acknowledges and accepts responsibility for the care and use of animals involved in activities covered by this Assurance. As partial fulfillment of this responsibility, this Institution will ensure that all individuals involved in the care and use of laboratory animals understand their individual and collective responsibilities for compliance with this Assurance, and other applicable laws and regulations pertaining to animal care and use.
- D. This Institution has established and will maintain a program for activities involving animals according to the *Guide for the Care and Use of Laboratory Animals* (Guide).
- E. This Institution agrees to ensure that all performance sites engaged in activities involving live vertebrate animals under consortium (sub-award) or subcontract agreements have an Animal Welfare Assurance and that the activities have Institutional Animal Care and Use Committee (IACUC) approval.

### III. Institutional Program for Animal Care and Use

The lines of authority and responsibility for administering the program and ensuring compliance with the PHS Policy is outlined below. Dr. Stephen Ostroff, Acting Commissioner of Food and Drugs, appointed Dr. Peter Marks, Director, CBER, as the IO for the WOC Animal Program, January 2016. Dr. Marks maintains his responsibilities under Dr. Robert Califf, the new Commissioner of Food and Drugs.



Note: Dashed line (----) indicates direct access for animal care or scientific issues

A. The qualifications, authority, and percent of time contributed by the veterinarian(s) who will participate in the program are as follows:

1) Name: Dr. John Dennis

#### Qualifications

- Degrees:
  - D.V.M. (NC State College of Veterinary Medicine), M.S. (Penn State College of Medicine), DACLAM
- Training or experience in laboratory animal medicine or in the use of the species at the institution:
  - 20 years of full time work as a Laboratory Animal Veterinarian
  - Residency training and Board Certification in Laboratory Animal Medicine
  - Private Veterinary Practice
  - Continuing education obtained through AALAS, ASLAP national meetings, as well as local programs sponsored by SCAW, OLAW, PRIM&R, vendors, professional veterinary groups, FDA, and NIH.

Authority: Dr. John Dennis is the Director of CBER, Division of Veterinary Services (DVS) and has delegated program authority and responsibility for the Institution's animal care and use program including access to all animals. Responsibilities include clinical care and oversight of

animals, supervision of key staff, review of animal study proposals and consultation with scientific staff on new or existing projects.

Time contributed to program:

Full time employee: 90% of his time dedicated to the animal care and use program.

2) Name: (b) (6)

Qualifications

- Degrees:
  - M.A. (b) (6) D.V.M. (b) (6)
  - M.P.H. (b) (6) DACLAM
- Training or experience in laboratory animal medicine or in the use of the species at the institution:
  - Over 22 years of experience as a clinical veterinarian skilled in medicine and surgery.
  - More than 7 years of experience in laboratory animal medicine including residency training in laboratory medicine.
  - Continuing education obtained through AALAS, ASLAP, as well as local programs sponsored by SCAW, OLAW, PRIM&R, FDA, and NIH.

Responsibilities:

Dr. (b) (6) Deputy Director, CBER, DVS, is the second veterinarian employed full time by CBER and is responsible for the clinical care and assessment of research animals and related projects along with ASP review.

Time contributed to program:

Full time employee: 100% of time dedicated to the animal care and use program.

- B. The IACUC at this Institution is properly appointed according to PHS Policy IV.A.3.a. and is qualified through the experience and expertise of its members to oversee the Institution's animal care and use program and facilities. The IACUC consists of at least 5 members, and its membership meets the composition requirements of PHS Policy IV.A.3.b. Attached is a list of the chairperson and members of the IACUC and their names, degrees, profession, titles or specialties, and institutional affiliations.

Date: April 8, 2016	
Name of Institution: Food and Drug Administration, WOC Animal Program	
Assurance Number: A4300-01	
<b>IACUC Chairperson</b>	
Name: (b) (6)	
Title*: Biologist	Degree/Credentials*: Ph.D.
Address*: (street, city, state, zip code)	
10903 New Hampshire Ave. Bldg 52/72, Room 1124, HFM460 Silver Spring, MD 20993	
E-mail: (b) (6)	@fda.hhs.gov
Phone: (b) (6)	Fax: (b) (6)
<b>IACUC Roster</b>	

Name of Member/ Code**	Degree/ Credentials	Position Title***	PHS Policy Membership Requirements****
(b) (6)	DVM., MS, DACLAM	Director, Veterinarian	Attending Veterinarian
	DVM., MPH, DACLAM	Deputy Director, Clinical Veterinarian	Veterinarian
	DVM, PhD, MBA	Research Veterinary Medical Officer	Vice Chair, Scientist
	MS	Microbiologist	Scientist
	DVM	Safety and Health Specialist	Occupational Health and Safety Specialist (voting)
	PhD	Staff Scientist	Scientist
	PhD	Biologist	Scientist
	PhD	Scientist	Scientist
	PhD	Biologist	Scientist
	PhD	Research Pharmacologist	Scientist
	MS	Biologist	Scientist
	MD, PhD	Medical Officer	Scientist
	MS	Industrial Engineer	Non-Affiliated, Non-Scientist
	MFA	Faculty Emeritus, NVCC	Non-Affiliated, Non-Scientist
	PhD	Microbiologist	Alternate Scientist
	PhD	Biologist	Alternate Scientist
	MS	Biologist	Alternate Scientist
	PhD	Visiting Associate	Alternate Scientist
	PhD	Research Pharmacologist	Alternate Scientist
	DVM, PhD	Research Veterinary Medical Officer	Alternate Scientist
	MD, PhD	Biologist	Alternate Scientist
	PhD	Staff Fellow	Alternate Scientist
	PhD	Contractor	Alternate Scientist
	PhD	Supervisory Electrical Engineer	Alternate Scientist
	PhD	Research Biologist	Alternate Scientist
	MS	Safety and Health Specialist	Alternate, Occupational Health and Safety Specialist
	MS, CMAR, LATG	IACUC Administrator	Non-Voting
	BS	IACUC Administrator	Non-Voting



Other general features of the OMS program include:

- PPD testing (annually for NHP handlers or users)
- Diphtheria and tetanus prophylaxis (offered to employees and updated each 10 years)
- Hepatitis B and A vaccination
- Seasonal Flu vaccine
- Vaccinia (updated each 10 years, when recommended)
- Rubella, measles, rabies, and pertussis vaccination (based on risk factors or agent use)
- NHP users are briefed about zoonotic risks associated with NHPs and their tissues by the OMS nurse. A PPD is also required annually for those handling NHPs. Additional critical information and special training is also provided to all NHP users by the DVS veterinarian, including Herpes B training, location of bite/scratch kits, first aid procedures following a potential exposure, reporting procedures and after-hours procedures, along with other topics. This special training is mandatory for handlers of NHPs and/or their tissues.

The FDA Employee Safety and Environmental Management (ESEM) ensure there is an Occupational Health and Safety (OHS) specialist as a representative on the IACUC. The OHS specialist verifies that ASPs clearly identify any hazards, are reviewed by appropriate committees, and that necessary safeguards have been incorporated into study procedures. The OHS specialist is also available to consult with or to survey the proposed work animal work area and periodically review safe work practices. Institutional policies for personal hygiene covering prohibition of eating in animal rooms and where to wear protective clothing are covered in Standard Operating Procedures (SOPs). Specific hazardous agent handling requirements and the wearing of protective clothing are covered by specific SOP and should be listed in ASPs. All animal users (FDA and contract employees) are required to complete an online course, "White Oak Comprehensive Laboratory Safety Training" and a refresher course annually if they are working with human blood and body fluids or any BSL2 agents related to animal use. Training sessions emphasize safety practices and reduction of physical injury risks, and safety-related topics are also covered by the contractor-provided training regularly throughout the year.

FDA has institutional policies in place for personal hygiene, handling hazardous agents, and personnel protection. The White Oak Exposure Control Plan and Chemical Hygiene Plans are readily accessible to employees. Special precautions to be taken during pregnancy, illness, or decreased immunocompetence are risk-managed, based on the agent and the procedures used to manipulate the agent. SOPs are in place for working with BSL-2 and BSL-3 agents. OMS provides consultation to pregnant persons and to those looking to become pregnant. In the event of bites, scratches, illness, or injury, basic first aid is provided by OMS, with all accidents and injuries reported to the OHS Specialist.

- 2 The total gross number of square feet in each animal facility (including each satellite facility), the species of animals housed there and the average daily inventory of animals, by species, in each facility is provided in the attached Facility and Species Inventory table.

## Facility and Species Inventory

Date: November 13, 2015			
Name of Institution: Food and Drug Administration, WOC Animal Program			
Assurance Number: A4300-01			
Laboratory, Unit, or Building	Gross Square Feet [include	Species Housed [use common names, e.g., mouse, rat,	Approximate Average Daily

	service areas]	<i>rhesus, baboon, zebrafish, African clawed frog]</i>	Inventory
(b) (4)		Mouse	28,287
		Rat	276
		Hamsters	204
		Rabbits	25
		African clawed frog	46
		Ferrets	29
		Guinea Pigs	145
		Canine	4
		Rhesus	87
		Baboons	22
		Cynomolgus	2
		Mouse	123
		Rat	77
		Guinea Pigs	15
		Ferrets	2
		Sheep	13

- 3 The training or instruction available to scientists, animal technicians, and other personnel involved in animal care, treatment, or use is as follows:

Online training courses from the Collaborative Institutional Training Initiative and the AALAS Learning Library are used to communicate laws and regulations relevant to working with laboratory animals, ethical issues, and humane practices. Basic course work is required for all PIs, researchers, and animal technicians consisting of Federal Mandates; Principal Investigator responsibilities; Alternatives; Avoiding Duplication; Pain Categories; Endpoint criteria; Anesthesia; Analgesia; Surgery; Euthanasia, and Reporting Misuse, Mistreatment, or Non-compliance. Species specific courses supplement the basic course work. Individuals are encouraged to take additional courses that may facilitate their knowledge. The PI, researchers, and animal technicians must complete the course work prior to ASP submission.

A separate set of courses is required for IACUC members, consisting of Responsibilities of the IACUC and members, CEO, and the IO; Authority of the IACUC; The Quorum, Procedures for reviewing protocol forms; Types of protocol reviews; Semiannual Evaluations; Performing Facility Inspections and Program Review; Identifying and Correcting Deficiencies; and Improper Animal Care or Use.

All animal users and IACUC members are required to take an online refresher course every 3 years.

The DVS veterinarians provide training to PIs and Individuals involved in working with NHPs, with a presentation entitled "Working Safely with Non-Human Primates." The DVS training protocol includes both animal handling and restraint procedures and technical procedures. DVS also sponsors webinars and delivers presentations targeted to research teams and their interests on topics such as cryopreservation of mouse