

**MEMORANDUM OF UNDERSTANDING**

**BETWEEN**

**THE OFFICE OF LABORATORY ANIMAL WELFARE  
NATIONAL INSTITUTES OF HEALTH  
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**AND**

**THE OFFICE OF RESEARCH OVERSIGHT AND  
THE OFFICE OF RESEARCH AND DEVELOPMENT  
VETERANS HEALTH ADMINISTRATION  
U.S. DEPARTMENT OF VETERANS AFFAIRS**

**CONCERNING  
LABORATORY ANIMAL WELFARE**

**I. PURPOSE**

The National Institutes of Health (NIH), Department of Health and Human Services (HHS) Office of Laboratory Animal Welfare (OLAW) and the Veterans Health Administration (VHA), Department of Veterans Affairs (VA) Office of Research Oversight (ORO) and Office of Research and Development (ORD), hereinafter referred to as the cooperating agencies, collectively share a common interest in the care and welfare of laboratory animals used in research and testing. This agreement sets forth procedures for cooperation to assist each agency in meeting its responsibilities to ensure appropriate laboratory animal care and welfare.

The intent of this agreement is to:

- maintain and enhance agency effectiveness by coordinating efforts and sharing resources and information, particularly in the areas of education and compliance;
- avoid duplication of effort in achieving standards for the care and use of laboratory animals, thereby reducing regulatory burden on the VA and VA-affiliated institutions; and
- promote harmonization among VA sponsored activities and between VA institutions and other Public Health Service (PHS) Assured institutions.

Interagency cooperation provides an excellent opportunity to bolster individual agency efforts, achieve program benefits, and facilitate program operations. A shared perspective on acceptable standards of laboratory animal care presents a uniform Federal approach and fosters compliance with the PHS Policy on Humane Care and Use of Laboratory Animals within VA and VA-affiliated institutions.

## II. AGENCY RESPONSIBILITIES

### **PHS Office of Laboratory Animal Welfare (OLAW)**

OLAW, Office of Extramural Research, NIH, is responsible for the implementation, general administration, and interpretation of the PHS Policy on Humane Care and Use of Laboratory Animals (PHS Policy). The PHS Policy implements the Health Research Extension Act of 1985 (Public Law 99-158), and incorporates the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training and the standards for institutional programs and facilities described in the National Academy of Sciences' *Guide for the Care and Use of Laboratory Animals (Guide)*.

The PHS Policy requires each institution receiving PHS support for an activity involving live, vertebrate animals to establish an appropriate institutional animal care and use program, including an Institutional Animal Care and Use Committee (IACUC) with specific responsibilities as described in the PHS Policy. Adherence to the Policy and Guide are achieved primarily through voluntary compliance with an institutional animal care and use program described in an Animal Welfare Assurance (Assurance). Assurances are submitted to and must be approved by OLAW, on behalf of the Director, NIH, before PHS funds may be released for activities involving laboratory animals.

In addition to the Assurance mechanism, OLAW fosters compliance with the PHS Policy through a nationwide educational program for research administrators, IACUC members, investigators, laboratory animal veterinarians, and others with responsibility for animal care and use. OLAW also conducts site visits to institutions and evaluates alleged noncompliance with the PHS Policy. Institutions are required to correct confirmed noncompliance and to institute appropriate measures to prevent recurrence. Possible sanctions for continued noncompliance without appropriate corrective actions range from exclusion of individual projects from an approved Assurance to withdrawal of approval of the institution's entire Assurance. Without coverage by an approved Assurance, PHS support may not be applied to animal-related activities of a project.

### **VA Office of Research Oversight (ORO)**

ORO serves as the primary component of the VHA to advise the Under Secretary for Health on all matters affecting the integrity of research by ensuring the welfare of research animals through promoting compliance with relevant regulations and policies. Through VA Handbook 1200.7, Use of Animals in Research, VA has adopted the standards of the PHS Policy on Humane Care and Use of Laboratory Animals for all animal research conducted under VA auspices and further requires that VA medical centers conducting animal studies and accepting any PHS funds should have a PHS Animal Welfare Assurance (See VHA Handbook 1200.7.7e).

### **VHA Office of Research and Development (ORD)**

VHA ORD serves as the primary internal research funding and research policy formulation component within VA. It bears primary responsibility for supporting field research programs through education, training, and consultation. Support for VA field programs is managed

primarily through the office of the Chief Veterinary Medical Officer (CVMO), who assumes responsibility for interactions with other federal agencies regarding policy and training matters. No VA funds are disbursed for research involving animals until the CVMO's office has performed a secondary review of IACUC-approved animal protocol forms. Per VHA Handbook 1200.7, all VA animal research must be conducted according to the USDA Animal Welfare Act Regulations and the PHS Policy. OLAW is consulted whenever VA program or protocol review issues require more than routine interpretation of the PHS Policy, and OLAW's interpretation is considered definitive.

### **III. SHARED INTERESTS**

The VA and HHS share common interests for the care and use of laboratory animals and for the quality of the research conducted under their auspices. OLAW has statutory responsibility for implementing the PHS Policy as described above. The VA recognizes the value of the standards contained within PHS Policy in promoting high quality animal care and use programs and requires compliance with them even if PHS funds are not received by the local VA medical center. A VA-affiliated institution is one of more than 100 medical or academic institutions that formally collaborate with the VA in conducting both human and animal research.

Program features common to VA and NIH include promotion of PHS Policy standards, monitoring of standards, correction of programmatic deficiencies, promotion of voluntary compliance, and creation and implementation of educational programs that foster compliance, dissemination of information, and quality animal care.

### **IV. SUBSTANCE OF AGREEMENT**

- A. Interpretation of and determination of noncompliance with PHS Policy remain the exclusive purview of NIH/OLAW as authorized by Public Law 99-158.
- B. The cooperating agencies agree to share information of mutual concern and interest regarding animal welfare at VA and VA-affiliated PHS assured institutions, including, but not limited to, evidence of serious noncompliance with standards for the care and use of laboratory animals, significant adverse findings regarding animal care and use investigated, inspected, or site-visited, and actions taken by the agencies in response to the findings.
- C. The cooperating agencies agree to limit the dissemination of shared information received to internal agency officials who have a need to know. If a cooperating agency receives a Freedom of Information Act request for records provided by another agency, the recipient agency will refer the request to the agency that provided the records. The recipient agency will promptly notify the agency that provided the information of any judicial order that compels the release of information.

- D. The cooperating agencies agree, to the extent possible, to avoid redundant evaluations of VA and VA-affiliated animal care and use programs and duplication of respective efforts to minimize the burden on Assured institutions and on the cooperating agencies.
- E. ORO and OLAW will consult with one another with regard to investigations of noncompliance at VA institutions holding a PHS Assurance. ORO and OLAW will notify each other of information concerning potential noncompliance at VA-affiliated institutions with PHS Assurances. The ORD CVMO will share information relevant to VA compliance with PHS Policy with OLAW and ORO.
- F. ORO or ORD may request that OLAW negotiate Animal Welfare Assurances for VA or VA-affiliated institutions that do not receive direct PHS support for activities involving live vertebrate animals.
- G. At the request of ORO or ORD, OLAW will provide substantive review and consultation of internal VA policies and educational materials for compliance with PHS Policy and harmonization of standards.
- H. The cooperating agencies agree to work collaboratively to co-sponsor educational meetings and workshops, to collaborate on online training, and to provide each other with resource persons, to the extent possible, for seminars, presentations and workshops related to laboratory animal welfare and their respective agency responsibilities.
- I. Nothing in this agreement shall limit or otherwise affect each party's ability to exercise its own authorities or gives the other party approval power over the exercise of the other party's authorities. Nothing in this agreement is intended or should be construed to authorize the transfer of funds between the cooperating agencies.

## **V. LIAISON OFFICERS**

The cooperating agencies each agree to designate a liaison officer who will represent the agency in the implementation of this agreement. The liaison officers will coordinate exchanges of information as necessary and the provision of other items under the Substance of Agreement described above.

**For the NIH Office of Laboratory Animal Welfare:**

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**For the VA Office of Research and Development:**

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**VI. PERIOD OF AGREEMENT**

This agreement becomes effective on the date of the last signature and continues for 5 years. It may be modified by mutual written consent. Either party upon 90-day advance written notice to the other party may terminate this agreement. At the conclusion of 5 years the parties will consider the development of a new agreement.

**VII. ACCEPTANCE AND APPROVAL OF AUTHORIZING OFFICIALS**

**For the Office of Laboratory Animal Welfare, OER, NIH:**

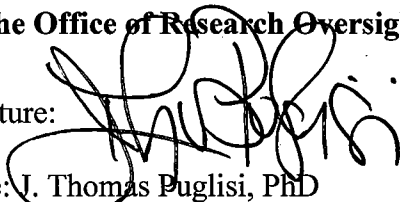
Signature: *Norka Ruiz Bravo*

Date: *11/21/2007*

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**For the Office of Research Oversight, VHA, VA:**

Signature:



Date: *11.08.2007*

Name: J. Thomas Puglisi, PhD  
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**For the Office of Research and Development, VHA, VA:**

Signature:



Date: *11/13/07*

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