MEMORANDUM OF UNDERSTANDING
AMONG
THE ANIMAL AND PLANT HEALTH INSPECTION SERVICE
U.S. DEPARTMENT OF AGRICULTURE
AND
THE FOOD AND DRUG ADMINISTRATION
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
THE NATIONAL INSTITUTES OF HEALTH
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
CONCERNING
LABORATORY ANIMAL WELFARE

I. PURPOSE

The participating agencies share a common concern for the care and welfare of laboratory animals used in research and testing. Each agency, operating under its own authority, has specific responsibilities for fostering proper animal care and welfare. This agreement sets forth procedures of reciprocal cooperation which will assist each agency in meeting its responsibilities in promoting proper laboratory animal care and welfare. Implementation of this agreement is intended to maintain and enhance agency effectiveness while avoiding duplication of efforts to achieve required standards for the care and use of laboratory animals.

II. AGENCY RESPONSIBILITIES

The Animal and Plant Health Inspection Service, USDA

Primary responsibility for the Animal Welfare Act (AWA) is assigned to the U.S. Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS). Implementing regulations of the AWA are established in the Code of Federal Regulations, Title 9, Chapter 1, Subchapter A, Parts 1, 2, and 3. The Department has regulatory responsibility to enforce the implementing regulations. The USDA regulations establish standards for the humane treatment of laboratory animals and a registration/licensing procedure for identifying institutions that breed, sell, transport, hold, and use such animals. Adherence to these standards is achieved primarily through voluntary compliance. Compliance with the USDA regulations is monitored by an active inspection program that provides for periodic inspections by veterinary medical officers or suitably trained paraprofessionals. Serious noncompliance is dealt with by procedures that range from civil penalties, to the issuance of "cease and desist" orders, to the confiscation of animals.

Food and Drug Administration, HHS

The Food and Drug Administration (FDA) is also involved in ensuring proper procedures for the care and use of laboratory animals. The source statute is the Federal Food, Drug, and Cosmetic Act as implemented by the Good Laboratory Practice Regulations (21 CFR Part 58). These regulations establish standards for the proper conduct of nonclinical laboratory studies that include animals. Adherence to the regulations is achieved primarily through voluntary compliance. Compliance is assessed through an active program of periodic inspections carried out by trained field inspectors. Serious noncompliance is dealt with by procedures ranging from study rejection to laboratory disqualification.

National Institutes of Health, HHS

The Office of Laboratory Animal Welfare (OLAW), Office of Extramural Research, National Institutes of Health (NIH), is responsible for the implementation and general administration of the Public Health Service (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). The PHS Policy is based on the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training; standards for institutional programs and facilities are 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 OLAW and must be approved by OLAW 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 (including regional workshops, web-based materials and an email listserv) 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 repeated noncompliance. Possible sanctions for continued noncompliance 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.

Scientific review groups charged with the scientific merit review of research applications and proposals, and awarding units, are responsible for ensuring that the required information regarding the use of vertebrate animals is contained in the application/proposal, that all animal welfare concerns raised during scientific review are resolved, and that the appropriate IACUC has reviewed and approved the project before an award is made.

III. SHARED CONCERNS

USDA, FDA, and NIH share a common concern for the care and use of laboratory animals, although there are necessary operational differences among the animal welfare programs of the cooperating agencies. Congress acknowledged the need for transagency cooperation in the AWA by calling for the Secretary of Agriculture to consult and cooperate with other Federal departments and agencies concerned with the welfare of animals used in research, and to consult with the Secretary of Health and Human Services prior to the issuance of regulations.

Common program features include the promulgation of standards and policies aimed at promoting laboratory animal welfare, the maintenance of registries/inventories of institutions and facilities subject to agency policies and regulations, the periodic conduct of routine and "for cause" inspections or site visits, efforts designed to promote voluntary compliance, and the application of a range of sanctions when necessary.

Interagency cooperation provides an excellent opportunity to bolster individual agency efforts, achieve program benefits, and facilitate program operations. A mutually shared perspective on acceptable standards of laboratory animal care presents a consistent Federal approach and fosters compliance by regulated entities.

IV. SUBSTANCE OF AGREEMENT

The cooperating agencies agree to share information of mutual concern and interest regarding animal welfare. Specific agency responsibilities under this Memorandum of Understanding are detailed below.

A. The cooperating agencies agree to share information contained in their respective registries/inventories/listings of organizations that fall under their purview.

B. The cooperating agencies agree to provide one another with information concerning significant adverse findings regarding animal care and use at organizations investigated, inspected, or site-visited, and the actions taken by the agency in response to the findings.

C. The cooperating agencies agree to provide one another with information regarding evidence of serious noncompliance with required standards or policies for the care and use of laboratory animals at organizations that fall under the authority of the participating agencies.

D. The cooperating agencies agree, to the extent possible, to inform successive evaluations and to avoid redundant evaluations of the same entities.

E. The cooperating agencies agree to consult and coordinate with each other on regulatory or policy proposals and significant policy interpretations involving animal care and use under consideration by each agency.

F. The cooperating agencies agree to provide each other with resource persons for scientific and educational seminars, speeches, and workshops related to laboratory animal welfare.

V. STANDING COMMITTEE

To facilitate the implementation of this agreement, the cooperating agencies each agree to designate a liaison officer to serve on a standing committee that will meet as needed, but no less than once per year. Matters for consideration by the standing committee are to include a review of each agency's participation in this agreement, an assessment of the agreement's effectiveness, and modifications that might be necessary. As appropriate, the committee will address urgent issues and specific cases of serious noncompliance.

VI. LIAISON OFFICERS

For the Animal and Plant Health Inspection Service:

William R. DeHaven, D.V.M.
Deputy Administrator
USDA, APHIS, AC
4700 River Road, Unit 84
Riverdale, Maryland 20737-1234
Phone: 301-734-4981
Fax: 301-734-4993

For the Food and Drug Administration:

James F. McCormack, Ph.D.
Bioresearch Monitoring Program CoordinatorDivision of Compliance Policy,
HFC-23Office of EnforcementOffice of Regulatory Affairs
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857
Phone: 301-827-0425
Fax: 301-827-0482

For the National Institutes of Health:

Nelson L. Garnett, D.V.M.
Director, Office of Laboratory Animal Welfare
Office of Extramural Research
National Institutes of Health
RKLI, Suite 1050, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7982
Phone: 301-496-7163
Fax: 301-402-2803

VII. PERIOD OF AGREEMENT

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

VIII. ACCEPTANCE AND APPROVAL OF AUTHORIZING OFFICIALS

For the Animal and Plant Health Inspection Service, USDA:

Signature: /s/
Name: Craig A. Reed, D.V.M.
Title: Administrator
Animal and Plant Health Inspection Service
U.S. Department of Agriculture
Date: January 19, 2001

For the Food and Drug Administration, HHS:

Signature: /s/
Name: Bernard A. Schwetz, D.V.M., Ph.D.
Title: Acting Principal Deputy Commissioner of Food and Drugs
U.S. Department of Health and Human Services
Date: January 30, 2001

For the National Institutes of Health, HHS:

Signature: /s/
Name: Ruth L. Kirschstein, M.D.
Title: Acting Director, National Institutes of Health
U.S. Department of Health and Human Services
Date: January 16, 2001