

**ASSURANCE OF COMPLIANCE
WITH
PUBLIC HEALTH SERVICE
POLICY ON HUMANE CARE AND
USE OF LABORATORY ANIMALS**

Howard University, hereinafter referred to as institution, hereby gives assurance that it will comply with the Public Health Service Policy on Humane Care and Use of Laboratory Animals, hereinafter referred to as PHS Policy.

I. APPLICABILITY

This Assurance is applicable to all research, research training, experimentation, biological testing, and related activities, hereinafter referred to as activities, involving live, vertebrate animals supported by the Public Health Service (PHS) and conducted at this institution, or at another institution as a consequence of the subgranting or subcontracting of PHS-conducted or supported activity by this institution, including the following branches and major components of Howard University:

- I. E.E. Just Hall, College of Arts and Sciences
- II. Numa P.G. Adams Building, College of Medicine

II INSTITUTIONAL POLICY

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 AU.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 make a reasonable effort to ensure that all individuals involved in the care and use of laboratory animals understand their individual and collective responsibilities for compliance with this Assurance as well as all 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 in accordance with the Guide for the Care and Use of Laboratory Animals (Guide).

III. INSTITUTIONAL PROGRAM FOR ANIMAL CARE AND USE

A. The lines of authority and responsibility for administering the program and ensuring compliance with this Policy are: The Institutional Animal Care and Use Committee (IACUC) oversee and evaluate the institutions animal program, procedures, and facilities, to ensure that they are consistent with the recommendations in the Guide, the Animal Welfare Regulations (AWR) and the PHS Policy. The IACUC reports to the University President (the Institutional Official), through the Provost, who is designated as the University Designated Verifier (UDV) responsible to the President for administering Howard's animal welfare assurance. Dr. LaVal N. Cothran, Acting Director of Veterinary Services in the College of Medicine, has responsibility for the Core Animal Facility. Dr. Cothran reports to the Dean, College of Medicine, who reports to the Senior Vice President for Health Sciences (Interim), who reports to the President. Dr. Cothran is also the Consulting Veterinarian for the Biology Satellite Facility. Additionally, Dr. Cothran is a member of the IACUC.

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

1. **LaVal N. Cothran, D.V.M., Ph.D.**

Dr. Cothran received his A.B. degree in 1953 from Lincoln University, the D.V.M. degree in 1957 from Tuskegee Institute, the M.S. degree in 1964 from Wayne State University, and the Ph.D. degree in 1971 from Howard University. Dr. Cothran is the Acting Director of the Animal Facility in the College of Medicine, the Consulting Veterinarian for the Biology Satellite Facility and serves as a member of the IACUC. The percent of time that Dr. Cruise contributes to the animal care program is 100% time and effort.

2. **Doris E. Hughes-Moore, D.V.M.**

Dr. Hughes-Moore received her B.S. degree in 1967 from Tuskegee Institute and her D.V.M. degree in 1973 from Purdue University. Her residency training in veterinary clinical pathology and pathology occurred at Purdue University and Washington State University, respectively during the years 1974-1976. She has considerable experience in research and in writing reports of studies performed as a result of contractual agreements. Dr. Hughes-Moore is the Director, Animal Research Facility, George Washington University serves as back-up/relief veterinarian, who provides veterinary clinical coverage and operational oversight during times of absence of the facility director/veterinarian. She serves as Coordinator for the Occupational Health and Safety Course and is an Ad hoc Member of the IACUC. The percent of time that Dr. Hughes contributes to the animal care program is 10% time and effort.

In the matter of veterinary care, as it relates to the health of the animal, the veterinarians have the ultimate authority to exercise their professional judgment in implementing the PHS Policy and the recommendations of the Guide.

C. This institution has established an Institutional Animal Care and Use Committee (IACUC), which is qualified through the experience and expertise of its members to oversee the institution's animal program, facilities, and procedures. The IACUC consists of at least five members, and its membership meets the composition requirements set forth in the PHS Policy at IV.A.3.b. Attached is a list of the names, degrees, position titles, specialties and institutional affiliations of the IACUC chairperson and members. (See Attachment A)

D. The IACUC will:

1. Review at least once every six months the institution's program for humane care and use of animals, using the Guide as a basis for evaluation. Prior to committee inspection, the attending veterinarians will inform the Committee of any existing irregularities or deviations from the Guide. The IACUC procedures for conducting semiannual program evaluations are: Review institutional policies and responsibilities to ensure compliance, including Standard Operating Procedures (SOP); Review laboratory records to verify that the investigator is adhering to his/her approved protocol; Review animal ordering requests, health records, medication and medical equipment throughout the facilities and investigator laboratories; and review institutional training and occupational health and safety program for all animal caregivers and users.

2. Inspect at least once every six months all of the institution's animal facilities, including satellite facilities, using the Guide as a basis for evaluation. The IACUC procedures for conducting semiannual facility inspections are: A subcommittee of the IACUC composed of volunteer members, including one or more veterinarians, will perform a walking inspection of all relevant facilities. The individual reports will be used to prepare a final report which must be approved by the full committee.

3. Prepare reports of the IACUC evaluations as set forth in the PHS Policy at IV.B.3. and submit the reports to the President. The IACUC process for developing reports and submitting them to the Institutional Official is: Following inspection, the IACUC will determine if the facilities are in compliance with the Guide. If the IACUC determines that a facility is not in compliance with the Guide, the IACUC will make a recommendation to the Institutional Official through the University Designated Verifier (UDV, the Provost) to have the deficiency(ies) corrected. The attending veterinarian will have the responsibility of ensuring correction of any violations that require immediate intervention to prevent or eliminate a threat to the health or safety of any animal or person.

4. Review concerns involving the care and use of animals at the institution. The IACUC procedures for reviewing concerns are: The IACUC will inspect a facility upon request whether from the Institutional Official, the UDV, faculty, staff, students or the general public. The IACUC will review any inquiry regarding the care or use of animals at this institution, whether from faculty, staff, students or the general public. The IACUC reserves the right to request that such concerns or inquiries be submitted in writing. The IACUC will investigate and take appropriate action necessary to assure compliance with the Guide and AWR. These actions and further recommendations disposition will be submitted to the IO through UDV in writing.

5. Make written recommendations to the Institutional Official, regarding any aspect of the institution's animal program, facilities, or personnel training. The procedures for making recommendations to the Institutional Official are: Recommendations will be transmitted directly to the Institutional Official through the UDV.

6. Review and approve, require modifications in (to secure approval), or withhold approval of those activities related to the care and use of animals as set forth in the PHS Policy at IV.C. The IACUC procedures for protocol review are: The IACUC will meet at regularly scheduled bi-monthly sessions to review pending proposals and applications to determine compliance with PHS guidelines. For the purpose of ascertaining a quorum, only those members who have participated in at least one meeting during the preceding six months will be counted. Consecutive non-attendance for six months, unless a member is on Sabbatical leave, shall be deemed tantamount to resignation, and the quorum requirement will be reduced accordingly though no such adjustment will be made if to do so would be to certify a quorum that is below statutory requirements. Prior to the review the Administrative Assistant to the IACUC will distribute complete copies of proposals and applications to designated reviewers (ordinarily three for each proposal). All members of the Committee will receive a full list of applications and proposals to be reviewed, and will be provided access upon request to complete copies of each proposal. Though rarely applicable, it is IACUC policy to conduct full committee review of any proposals involving research on primates. No member shall participate in the IACUC review or approval of an application or proposal in which the member has a real or apparent conflict of interest except to provide information requested by the IACUC. The IACUC may invite consultants to assist in the review of specialized areas. Consultants may not approve or withhold approval of an application or proposal or vote with the IACUC. The reviewers will report their findings to the IACUC at the scheduled meeting. The IACUC will review proposals and applications to determine that the proposed activities are in accordance with PHS Policy as outlined in Section IV.C, the Animal Welfare Act, and other statutes as applicable. The IACUC will withhold approval when such proposals and applications are not in compliance. Approved proposals will be returned to the appropriate sources for processing and submission to appropriate agencies accompanied by a letter to verify IACUC approval of the project relating to the proposed care and use of animals. The Howard University Vertebrate Animal Care and Use Assurance/Certification/Declaration will be signed by the IACUC Chairman, who has been authorized by the Institutional Official to be administratively responsible for the program. In accordance with Section IV.D.2 of the PHS Policy, such verification will be submitted subsequent to peer review but prior to award.

7. Review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the use of animals in ongoing activities as set forth in the PHS Policy at IV.C. The IACUC procedures for reviewing proposed significant changes in ongoing research projects are: Changes in ongoing research or teaching activities that have an impact on the care and use of animals should not be initiated without IACUC approval. The researcher/ instructor is responsible for submitting a request for prior approval of a modification prior to implementation. Examples of proposed modifications that require prior approval include the following: (a) change in venue; (b) change in principal investigator; **8**) change in number of animals or species; (d) modification(s) of experimental procedures such as type of drug to be administered or method of euthanasia to be used.

8. Notify investigators and the institution in writing of its decision to approve or withhold approval of those activities related to the care and use of animals, or of modifications required to secure IACUC approval as set forth in the PHS Policy at IV.C.4. The IACUC procedures to notify investigators and the institution of its decision regarding protocol review are: In those cases in which approval of the proposal is withheld or a proposal requires modifications(s), animal care and use deficiencies shall be identified in writing. Proposals that require modifications in animal care and use aspects will be returned by the IACUC to the submitter for revisions. Such proposals will not be approved by the IACUC until the recommended revisions are made. IACUC approval also will be communicated to investigators in writing.

9. Conduct continuing review of each previously approved, ongoing activity covered by PHS Policy at appropriate intervals as determined by the IACUC, including a complete review in accordance with the PHS Policy at IV.C. 1-4. at least once every three years, of research protocols that span periods greater than three years. The IACUC procedures for conducting continuing review are: The committee reviews at least once annually all continuing animal care and use proposals; and progress reports, including the number of animals used in the prior approval period and the number to be used for each year of research. IACUC approval is for one year only, and all continuing proposals are given a complete review every three years as mandated by PHS policy.

10. Be authorized to suspend an activity involving animals as set forth in the PHS Policy at IV.C.6. The IACUC procedures for suspending an ongoing activity are: The IACUC will suspend an activity involving animals set forth in the PHS Policy, if it is determined that the activity is not being conducted in accordance with the provisions of the Animal Welfare Act, the Guide and this institution's Assurance. The issue will be reviewed at a specially convened meeting of the IACUC, and a majority vote of the quorum will be required for suspension. The Committee chairperson will report the vote to the Institutional Official through the UDV, who will consult with the IACUC regarding the suspension. If suspension is upheld, the IO will take appropriate corrective action and a full report of that action with an explanation will be made to the Office of Laboratory Animal Welfare (OLAW).

E. The individual(s) authorized by this institution to verify IACUC approval of those sections of applications and proposals related to the care and use of animals is the Chairperson of the IACUC.

F. The occupational health and safety program for personnel who work in laboratory animal facilities or have continued contact with animals is: See Attachment B.

G. The total gross number of square feet in each animal facility (including each satellite facility), the species of animals housed therein and the average daily inventory of animals, by species, in each facility is provided in the attached table. See Attachment C.

H. The training or instruction available to scientists, animal technicians, and other personnel involved in animal care, treatment, or use will be provided by the Laboratory Animal Training Association (L.A.T.A.) There are three interactive modules The Base Module which include laws, regulations, ethics, alternatives, IACUC and staff responsibilities; The Species Modules which

include housing, social needs, nutrition, health considerations, handling, restraint, experimental techniques, environmental practices and euthanasia; and The Techniques Module which demonstrate current acceptable practices and techniques. The Occupational Health Training Course is given formally every two years.

IV. INSTITUTIONAL STATUS

As specified in the PHS Policy at IV.A.2. the College of Medicine Facility is a Category I facility. The other satellite facility is Category 2. All of this institution's programs and facilities (including satellite facilities) for activities involving animals are inspected by the IACUC twice a year. The IACUC will continue to use the Guide as a basis for evaluating the institution's programs and facilities. The report contains a description of the nature and extent of the institution's adherence to the Guide. Any departures from the Guide are identified specifically and reasons for each departure are stated. Where program or facility deficiencies are noted, the report contains a reasonable and specific plan and schedule for correcting each deficiency. The report distinguishes significant deficiencies from minor deficiencies.

V. RECORD KEEPING REQUIREMENTS

A. This institution will maintain for at least three years:

1. A copy of this Assurance and any modifications thereto, as approved by PHS.
2. Minutes of IACUC meetings, including records of attendance, activities of the committee, and committee deliberations.
3. Records of applications, proposals, and proposed significant changes in the care and use of animals and whether IACUC approval was given or withheld.
4. Records of semiannual IACUC reports and recommendations (including minority views) as forwarded to Institutional Official.
5. Records of accrediting body determinations.

B. This institution will maintain records that relate directly to applications, proposals, and proposed changes in ongoing activities reviewed and approved by the IACUC for the duration of the activity and for an additional three years after completion of the activity.

C. All records shall be accessible for inspection and copying by authorized OLAW or other PHS representatives at reasonable times and in a reasonable manner.

VI. REPORTING REQUIREMENTS

A. At least once every 12 months, the IACUC, through the Institutional Official, will report in writing to OLAW:

1. Any change in the status of the institution or change in the description of the institution's program for animal care and use as described in this Assurance, or any changes in IACUC membership. If there are no changes to report, this institution will provide OLAW with written notification that there are no changes.

2. Notification of the dates that the IACUC conducted its semiannual evaluations of the institution's program and facilities (including satellite facilities) and submit the evaluations to the President.

B. The IACUC, through the Institutional Official, will provide the OLAW promptly with a full explanation of the circumstances and actions taken with respect to:

1. Any serious or continuing noncompliance with the PHS Policy.

2. Any serious deviations from the provisions of the Guide.

3. Any suspension of an activity by the IACUC.

C. Reports filed under VIA. and VI.B. above shall include any minority views filed by members of the IACUC.

VII. INSTITUTIONAL ENDORSEMENT AND PHS APPROVAL

A. Authorized Institutional Official

Name: H. Patrick Swygert

Title: President

Address: Howard University
2400 Sixth Street, N.W.
Washington, D.C. 20059

Phone: (202) 806-2500

Fax: (202) 806-9243

Signature: _____

Date: _____

B. PHS Approving Official

Name:

Title:

Address: 6705 Rockledge Drive-RKL1, Suite 360, MSC 7982
Bethesda, MD 20892-7982

Phone: 301-496-7163

Fax: 301-402-7065

Signature: _____

Date: _____

C. Effective Date of Assurance: _____

D. Expiration Date of Assurance: _____