URSINUS COLLEGE A4347-01

ANIMAL WELFARE ASSURANCE In accordance with the PHS Policy for Human Care and Use of Laboratory Animals

I, Lucien T. Winegar as named Institutional Official for animals care and use at Ursinus College, hereinafter referred to as Institution, by means of this document, provide assurance that this Institution will comply with the Public Health Service Policy on Humane Care and Use of Laboratory Animals, hereinafter referred to as PHS Policy.

I. APPLICABILITY OF ASSURANCE

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 a PHS-conducted or -supported activity by this institution. "Institution" includes the following branches and major components of Ursinus College: Ursinus College Campus.

"Institution" also includes the following: none

II. INSTITUTIONAL COMMITMENT

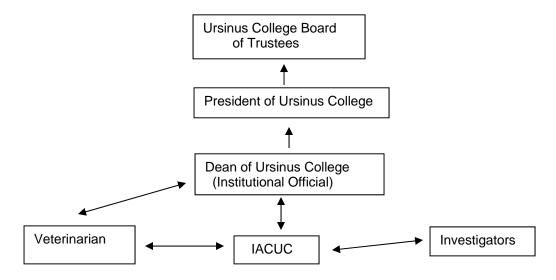
- A. This institution will comply with all applicable provisions of the Animal Welfare Act and other Federal statutes and regulations relating to animals.
- B. This institution is guided by the "U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and 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 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."

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 as follows: The IACUC reports directly to the Vice President for Academic Affairs and Dean of the College who serves as the

Designated Institutional Official overseeing the Animal program. The Dean of the College reports directly to the President of the College. The animal facility is managed and maintained by the Department of Biology. Dr. Beth Bailey, Associate Professor of Biology and Chairperson of the IACUC reports directly to the IACUC and has direct access to the veterinarian and the Dean of the College. The veterinarian will have direct communication with the IACUC, and the Dean of the College. These relationships are outlined in Fig. 1.

Fig. 1. Lines of authority and responsibility for administering the program and ensuring compliance.



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

Name: Dr. William Singleton

Qualitications:

- Degrees: B.S. University of Maryland, 1987; DVM Tuskegee University, 1991
- Training and/or experience in laboratory animal medicine: Dr. Singleton is a member of the American College of Laboratory Animal Medicine, the American Association for Laboratory Animal Science, and the American Society of Training and Development. After receiving his DVM he trained as the staff veterinarian at the Southwest Foundation for Biomedical Research, San Antonio, TX from 1991-1995, then was employed as staff veterinarian at Rhone-Poulenc Rorer Pharmaceuticals, Collegeville, PA from 1995-1999, as Manager of Veterinary Services and Attending Veterinarian at Aventis Pharmaceuticals, Collegeville, PA from 1999-2000, and was the Associate Director of Clinical Care and Training at the University of Pennsylvania, Philadelphia, PA from 2001-2007. In 1999 he was awarded Diplomate status from the American College of Laboratory Animal Medicine. Since 2007, Dr. Singleton has been the Principle Training Consultant for Animal Care Training Services, King of Prussia, PA.

Authority: Dr. Singleton has direct program authority and responsibility for the Institution's animal care and use program.

Time Contributed to Program: The veterinarian is available on an as-needed or consultant basis. The small animal facility and small animal population does not warrant a full-time or part-time veterinarian. A local veterinarian, Dr. Sarah J. Callow, is available to handle emergencies should the veterinarian not be available.

C. The Institutional Animal Care and Use Committee (IACUC) at this Institution is properly appointed in accordance with the 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 five members, and its membership meets the composition requirements set forth in the PHS Policy, Section 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.

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 and the OLAW Sample Semiannual Program Review and Facility Checklist. The IACUC procedures for conducting semiannual program reviews are as follows:

The IACUC conducts a program review at least once every six months by the veterinarian, nonscientist/non-affiliated member, at least one scientist, and the Chair to evaluate the institution's program for the humane care and use of animals, using the "Guide" as a basis for evaluation. Items included are: IACUC membership and function; IACUC records and reporting requirements; veterinary care; personnel qualifications and training, and occupational health and safety of personnel. A report is prepared according to PHS policy criteria and is discussed at a meeting or meetings of the full Committee. If necessary, modifications are made prior to taking action and then

the finalized report is forwarded to the Institutional Official.

- 2. Inspect at least once every six months all of the Institution's animal facilities, including satellite facilities, using the "Guide" as a basis of evaluation and the OLAW Sample Semiannual Program Review and Facility Inspection Checklist. The IACUC procedures for conducting semiannual facility inspections are as follows:

 The IACUC Chair designates IACUC members to conduct these inspections and this group or subcommittee includes the Consulting Veterinarian, nonscientist/non-affiliated member, at least one scientist, and the Chair. All committee members are invited to participate in the semiannual inspections. The members of the group or subcommittee are briefed about the findings of the previous inspection and the steps taken to address any problems or concerns, if applicable. A written report of the inspection is prepared according to PHS policy criteria and is submitted to the full committee for discussion and modification, if necessary, prior to taking action. The finalized report is then forwarded to the Institutional Official.
- 3. Prepare reports of the IACUC evaluation set forth in the PHS Policy at IV.B.3. and submit the reports to the Dean of the College. The IACUC procedures for developing reports and submitting them to the Institutional Official are as follows:

The Chair prepares a draft report using the OLAW Sample Semiannual Report to the IO (http://grants.nih.gov/grants/olaw/sampledoc/ioreport.htm) which incorporates the results of the facilities inspection subcommittee reports and applicable program review results. The reports also include any IACUC-approved departures from the "Guide," as well as the reasons for each departure. At a convened meeting, the draft report along with any additional facilities inspection or program review information is discussed and compiled into a final report. This report, along with any minority opinions and/or recommendations, are signed by a majority of the IACUC members and forwarded to the Institutional Official. Deficiencies, categorized as minor or significant are tracked using a review check list. This checklist also indicates the plan and schedule for correction of each deficiency and is included in the report to the IO. All identified deficiencies are corrected, or a plan is in place, before the next meeting of the IACUC.

- 4. Review concerns involving the care and use of animals at the institution. The IACUC procedures for reviewing concerns are:
- Concern(s) involving the care and use of animals may be submitted to the IACUC, the Chair of the Biology Department, or the Dean of the College. Anonymous concerns may be directed to Georgette Druckenmiller, the unaffiliated member. Individuals at Ursinus College are alerted to these reporting avenues by signs posted in animal use and housing areas, and information posted on the Ursinus College website. All such concerns will be presented to the IACUC for review, discussion, and suggested resolution, all of which will be recorded and kept on file. Every concern of which the IACUC is made aware will receive attention and responses will be documented. All appropriate parties, including the Institutional Official and appropriate (e.g., Federal) oversight agencies (such as OLAW), will be made aware, in writing, of the outcome(s). The College assures protection against reprisal as required under the Animal Welfare Act.
- 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 as follows:

 The IACUC as a whole discusses and approves recommendations, which the Chair writes up to be submitted to the Institutional Official. Records are kept of all aspects thereof.
- 6. In accord with the PHS Policy IV.C.1-3, the IACUC shall review and approve, require modifications in (to secure approval), or withhold approval of PHS-supported activities related to the care and use of animals. The IACUC procedures for protocol review are as follows:

Completed requests for approval of animal utilization are submitted to the IACUC by the Principal Investigator (PI) for each project. Copies are provided to all IACUC members for discussion at the next scheduled meeting. If any question arises prior to the IACUC meeting, additional details and/or a meeting with the PI is requested. A full committee review (FCR) occurs at a convened meeting with a quorum of voting members present. A majority vote of the IACUC members present at the meeting is required to approve, require modifications in (to secure approval), or withhold approval of PHS-supported activities related to the care and use of animals. Minority opinions are allowed to

accompany any action. Committee members will inform the Chair of the IACUC if they, or any other member, have a conflict of interest. No IACUC member may participate in the IACUC review or approval of an activity in which that member has a conflicting interest (e.g., is personally involved in the activity) except to provide information requested by the IACUC. Conflict of interest may arise under a number of circumstances, including where a member's personal biases may interfere with his or her impartial judgment, a member is involved in a competing research program, or access to funding or intellectual information may provide an unfair competitive advantage. Any member with a conflict of interest is required to inform the IACUC chair and must recuse themselves from voting. If an investigator who has submitted a protocol or an amendment believes that an IACUC member has a potential conflict, the investigator may request that the member be excluded. Neither recused nor excluded members will contribute to the quorum necessary to conduct IACUC business. Outcomes of the IACUC's deliberation (i.e., approval, require modifications in (to secure approval), or withhold approval) are communicated to investigators, in writing, with required modifications or reasons for the IACUC's decision itemized. If the members of the full committee vote to require modifications in a protocol to secure approval and all members are present, they may either vote to, have the revised research protocol subsequently reviewed by designated member review (DMR) or returned for full committee review at a convened meeting. The vote to conduct DMR must be unanimous. However, if all members of the IACUC are not present at the meeting where a protocol was voted to require modifications, then they will follow the unanimously agreed upon written policy that the quorum of members present at a convened meeting may decide, by unanimous vote, to use DMR subsequent to FCR. In addition, any IACUC member may request to see the revised protocol and/or request FCR of the protocol. If DMR is selected, then the IACUC Chair will select at least one designated reviewer in addition to the IACUC veterinarian to conduct DMR. Each reviewer will review identical versions of the revised proposal and all designated reviewers must be unanimous in their decisions to approve, require further modifications in (to secure approval), or refer back to the full committee for further review. The decisions resulting from the DMR are final and documented in IACUC meeting minutes. DMR also may be used to review new protocols or proposed significant changes to an ongoing approved protocol that require approval before the next regularly scheduled IACUC meeting. In this case, prior to DMR, all IACUC members shall be given a copy of the proposed action and afforded an opportunity to comment and/or request full Committee review. Any one request for full Committee review will make a FCR mandatory. If DMR is allowed, then the IACUC Chair will select at least one designated reviewer in addition to the IACUC veterinarian to conduct DMR. Each reviewer will review identical versions of the revised proposal and must be unanimous in their decisions to approve, require modifications in (to secure approval), or refer back to the full committee for further review. The decisions resulting from the DMR are final and documented in IACUC meeting minutes.

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 IV.C. The IACUC procedures for reviewing proposed significant changes in ongoing research projects are as follows: The IACUC procedures for reviewing such proposed significant changes in ongoing research projects are identical to the procedures outlined in Item III.D.6 (above).
- 8. Notify investigators and the Institution in writing of its decision to approve or withhold approval of those activities related to the care and the use of animals, or of modifications required to secure IACUC approval as set forth in the PHS Policy IV.C.4. The IACUC procedures to notify investigators and the Institution of its decisions regarding protocol review are as follows:

 Notification of investigators and the institution of IACUC decisions shall be the responsibility of the Chairperson of the IACUC. All such correspondence shall include any required modifications needed to secure approval or any reasons for withholding approval, and giving investigators the opportunity to respond in person or 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 IV.C.1-4 at least once every three years. The IACUC procedures for conducting continuing reviews are as follows: Continuing reviews will be conducted at approximately twelve (12) month intervals. Continuing reviews will be conducted administratively by two (2) committee members (one of which should be the Veterinarian) with notification of the IACUC unless full Committee review is requested by either administrative reviewer. All correspondence regarding continuing reviews shall be handled by the IACUC as previously described (Item III.D.8.). Because each Animal-use protocol is considered unique and active for a maximum of three years, every three years investigators will be notified by the IACUC in writing prior to the expiration date of their protocol and requested to submit a completed questionnaire and summary of the previous period's activities. If the activity is to continue, investigators should submit a new protocol, which will be reviewed using the criteria and procedures for review specified in IV.C. of the PHS Policy and described in Part III.D.6 of this Assurance. Animal work may not continue past the expiration date of the previous protocol even if review of a protocol is pending; continuation of animal activities in the absence of valid approval is a serious and reportable violation of PHS Policy.
- 10. Be authorized to suspend an activity involving animals as set forth in the PHS Policy IV.C.6. The IACUC procedures for suspending an ongoing activity are as follows: The IACUC may suspend an activity only after review of the matter at a convened meeting of a quorum of the IACUC present. A majority vote is required. IACUC may suspend an activity that it previously approved if it determines that the activity is not conducted in accordance with applicable provisions of the Animal Welfare Act, the "Guide", the Ursinus Assurance, or IV.C.1.a-g of the PHS Policy. If a suspension is authorized, all activity will immediately cease, and the Institutional Official, in consultation with the IACUC, will review the reasons for suspension, take appropriate action, and report that action with a full explanation to the OLAW. If circumstances involving animal health, safety, and/or welfare dictate, the Veterinarian, a subcommittee

of the IACUC or the Institutional Official may temporarily suspend an activity. Such suspension and supporting evidence shall be reviewed by the full IACUC. All affected parties including, but not limited to, the investigator, the Institutional Official, and the appropriate oversight (e.g., Federal) agencies, shall be notified of the reasons for the suspension, any applicable corrective action(s) and any further action(s) anticipated.

- E. The occupational health and safety program for personnel working in laboratory animal facilities or have frequent contact with animals is as follows:
 - Employees and students involved in animal research are provided with an
 "Occupational Health for Students and Faculty Engaged in Animal Research
 Education and Prevention Packet". This packet provides information regarding the
 Occupational Health and Safety/Animal Hazard Program of the College, which is
 based upon Risk Assessment and Hazard Identification as described in the
 "Guide.". The 3-part program includes a health care Program, an education
 program and compliance policies for faculty and students engaged in animal
 research.
 - Employees, and academically enrolled students involved in animal research are required to submit the Health History/Medical Evaluation form to The Wellness Center. The campus Wellness Center has a clinician on staff who is involved in planning and monitoring occupational health, -who makes individual recommendations based upon the Health History/Medical Evaluation forms, who provides training regarding allergies to laboratory animals, and who handles minor emergencies. This clinician would also advise students and employees on precautions to be taken during pregnancy, illness, or decreased immunocompetence. The College maintains a contract with a local physician group to handle medical emergencies when the Wellness Center is not open. The Environmental Health and Safety Coordinator reviews and monitors the entire occupational health and safety program.
 - Any accidents or injuries to employees are reported to the College via an accident/incident report form supplied by the Physical Plant.
 - The Packet described above includes information regarding hazards and zoonoses associated with specific laboratory animals. In addition, those working with animals are encouraged to visit the University of California, Davis Risk Analysis Tools website for further information.
 - Students and faculty must document that they understand the College's
 Occupational Health and Safety/Animal Hazard Program before IACUC approval is
 given. The documentation of such is included in the IACUC Training Certification
 Form discussed in section G below.
 - There are currently no biohazards being used in any animal experimentation.

F. 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 Facility and Species Inventory table.

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

Students and faculty follow a standard training protocol that includes video training in humane practices of animal care, humane practices of animal use, and research methods that minimize animal pain and distress. In addition, experienced faculty will train students in the specific procedures required for their research. Students and faculty using animals in their research projects must document their training using the IACUC Training Certification Form. Students are under direct supervision of their faculty mentors. Submitted protocols must document why specific animals numbers are required for valid results and ways in which to limit animal pain and distress. IACUC members are supplied with Guides from the National Research Council for the care and use of laboratory animals and the care and use of mammals in neuroscience and behavioral research, publications from the Animal Welfare Institute, as well as occasional publications from the Humane Society on pain and distress.

IV. INSTITUTIONAL PROGRAM EVALUATION AND ACCREDITATION

All of this Institution's programs and facilities (including satellite facilities) for activities involving animals have been evaluated by the IACUC within the past six months and will be re-evaluated by the IACUC at least once every six months thereafter, in accord with the PHS Policy IV.B.1-2. Reports have been and will continue to be prepared in accord with the PHS Policy IV.B.3. All IACUC semiannual reports will include a description of the nature and extent of this Institution's adherence to the "Guide." Any departures from the "Guide" will be identified specifically and reasons for each departure will be stated. Reports will distinguish significant deficiencies from minor deficiencies. Where program or facility deficiencies are noted, reports will contain a reasonable and specific plan and schedule for correcting each deficiency. Semiannual reports of the IACUC's evaluations will be submitted to the Institutional Official. Semiannual reports of the IACUC evaluations will be maintained by this Institution and made available to the OLAW upon request.

This Institution is Category Two (2) – not accredited by the Association for Assessment and Accreditation of Laboratory Animal Care, International (AAALAC). As noted above, reports of the IACUC's semiannual evaluations (program reviews and facility inspections) will be made available upon request. The report of the most recent evaluations (program review and facility inspection) is attached.

V. RECORDKEEPING 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 Dr. Lucien T. Winegar, Dean of the College.
- 5. Records of accrediting body determinations.
- B. This Institution will maintain records that related 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. This Institution's reporting period is January 1 December 31. The IACUC, through the Institutional Official, will submit an annual report to OLAW on January 31 of each year. The report will include:
 - 1. Any change in the accreditation status of the institution (e.g., if the Institution obtains accreditation by AAALAC or AAALAC accreditation is revoked), any 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, the 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 submitted the evaluations to the Dean of the College.
- B. The IACUC, through the Institutional Official, will promptly provide OLAW 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 sections VI.A and VI.B of this document shall include any minority views filed by members of the IACUC.

VII. INSTITUTIONAL ENDORSEMENT AND PHS APPROVAL

A. Authorized Institutional Official
Name: Lucien T. Winegar
Title: Vice President for Academic Affairs, Dean of the College
Name of Institution: Ursinus College
Address: Box 1000, Collegeville, PA 19426
Phone: 610-409-3720
FAX: 610-409-3720
E-mail:
Signature:
Date:
B. PHS Approving Official
Name:
Title:
Address:
Phone:
Fax:
E-mail:
Signature:
Date:
C. Effective Date of Assurance:

D. Expiration Date of Assurance: