

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

Bowling Green State 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 a PHS-conducted or supported activity by this institution.

"Institution" includes the following branches and major components of Bowling Green State University:

- Bowling Green State University Main Campus, Bowling Green, OH 43403
 - Life Science Annex (LSCA)
 - Behavioral Neuroscience Animal Facility (BNAF)
 - Ecological and Ethological Research Station (EERS) – 3 miles north of the LSCA
 - Selected rooms within the Life Science Building
- Bowling Green State University Firelands Campus – 70 miles east north east of the Main Campus, in Sandusky, OH
 - Note – at this time no vertebrate animals are housed or used on this campus for teaching, research or testing. At such time as vertebrate animals to be used in teaching, research, or testing are housed at this location, this Assurance will be updated relative to how oversight and veterinary care will be ensured.

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.

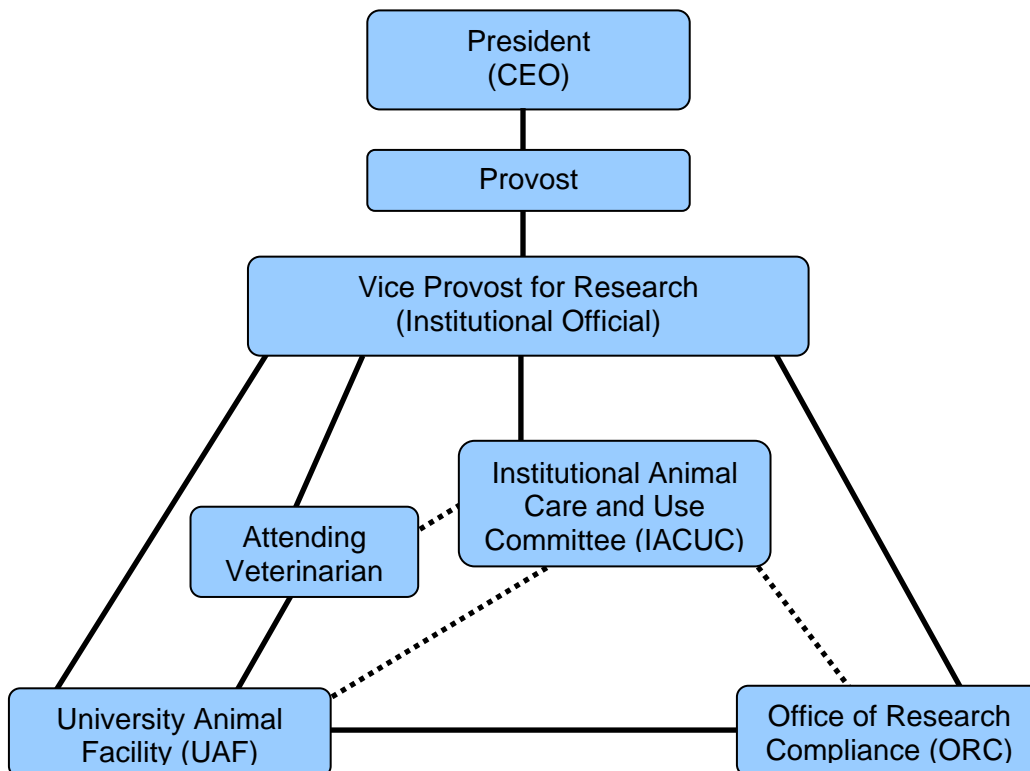
B. This institution is guided by the "U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training."

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 (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 as indicated in the following diagram:



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

Name: David A. Clark

Qualifications:

- Degrees: D.V.M., Ph.D.
- Training and/or experience in laboratory animal medicine: 18 years of veterinary experience in the use of various laboratory animal species, 7 years of pharmacology/endocrinology experience

Authority: Dr. Clark has direct program authority and responsibility to implement the PHS Policy and the recommendations of the Guide.

Time Contributed to Program: 10 hours each month with 50% dedicated to the Care and Use program.

Responsibilities:

- (a) Site visits to Bowling Green State University; conduct of clinical rounds at least once a month
- (b) Attendance at Bowling Green State University IACUC meetings
- (c) Faculty and staff training, as necessary

Name: Harold F. Stills

Qualifications:

- Degrees: D.V.M., Ph.D.
- Training and/or experience in laboratory animal medicine: 28 years of veterinary experience in the use of various laboratory animal species; Director, Laboratory Animal Resources Program, Wright State University School of Medicine, Dayton, OH

Authority: Dr. Stills is available as needed by telephone, fax, or e-mail for consulting purposes by UAF staff and Dr. Clark, on an as-needed basis. Dr. Stills has neither direct nor delegated responsibility to implement the PHS Policy and recommendations of the Guide.

Name: David P. Ernsthausen

Qualifications:

- Degrees: D.V.M.
- Training and/or experience in laboratory animal medicine: 11 years of veterinary experience with small animal medicine and surgery

Authority: Dr. Ernsthausen is available for emergency animal care services for evenings, weekends and holidays, on an as-needed bases, when the Dr. Clark is not available. Advise Dr. Clark on the condition of the animal(s) and any treatments provided. Dr. Ernsthausen has neither direct nor delegated responsibility to implement the PHS Policy and 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

chairperson and members of the IACUC and their names, degrees, position titles, specialties and institutional affiliations (**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. The IACUC procedures for conducting semiannual program evaluations are: The IACUC will meet at least once every six months to review the Institutional Program for Humane Care and Use of Animals. The Committee uses the Guide and other pertinent resources, e.g., the PHS Policy, the Code of Federal Regulations (Animal Welfare) as a basis for the review. To facilitate the evaluation, the Committee will use a checklist based on the Sample OLAW Program and Facility Review Checklist from the OLAW website. The evaluation will include, but not necessarily be limited to, a review of the following: a) IACUC Membership and Functions; b) IACUC Records and Reporting Requirements; c) Husbandry and Veterinary Care (all aspects); d) Personnel Qualifications (Experience and Training); and d) Occupational Health and Safety. In addition, the evaluation will include a review of the Institution's PHS Assurance. If program deficiencies are noted during the review, they will be categorized as significant or minor and the Committee will develop a reasonable and specific plan and schedule for correcting each deficiency. A significant deficiency is one that is or may be a threat to the health and safety of the animals. No member will be involuntarily excluded from participation in any portion of the reviews.

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: At least once every six months the IACUC will visit all of the institute's facilities where animals are housed or used, i.e., holding areas, animal care support areas, storage areas, procedure areas, and laboratories where animal manipulations are conducted. Equipment used for transporting of the animals is also inspected. The Committee uses the Guide and other pertinent resources, e.g., the PHS Policy, the Code of Federal Regulations (Animal Welfare) as a basis for the review. To facilitate the evaluation, the Committee will use a checklist based on the Sample OLAW Program and Facility Review Checklist from the OLAW website. If deficiencies are noted during the inspection, they will be categorized as significant or minor and the Committee will develop a reasonable and specific plan and schedule for correcting each deficiency. A significant deficiency is one that is or may be a threat to the health and safety of the animals. No member will be involuntarily excluded from participation in any portion of the inspections.

3. Prepare reports of the IACUC evaluations as set forth in the PHS Policy at IV.B.3. and submit the reports to the Institutional Official. The IACUC process for developing reports and submitting them to the Institutional Official is: Individual IACUC members will convey their observations to the IACUC Chairperson and Research Compliance Officer who, in turn, will draft the reports using the sample OLAW Semiannual Report to the Institutional Official format from the OLAW website. The reports will contain a description of the nature and extent of the institution's adherence to the Guide and the PHS Policy, identify specifically any departures from the provisions of the Guide and the

PHS Policy, and state the reasons for each departure. The reports will distinguish significant deficiencies from minor deficiencies. If program or facility deficiencies are noted, the reports will contain a reasonable and specific plan and schedule for correcting each deficiency. If some or all of the institution's facilities are accredited by AAALAC International the report will identify those facilities as such. Copies of the draft reports will be reviewed, revised as appropriate, and approved by the Committee. The final reports will be signed by a majority of the IACUC members and will include any minority opinions. If there are no minority opinions, the reports will reflect such. The completed reports will be submitted to the Institutional Official within 30 days following the evaluation.

4. Review concerns involving the care and use of animals at the institution. The IACUC procedures for reviewing concerns are: Any individual may report concerns to the IO, IACUC Chair, Institutional Veterinarian, or any member of the IACUC. Notices are located in the animal facilities advising individuals how and where to report animal welfare concerns and stating that any individual who, in good faith, reports an animal welfare concern will be protected against reprisals (**Attachment B**). All reported concerns will be brought to the attention of the full Committee. If necessary the IACUC Chair will convene a meeting to discuss, investigate, and address any reported concern. Reported concerns and all associated IACUC actions will be recorded in the IACUC meeting minutes. The Committee will report such actions to the IO and, as warranted, to OLAW.

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 regarding any aspects of the institution's animal program or facilities are discussed and developed by the Committee. The Committee's recommendations are included in the IACUC Meeting minutes or a report of the IACUC's evaluations or a separate letter. Such documents are approved by the Committee and then submitted to the IO.

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 review of activities involving animals (protocols) are: Prior to the review, each IACUC member shall be provided with written descriptions of activities (protocols) that involve the care and use of animals. Approval of those protocols may be granted only after review at a convened meeting of a quorum of the IACUC and with the approval vote of a majority of the quorum present. No member may participate in the IACUC review or approval of a protocol in which the member has a conflicting interest (e.g., is personally involved in the project) except to provide information requested by the IACUC; nor may a member who has a conflicting interest contribute to the constitution of a quorum. The IACUC may invite consultants to assist in the review of complex issues. Consultants may not vote with the IACUC unless they are also members of the IACUC.

If the IACUC requires modifications in activities involving animals, the committee can designate at least one member, qualified to conduct the review of these modifications and have the authority to approve, require further modifications in (to secure approval) or request full committee review of those modifications. Otherwise, approval of those

modifications may be granted only after review at a convened meeting of a quorum of the IACUC with the approval vote of a majority of the quorum present.

In order to approve proposed protocols or proposed significant changes in ongoing protocols, the IACUC shall conduct a review of those components related to the care and use of animals and determine that the proposed protocols are in accordance with this Policy. In making this determination, the IACUC shall confirm that the protocol will be conducted in accordance with the Animal Welfare Act insofar as it applies to the activity, and that the protocol is consistent with the Guide unless acceptable justification for a departure is presented. Further, the IACUC shall determine that the protocol conforms to the institution's PHS Assurance and meets the following requirements:

- a. Procedures with animals will avoid or minimize discomfort, distress, and pain to the animals, consistent with sound research design.
- b. Procedures that may cause more than momentary or slight pain or distress to the animals will be performed with appropriate sedation, analgesia, or anesthesia, unless the procedure is justified for scientific reasons in writing by the investigator.
- c. Animals that would otherwise experience severe or chronic pain or distress that cannot be relieved will be painlessly killed at the end of the procedure or, if appropriate, during the procedure.
- d. The living conditions of animals will be appropriate for their species and contribute to their health and comfort. The housing, feeding, and nonmedical care of the animals will be directed by a veterinarian or other scientist trained and experienced in the proper care, handling, and use of the species being maintained or studied.
- e. Medical care for animals will be available and provided as necessary by a qualified veterinarian.
- f. Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures.
- g. Methods of euthanasia used will be consistent with the recommendations of the American Veterinary Medical Association (AVMA) Panel on Euthanasia, unless a deviation is justified for scientific reasons in writing by the investigator.

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: Review and approval of significant changes are handled in the same manner as new protocols. See Paragraph 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 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 decisions regarding protocol review are: Principal Investigators are notified either by e-mail or letter from the Research Compliance Officer. The Institutional Official is notified by receiving a copy of the PI's notification letter and/or a copy of the IACUC meeting minutes, as well as a monthly report of protocol-related IACUC actions.

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. The IACUC procedures for conducting continuing review are: All ongoing activities are monitored continuously by the animal care and use staff and the associated protocols are reviewed by the IACUC at least annually. Annual protocol reviews are recorded in the IACUC meeting minutes. The IACUC meeting minutes are reviewed and approved by the Committee.

Protocols are approved for a maximum of 36 months. That is, all protocols expire no later than the three-year anniversary of the date of initial IACUC approval. If activities are to continue beyond the expiration date, a new protocol must be submitted, reviewed, and approved as described in Paragraph III.D.6. above.

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 may suspend an activity that it previously approved if it determines that the activity is not being conducted in accordance with applicable provisions of the Animal Welfare Act, the Guide, this Assurance, or IV.C.1.a.-g. of the PHS Policy. The IACUC may suspend an activity only after review of the matter at a convened meeting of a quorum of the IACUC and with the suspension vote of a majority of the quorum present. If the IACUC suspends an activity involving animals, or any other institutional intervention results in the temporary or permanent suspension of an activity due to noncompliance with the Policy, Animal Welfare Act, the *Guide*, or this Assurance, the Institutional Official in consultation with the IACUC shall review the reasons for suspension, take appropriate corrective action, and report that action with a full explanation to 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/are as follows: The IACUC Chairperson, the Institutional Official, or the Research Compliance Officer.

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

1. Personnel covered by BGSU's occupational health and safety OH&S portion of the Animal Care Program include everyone who has approved access to animal facility space. Full participation is not required though it is recommended. Only

permanent employees of UAF are required to participate to the fullest of the available program.

2. OH&S oversight is provided by Environmental Health & Safety (EH&S) in the following institutional policies: Lab Safety-Chemical Hygiene, Personal Protective Equipment – including Respiratory Protection and Hazard Communication. The following procedures are in place through EH&S for OH&S: Hazardous Waste, Emergency Response, Fire Safety and Radiation Safety
3. Personal hygiene is addressed by the provision of hand soap and paper towels in all animal housing rooms and throughout each facility. Dust masks, respirators, latex or vinyl gloves, lab coats, shoe covers and hair covers are provided to clients. Shower facilities are located adjacent to the lobby of the LSCA. Limited locker space is available. All UAF employees change from street clothes into designated work clothes before entering the facility. UAF provides laundry facilities in the LSCA for UAF designated clothing.

Animal Facilities Hazard and Risk Assessment

	LEP	MEP	HEP
Animal Related Injury	Low	Medium	Low
zoonoses	Low	Low	Low
Equipment related Injury	Low	Low	Medium
Chemical	Low	Low	Medium
Slip and Fall	Medium	Medium	High
Laboratory Animal Allergy	Low	Medium	High

Low Exposure Person (LEP): Less than 1 hour a week contact time.

Medium Exposure Person (MEP): Between 1 hour a week and 20 hours a week contact time.

High Exposure Person (HEP): UAF staff and individuals with 20 or more hours a week contact time.

4. Measures taken to alleviate identified risks include but are not limited to: latex gloves, cotton laboratory coats and dust masks are provided to reduce allergen exposure. Individuals are trained in proper animal handling technique under supervision prior to working on their own with the animals. Open toed shoes are not allowed in UAF. Correct operation of all machinery is taught to those individuals who will use the equipment prior to using it. Wet floors are identified when possible by moveable signage and permanent signage where water is a frequent hazard.
5. All individuals who routinely come into contact with animals are required to have current tetanus vaccination.
6. Allergen information is provided during mandatory web based training. When an individual indicates they have allergies or asthma additional information on

laboratory animal allergens and the use of personal protective items is addressed in person by the Director. Personnel training on zoonoses, allergies, hazards, injuries, special precautions for pregnancy, illness, etc. are handled as a section of the training provided and required of covered personnel.

7. Personnel protection: all UAF staff participate in the OH&S respirator fit test program. Latex gloves, respirators and dust masks are provided by UAF for all individuals working in UAF.
8. Reporting and treating injuries: first aid is centrally located in both the BNAF and LSCA. If additional treatment is required individuals are taken to Wood County Hospital. All injuries are reported to EH&S.

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 (**Attachment C**).

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

1. Three BGSU-developed online courses and tests offered through www.researchtraining.org. These are based upon the core program delineated in Education and Training in the Care and Use of Laboratory Animals – A Guide to Developing Institutional Programs, National Academy Press, Washington, D.C., 1991. Topics covered include:
 - a. Regulations, guidelines, policies, and procedures; ethics in animal research; responsibilities of the institution, researchers, the IACUC and University Animal Facilities staff.
 - b. Pain and distress; alternatives to painful/distressful procedures; husbandry, care and the importance of the housing environment.
 - c. Anesthesia, tranquilizers, analgesics and neuromuscular blocking agents; surgery (survival and non-survival); euthanasia.
2. Seminars and workshops conducted by the UAF Director or the Attending Veterinarian on various topics related to the care and use of animals in research, testing, and teaching. Topics covered include federal regulations and policies, UAF and IACUC policies and procedures, animal handling techniques, anesthesia and euthanasia techniques, and aseptic surgical techniques.
3. Special training sessions may be arranged at the request of the IACUC Chair, UAF Director, Attending Veterinarian, or researchers.
4. Individual researchers provide species- and technique-specific training to graduate and undergraduate students and other personnel in their laboratories on a continuing, as-needed basis.

5. The Attending Veterinarian is available at all reasonable times for consultation with IACUC members, researchers, and UAF staff via telephone, e-mail, or in person.
6. Training provided by the Institution's Environmental Health and Safety department on topics such as BGSU's Chemical Hygiene Plan, Fire Safety, and Bloodborne Pathogens.
7. Supplemental training via additional selected online instructional programs (public courses) available from www.researchtraining.org. These programs include:
 - a. Working with the IACUC (Non-VA version)
 - b. Essentials for IACUC members
 - c. Post-Procedural Care of Mice and Rats in Research: Reducing Pain and Distress
 - d. Working with Mice in Research Settings
 - e. Working with Rabbits in Research Settings
 - f. Working with Rats in Research Settings
 - g. Working with Amphibians in Research Settings

In addition to the above, the Institution provides opportunities for UAF Staff to attend animal care related meetings and to attain American Association for Laboratory Animal Science (AALAS) certification (several of the UAF staff hold various AALAS Certifications). Members of the IACUC are encouraged and funded to attend various local, regional and national workshops and conferences on animal care and use provided by other institutions, organizations, OLAW, and the USDA. Reference information relative to the care and use of animals is also available on the IACUC's web site.

Training is documented via the following:

1. Sign-in/attendance logs for in-person training
2. Completion/attendance certificates from workshops and conferences
3. Validation of www.researchtraining.org course/exam completion by ORC

Training documentation is maintained by ORC and records of training "events" completed by each individual are logged into an ORC-maintained database.

IV. INSTITUTIONAL STATUS

As specified in the PHS Policy at IV.A.2, as Category 2, all of this institution's programs and facilities, including satellite facilities, for activities involving animals have been evaluated by the IACUC and will be reevaluated by the IACUC at least once every six months in accord with IV.B.1. and 2. of the PHS Policy, and reports prepared in accord with IV.B.3. of the PHS Policy.

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 evaluations will be submitted to the Institutional Official. Semiannual reports of IACUC evaluations will be maintained by this institution and made available to the Office of Laboratory Animal Welfare (OLAW) upon request. The most recent semiannual report of the IACUC is attached (**Attachment D**).

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 the 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 (*e.g., if the institution becomes accredited 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, 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 submitted the evaluations to the Institutional Official.

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 VI.A. 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: Heinz Bulmahn, Ph.D.

Title: Vice Provost for Research and Dean of the Graduate College

Address: 120 McFall Center
Bowling Green, OH 43403-0083

Phone: 419-372-7714

Fax: 419-372-8569

Signature:



Date:

12/19/06

B. PHS Approving Official

Name:

Dr. Patricia A. Brown

Title:

Acting Director, Division of Assurances, OLAW

National Institutes of Health

RKL1, Suite 360-MSB 7982

Address:

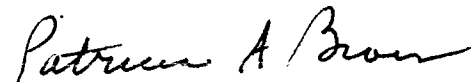
6705 Rockledge Drive

Bethesda, MD 20892-7982

Phone:

Fax:

Signature:



Date:

11/4/07

C. Effective Date of Assurance: 9/4/07

D. Expiration Date of Assurance: 11/31/11