

# Institutional Animal Care and Use Committee Procedure Guidebook

(apropos to the OLAW approved Animal Welfare Assurance, # A3784-01, which expires on 09/30/13)

# Position Statement

The University of Maryland Baltimore County believes the responsible use of laboratory animals is essential for research into the understanding, prevention and treatment of human and animal disease. We affirm the moral obligation of our scientists to carry out this research on behalf of mankind and animals. Millions of Americans are alive today, and live healthier and more productive lives because our nation's health care professionals are able to employ safe and effective treatments including vaccines, surgical procedures, drug therapies and other valuable therapeutic methods developed with animal research.

These same advancements in science, improving the quality of life for mankind, are also being used by veterinarians to save our cherished pets, companion animals, enhance the health of farm animals, and preserve a future for wildlife and endangered species. The benefits of animal research to human and animal health are virtually unchallengeable and are substantiated by scientific literature. UMBC supports this essential research for the benefit of current and future generations.

While we continue to seek other means of testing new medicines and techniques, animals continue to be the best model for researchers attempting to understand and cure human disease. For the most part, alternatives to animal use such as tissue and cell cultures are useful as supplements to research, but have not entirely replaced the necessity for live animal testing. Computer modeling is also a valuable adjunct to research, but cannot replace the prudent use of animals. However, the University of Maryland Baltimore County does believe in the three R's of research animal use whenever possible: replacing, reducing, and refining. This means replacing of animals with cell cultures, or vertebrates with invertebrates whenever possible; reducing the number of animals used by responsible experimental design and improved statistical inferences; and refining techniques to eliminate any possible pain or discomfort.

Researchers at UMBC share the public's concern about the responsible use of animals in research. Peer committees and stringent federal guidelines (Public Health Service Policy and Animal Welfare Act) require scientists to explore other means of experimentation before considering animal testing. All research, whether or not supported by Public Health Service (PHS) funds and conducted at UMBC, or at another institution as a result of a subgrant or subcontract, employing live vertebrates must be reviewed and approved in advance by UMBC's Institutional Animal Care and Use Committee to ensure that animal use is necessary and that high standards of humane care are observed.

In addition to ensuring the judicious use of animals, the University administration and researchers share the responsibility to safeguard the welfare of laboratory animals. UMBC's animal facilities are in full compliance with the applicable laws and regulations and are managed by highly qualified professionals who specialize in laboratory animal care.

UMBC defends the right of free speech. However, our responsibilities of providing and advancing medical care to society demand that we do not capitulate to tactics of intimidation and violence which undermine our democratic traditions and threaten the principle of free scientific inquiry. Therefore, UMBC cannot tolerate such acts on University property and will not allow such acts to influence University policy. To the extent necessary, we will prosecute or discipline those who break the law or UMBC regulations.

It is essential that we continue to preserve and protect the right of our researchers to pursue knowledge for those who wait for better therapies and treatments for disease and disability, and for the good of all human and animal kind.

## Contact Information

|  |                   |              |
|--|-------------------|--------------|
| UMBC Facilities Management                     | Work Control      | 410-455-2550 |
| University Police                              |                   | 410-455-5555 |
| Environmental Safety and Health                | Michael Pound     | 410-455-2918 |
| University Health Services                     | Jennifer Lepus    | 410-455-2542 |
| UMBC IACUC Chair                               | Suzanne Rosenberg | 410-455-2237 |
| Veterinary Resources                           |                   | 410-706-3540 |
| Office for Research Protections and Compliance | Timothy Sparklin  | 410-455-2737 |
| Institutional Official                         | Geoff Summers     | 410-455-5827 |

## Animal Welfare Assurance

UMBC has an Animal Welfare Assurance (A3784-01, approved through 09/30/2013) from the Office of Laboratory Animal Welfare.

UMBC is Category Two (2) institution, which is not accredited by the Association for Assessment and Accreditation of Laboratory Animal Care, International (AAALAC). However, all 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. 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. Semiannual reports of the IACUC evaluation submitted to the IO will also contain a reasonable and specific plan and schedule for correcting each deficiency and distinguish significant deficiencies from minor deficiencies. Semiannual reports of IACUC evaluations will be maintained by this institution and sent to OLAW as required or upon request.

As a matter of institutional policy, UMBC will comply with all applicable provisions of the "Animal Welfare Act" and other Federal statutes and regulations relating to animals. UMBC is guided by the "U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training." UMBC also acknowledges and accepts responsibility for the care and use of animals involved in activities covered by this Assurance. As partial fulfillment of this responsibility, UMBC will 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.

## Individual Institutional Responsibilities

### Institutional Official

The President of the University of Maryland, Baltimore County (UMBC) delegates, through the Provost, to the Vice President for Research to be the Institutional Official (IO) with the authority to

sign the UMBC Assurance. The IO is responsible for the overall administration of the Institutional Animal Care and Use Committee (IACUC) at UMBC. The IO ensures that UMBC complies with the "PHS Policy," *the Guide*, the "Animal Welfare Act," and other Federal statutes and regulations relating to animals. The Vice President for Research appoints members to serve on the UMBC IACUC for a three year term.

### **Institutional Animal Care and Use Committee**

The IACUC oversees the UMBC Animal Care and Use Program, facilities, and procedures. The Chair of the IACUC is selected from the membership of the Committee. The Chair of the IACUC and all of its members are appointed on an annual basis by the IO and report directly to the IO.

The primary mission of the IACUC is to provide humane and scientifically appropriate care of research animals at The University of Maryland Baltimore County. The facilities and program of animal care and use are maintained in compliance with the Animal Welfare Act of 1966 and all subsequent revisions (regulated by the USDA), and Public Health Service (PHS) guidelines.

### **Veterinary Resources**

The Veterinarians are voting members of the IACUC and have direct responsibility for activities involving animal care and use at UMBC. Specifically, the Veterinarians:

- Serve on the IACUC and have joint responsibility with the IACUC for animal use and welfare consistent with the *NIH Guide* and USDA "Animal Welfare Act."
- Provide advice on policies and procedures, experimental animal models, animal welfare, occupational health, hazard containment, and zoonosis control programs.
- Oversee activities of the animal care program supervisor and personnel.
- Provide clinical veterinary care and emergency treatment to animals.
- Review and inspect the housing and care of animals in each facility on a monthly basis and at each scheduled semi-annual inspection.

Backup and on-call veterinary care, off-site protocol review and consultation on various program related topics is delegated to and provided by licensed qualified veterinarians from the University of Maryland, Baltimore, Program of Comparative Medicine, Veterinary Resources.

### **Office for Research Protections and Compliance**

The Office for Research Protections and Compliance (ORPC) serves as the liaison between faculty members and senior research administrators and provides administrative support for the IACUC, including problem resolution, training, and coordination of IACUC administrative actions and management of the official records of the Committee.

### **Departmental Facility Supervisor**

The day to day management of a Departmental Animal Care Facility (Facility) is the responsibility of the Departmental Facility Supervisor (Supervisor). The Supervisor: 1) is a member of the faculty of the department where the facility is housed; 2) establishes Facility procedures in consultation with the Veterinarian and the IACUC that insure implementation of the policies and procedures of the IACUC, and the directives of the Veterinarian; 3) will make available and post in the Facility a copy of this Assurance; 4) directs the Animal Care Technician(s) and their assistants in the routine care of the animals and the maintenance of the facilities according to established procedures. The Departmental Facilities are also monitored by a faculty chair of the departmental animal care committee.

## **Animal Care Technicians**

The routine care of a Departmental Facility is done by the Animal Care Technicians and assistants. The Animal Care Technicians are responsible for implementing the written procedures and policies for animal care set forth by the Supervisor of the Departmental Facility. The Animal Care Technicians will keep written records as required, which are reviewed by the Veterinarian during his/her monthly visits and will immediately inform the Supervisor of any problems with the facility and the care of the animals.

## **Laws and Principles**

### **Federal Law**

Universities and the institutions or organizations, which carry out animal-based research or teaching, fall under the "Animal Welfare Act" (Public Law 890544, 1966 and subsequent amendments). In essence, the Act mandates unannounced inspections by officials of the U.S. Department of Agriculture to ensure compliance with regulations for humane care of animals used in research, their housing, and medical care including "the appropriate use of anesthetic, analgesic, or tranquilizing drugs, when such use would be proper in the opinion of the attending veterinarian at the research facility." The objective of the legislation is to "effectively minimize the pain and discomfort of the animals while under experimentation." Annual reports are required which the Human and Animal Research Protections Office prepares on behalf of UMBC.

### **Public Health Service Policy on Humane Care and Use of Laboratory Animals**

The policy requires that each institution receiving PHS funds for research involving animals submit detailed information in an Animal Welfare Assurance regarding the institution's program for the care and use of animals.

Awardee institutions are required to identify an institutional official who is ultimately responsible for the institution's program for the care and use of animals, and a veterinarian qualified in laboratory animal medicine that will direct or supervise the program. Institutions are also required to designate clear lines of authority and responsibility for those involved in animal care and use in PHS-supported activities.

The policy defines the role and responsibilities of the IACUC and requires the involvement of such committees in all aspects of PHS-supported research at those institutions. The policy requires that the IACUC include an individual unaffiliated with the institution, a veterinarian who has program responsibilities and who has training or experience in laboratory animal science and medicine, a practicing scientist experienced in research involving animals, and a member whose concerns are in a nonscientific area.

The policy requires the IACUC review and approves those sections of applications for PHS funds that relate to the care and use of animals before PHS funds may be awarded.

Institutions that are not accredited by the Association for Assessment and Accreditation of Laboratory Animal Care, International (AAALAC) are required to conduct a self-assessment of the institution's program, based on the [Guide for the Care and Use of Laboratory Animals](#), 2010. Significant deficiencies in the institution's program must be identified and the institution must adhere to an approved plan and schedule for correction of the deficiencies. Such institutions, including UMBC are assigned to "category 2" on PHS grants and contracts.

## **U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training**

The development of knowledge necessary for the improvement of the health and well-being of humans as well as other animals requires in vivo experimentation with a wide variety of animal species. Whenever U.S. Government agencies develop requirements for testing, research, or training procedures involving the use of vertebrate animals, the following principles shall be considered; and whenever these agencies actually perform or sponsor such procedures, the responsible Institutional Official shall ensure that these principles are adhered to:

I. The transportation, care, and use of animals should be in accordance with the [Animal Welfare Act \(7 U.S.C. 2131 et. seq.\)](#) and other applicable Federal laws, guidelines, and policies.\*

II. Procedures involving animals should be designed and performed with due consideration of their relevance to human or animal health, the advancement of knowledge, or the good of society.

III. The animals selected for a procedure should be of an appropriate species and quality and the minimum number required to obtain valid results. Methods such as mathematical models, computer simulation, and in vitro biological systems should be considered.

IV. Proper use of animals, including the avoidance or minimization of discomfort, distress, and pain when consistent with sound scientific practices, is imperative. Unless the contrary is established, investigators should consider that procedures that cause pain or distress in human beings may cause pain or distress in other animals.

V. Procedures with animals that may cause more than momentary or slight pain or distress should be performed with appropriate sedation, analgesia, or anesthesia. Surgical or other painful procedures should not be performed on unanesthetized animals paralyzed by chemical agents.

VI. Animals that would otherwise suffer severe or chronic pain or distress that cannot be relieved should be painlessly killed at the end of the procedure or, if appropriate, during the procedure.

VII. The living conditions of animals should be appropriate for their species and contribute to their health and comfort. Normally, the housing, feeding, and care of all animals used for biomedical purposes must 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. In any case, veterinary care shall be provided as indicated.

VIII. Investigators and other personnel shall be appropriately qualified and experienced for conducting procedures on living animals. Adequate arrangements shall be made for their in-service training, including the proper and humane care and use of laboratory animals.

IX. Where exceptions are required in relation to the provisions of these Principles, the decisions should not rest with the investigators directly concerned but should be made, with due regard to Principle II, by an appropriate review group such as an institutional animal care and use committee. Such exceptions should not be made solely for the purposes of teaching or demonstration.

\*For guidance throughout these Principles, the reader is referred to the [Guide for the Care and Use of Laboratory Animals](#) prepared by the Institute of Laboratory Animal Resources, National Academy of Sciences.

<http://grants.nih.gov/grants/olaw/references/phspol.htm#USGovPrinciples>

## **NIH Principles for Use of Animals**

(Federal Register, May 20, 1985, Vol. 50, No. 97, Office of Science and Technology Policy.)

These principles were prepared by the Interagency Research Animal Committee. This Committee, established in 1983, serves as a focal point for federal agencies' discussions of issues involving all animal species needed for biomedical research and testing. The committee's principal concerns are the conservation, use, care, and welfare of research animals. Its responsibilities include information exchange, program coordination, and contributions to policy development.

## **IACUC Roles and Responsibilities**

The UMBC IACUC meets quarterly to review and approval protocols. The committee:

- 1) Reviews all animal use protocols regardless of funding
- 2) Reviews significant changes to approved protocol
- 3) Reviews new protocols every three years by convened IACUC for continuing research

The usual practice of the IACUC is to review all protocols at convened meetings. All members are expected to review all protocols and be prepared to discuss the protocols and offer their comments. The use of telecommunications will be in accordance with NIH Notice NOT-OD-06-052 of March 24th, 2006, entitled Guidance on Use of Telecommunications for IACUC Meetings under the PHS Policy on Humane Care and Use of Laboratory Animals.

Prior to the review, each IACUC member will be provided with written descriptions of activities (protocols) or significant changes to protocols that involve the care and use of animals and any member of the may obtain, upon request, full committee review of those protocols. If full-committee review (FCR) is not requested, at least one member of the IACUC, designated by the chairperson and qualified to conduct the review, may be assigned to review those protocols and have the authority to approve, require modifications in (to secure approval) or request full committee review of those protocols. Other IACUC members may provide the designated reviewer with comments and/or suggestions for the reviewer's consideration only. That is, concurrence to use the DMR method may not be conditioned. If multiple designated reviewers are used, their decisions must be unanimous; if not, the protocol will be referred for FCR. If FCR is requested, 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.

Generally, the FCR method will be used. However, should a situation warrant it, the IACUC may use the designated-member review (DMR) method. In such instances the protocol will be distributed to all IACUC members to allow all members the opportunity to call for FCR; records of polling of members to obtain concurrence to use the DMR method, or concurrence by silent assent after seven (7) working days, and approval of protocols via DMR are maintained and recorded in the minutes of the next convened IACUC meeting.

Review and approval of significant changes are handled in the same manner as new protocols.

Examples of changes considered to be significant include, but are not limited to, changes:

- a. in the objectives of a study
- b. from non survival to survival surgery;
- c. resulting in greater discomfort or in a greater degree of invasiveness;
- d. in the species or in approximate number of animals used<sup>1</sup>;
- e. in Principal Investigator;
- f. in anesthetic agent(s) or the use or withholding of analgesics;

- g. in the method of euthanasia; and
- h. in the duration, frequency, or number of procedures performed on an animal

Principal Investigators are notified either by e-mail or letter from the IACUC Chairperson or his/her delegate (generally the ORPC). The Institutional Official is notified by receiving a copy of the PI's notification letter and/or a copy of the IACUC meeting minutes.

All ongoing activities are monitored continuously by the animal care and use staff and the associated protocols are reviewed by a member or members of 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 initial IACUC review.

### **Semi-annual program review and facility inspection**

The UMBC IACUC reviews the animal care and use programs and facilities every six months.

The program reviews include, but are not limited to, a review of the following:

- a. IACUC Membership and Functions
- b. IACUC Records and Reporting Requirements
- c. Veterinary Care (Animal Procurement and Transportation, Preventive Medicine, Surgery, Pain and Distress-Anesthesia and Analgesia, Euthanasia, Drug Storage and Control)
- d. Personnel Qualifications and Training
- e. 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 or personnel.

The facility inspections include, but are not limited to, inspection of the following:

- a. Animal Housing Areas
- b. Feed and Bedding Storage Areas
- c. Cage Wash Areas
- d. Surgery Areas
- e. Animal Procedure Areas
- f. Other Animal Care and Use (AC&U) Areas and AC&U Support Areas
- g. Any equipment used for transporting of the animals.

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 or personnel.

The IACUC will ensure no member desiring to participate in any portion of the program reviews or facility inspections is involuntarily excluded. All meetings will be posted on the UMBC IACUC website by the Administrator of ORPC and reminder notices will be sent at least two weeks prior to members.

IACUC members will draft a report based on the sample OLAW Semiannual Report to the Institutional Official format from the OLAW website. At a minimum, the report will:

- a. contain a description of the nature and extent of the institution's adherence to the Guide and "PHS Policy; and identify specifically any departures from the provisions of the Guide and "PHS Policy," and state the reasons for each departure
- b. distinguish significant deficiencies from minor deficiencies. A significant deficiency is one that, consistent with the "PHS Policy," and, in the judgment of the IACUC is or may be a threat to the health or safety of the animals
- c. note any program or facility deficiencies and specify a reasonable and specific plan and schedule for correcting each deficiency
- d. include any minority views filed by members of the IACUC; if there are no minority opinions the report will so state.
- e. will be signed by a majority of the IACUC members.

Copies of the draft reports will be reviewed, revised as appropriate, and approved by the Committee. Following completion of each evaluation, the completed report will be submitted to the Institutional Official in a timely manner.

## Protocol Submission, Review and Approval

### Protocol Submission and Review

The IACUC reviews all protocols for research and teaching involving live, vertebrate, non-human animals carried out in university facilities, as well as fieldwork conducted by UMBC personnel. This includes both sponsored and non-sponsored research. Non-sponsored research applications receive the same formal review as sponsored applications.

Protocol submissions must identify the species and approximate number of animals used; the rationale for using animals and the appropriateness of the species and numbers used; a complete description of the proposed use of the animals; a description of methods to minimize discomfort and pain when unavoidable; and a method of euthanasia. The investigators must also provide a justification for the animal model, for the number of animals required, and provide a description of the experimental manipulations to which the animals will be subjected.

The approval of animal use will be granted for a three-year period. The IACUC is required to review activities annually, even though it may be a multiple-year project.

Sufficient lead-time is necessary for the Committee to review each protocol; this should be taken into consideration in planning start dates or need for approval for funding agencies. Investigators will be provided opportunity to respond to Committee reviewer questions prior to full review and approval at each scheduled meeting. The IACUC will meet four (4) times a year and has instituted a schedule for investigators to submit protocols to allow for sufficient review. The protocol submission calendar is detailed on the ORPC web site, <http://www.umbc.edu/research/ORPC/> (click on IACUC).

See the [UMBC IACUC Forms](#) section of the web site for further guidance.

Upon receipt of the protocol, ORPC will review the protocol for completeness and forward the protocol to the members of IACUC within one week of the submission for review. The protocol will detail information on the species to be used, the projected number of animals required, the source of the animals, the method of euthanasia, and whether the animals will be used for teaching or research purposes. The investigators must also provide a justification for the animal model, for the number of animals required, and provide a description of the experimental manipulations to which the animals will be subjected

ORPC, on behalf of the IACUC Chair, will notify investigators of the IACUC's decision to approve or withhold approval of those sections of applications or proposals related to the care and use of animals, or of modifications required to secure IACUC approval. ORPC will electronically forward to investigators and instructors the IACUC's written decisions.

## Types of Approval

### Approval

Approval is granted when the Committee has no concerns about the application. The investigator is sent a response with a IACUC approval number, valid for three years, and may begin the project.

### Additional Information Requested

The committee agrees and requests additional information and/or justification regarding identified concerns before approval is reconsidered. The members will ask the investigator to clarify a point, provide further information, or make revisions in the protocol. The investigator's response must include a point-by-point response addressing all concerns, as well as a revised application. The response is then reviewed by the full committee. No approval is given until the questions and/or concerns of the Committee have been satisfactorily addressed.

### Disapproval

If disapproval is recommended by the committee, a letter detailing the reason(s) for the disapproval is sent to the principal investigator and the protocol is officially closed. The principal investigator must resubmit a new protocol that is reviewed as a new submission.

## Modifications or Amendments to Approved Protocols

Modifications to approved protocols must be documented appropriately, reviewed, and approved.

Minor modifications may entail such things as increasing by small numbers additional animal subjects, addition of new personnel (i.e. assignment of a new technician), the source or supplier of animals, minor procedure changes or changes to funding from sponsoring agencies. Minor changes must be proposed through submission of a Request for Minor Change/Amendment to an Animal Use Protocol form. Minor modifications are approved administratively by the IACUC Chair and the University Veterinarian without full committee review. See the [UMBC IACUC Forms](#) section of the web site for further guidance.

**Major modifications** may entail a large change in numbers of animals being used or requested, an increase in invasiveness, a change in species, an increase in pain or discomfort, or a change in the method of euthanasia. Significant changes in protocols for ongoing use of vertebrate animals in research, testing, and education will be submitted using a Request for Significant Change to Animal Use Protocol form for review at a regularly scheduled meeting of the full IACUC committee. Investigators must await approval by the IACUC before implementing the revised protocol procedures. Revised protocols must also meet the standards of the "Animal Welfare Act", the Guide, and State and local regulations. See the [UMBC IACUC Forms](#) section of the web site for further guidance.

## Annual Review Reports

The Human and Animal Research Protections Office (ORPC) will monitor the cycle and forward notification to investigators of the requirements for continuing review at least thirty (30) days before the scheduled end date.

An administrative review of vertebrate protocols is required prior to the end of the protocol period.

The investigator will submit to ORPC, at least thirty (30) days before the first day of the anniversary month, a report of any changes or departures from the originally submitted protocol and a narrative explanation for such changes. If no changes have been made, a statement to that effect must be submitted.

## Three-Year Renewals

PHS Policy (IV.C.5.) states "the IACUC shall conduct continuing review of activities covered by this policy at appropriate intervals as determined by the IACUC but not less than once every three (3) years". UMBC animal research protocols are approved for a three-year term. The investigator or instructor must resubmit, at least ninety (90) days before the next regularly scheduled IACUC meeting, a new application for Committee review in order to continue research activities.

It is the responsibility of the principal investigator (PI) to maintain the "approval" status of his or her protocol(s). ORPC will generally give advanced notice when protocols need three-year renewals and will provide help when requested.

Per PHS Policy, the IACUC may not extend the three-year approval by any means other than IACUC review and approval using the procedures of IV.C.2. When IACUC approval expires, it is no longer valid - there are no exceptions and no extensions of approval granted by the IACUC.

No experimental use or observation of animals may take place during a protocol lapse period. Continuation of animal activities beyond the expiration is a serious and reportable violation of PHS Policy.

Reports of adverse events, which are events that occur consistent with routine care or expected outcomes that results in an unexpected morbidity or mortality in animals that was not described in the animal use protocol, should be reported at the time of the problem or event and summarized in the Annual Report, including an explanation of how these events/problems were resolved.

A new Animal Research Protocol Form must be submitted; this form undergoes the same review process as any new protocol. The renewal should include all previous modifications or amendments made to the protocol since its original approval. See the [UMBC IACUC Forms](#) section of the web site for further guidance.

## Consideration of Alternatives

Animal research protocol applications should indicate that alternatives have been thought of and that a review of database searches been performed. A good faith effort must be made on the part of the researcher to consider the use of alternatives. This is an AWA requirement and is specified in the government principles for use and care of animals in the PHS policy. Alternatives can include non-animal models, procedures that cause less pain or distress, or non-mammalian models. The protocol narrative must include the databases searched, any consultation with experts, and the date of the search, the years covered by the search, and the key words utilized.

The animals selected for a procedure should be of an appropriate species and quality and the minimum number required to obtain valid results. Methods such as mathematical models, computer simulation, and in vitro biological systems should be considered. Researchers may use the variety of resources to complete the database search, found at Animal Welfare Information Center <http://www.nal.usda.gov/awic/databases/database.htm>

## Reporting Concerns Regarding the Care Treatment and Use of Animals

UMBC believes the responsible use of laboratory animals in research and instruction, and is committed to protecting the welfare of these animals. It is the responsibility of the UMBC IACUC to investigate all concerns regarding the care, treatment and use of animals for research or teaching on either campus or off campus if the concern involves faculty.

The IACUC will investigate all concerns regarding the care, treatment and use of animals for research or teaching on campus or off campus. Concerns are first discussed with the PI of the lab who should then discuss the concerns with the members of his/her laboratory. This will help eliminate the possibility of any erroneous perceptions. Many instances of noncompliance may be corrected within the laboratory. If this is not possible or is not successful, a report (anonymous or not) may be directed to the Chair of the IACUC. 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.

A report (anonymous or not) may be directed to the Chair of the IACUC. Alternatively, persons may contact the:

Office for Research Protections and Compliance (ORPC)  
bwtech@UMBC  
5523 Research Park Drive, Suite 310  
Baltimore, Maryland 21228  
Telephone: 410-455-2737  
Fax: 410-455-3868  
Email: [ORPC@umbc.edu](mailto:ORPC@umbc.edu)

Or

Attending Veterinarian  
Veterinary Resources-UM,B  
10 South Pine St., Room G-100, MSTF  
Baltimore, Maryland 21201  
410-706-3540

Such concerns may be written or verbal and no matter how initially raised, will be directed to the IACUC for preliminary evaluation of merit. 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.

Confidentiality of the individual raising the concern will be preserved to the extent necessary to conduct the review. The "Institution" will take steps to prevent any retaliatory action. The "Animal Welfare Act" protects the rights of individuals reporting animal welfare concerns and prohibits discrimination or reprisal for reporting violations of regulations or standards.

Regulatory Authority:

**Animal and Plant Health Inspection Service, USDA**

9 CFR Chapter 1, Subchapter A- Animal Welfare (Animal Welfare Act)

[http://oacu.od.nih.gov/regs/Title9\\_Part2.htm#23](http://oacu.od.nih.gov/regs/Title9_Part2.htm#23)

Section 2.31 Institutional Animal Care and Use Committee (IACUC), (c) IACUC Functions:

(4) "Review, and if warranted, investigate concerns involving the care and use of animals at the research facility resulting from public complaints received and from reports of non-compliance

received from laboratory or research facility personnel or employees."

### **Public Health Service Policy on Humane Care and Use of Laboratory Animals**

<http://grants.nih.gov/grants/olaw/references/phspol.htm>

#### IV. Implementation by Institutions

##### B. Functions of the Institutional Animal Care and Use Committee

(4). "review concerns involving the care and use of animals at the institution"

## Suspensions / Appeals of IACUC Decisions

The IACUC is authorized to suspend an activity involving animals as set forth in "PHS Policy" at IV.C.6. 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. The IO, in consultation with the IACUC, shall review the reasons for suspension, take appropriate corrective action, and report that action with full explanation to OLAW. A decision by the IACUC to suspend an activity may be appealed.

a. If approval of a proposal is denied by the IACUC because there are serious questions about the care and use of animals, the principal investigator or course instructor can request an appearance before IACUC to answer the questions raised by the Committee. The investigator or instructor may demonstrate, or be asked to demonstrate to the IACUC, the procedures to be used in the research.

b. If the first appeal to the Committee does not resolve matters to IACUC's satisfaction, the investigator or instructor may, after consultation with the Vice President for Research, request a second meeting with the IACUC. At this meeting the investigator or instructor may present expert witnesses from UMBC or elsewhere to testify to the adequacy or necessity of the animal care and use outlined in the proposal. The decision of the Committee following this meeting will be final.

## IACUC Files and Database

All IACUC files and databases are retained in the Human and Animal Research Protections Office. Paper copies of the IACUC files are kept in a file cabinet within the locked Human and Animal Research Protections Office. The database files pertaining to the IACUC are saved on a secure server with limited access. The IACUC files are retained under a password-protected sub-directory with limited access.

UMBC will maintain for at least three years:

1. A copy of the animal welfare assurance 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 any IACUC reports and recommendations as forwarded to the Institutional Official, University of Maryland, Baltimore County and to the Office of Laboratory Animal Welfare.

## Veterinary Medical Services

The staff of the University of Maryland, Baltimore, Program of Comparative Medicine, Veterinary Resources provides technical training such as blood withdrawal, administration of anesthetics, animal transportation, methods of euthanasia, etc. to support investigators in their research

activities. Training may also be provided for surgery, pathology and radiology. Inquiries and prior arrangements for these services can be arranged by contacting the Human and Animal Research Protections Office. Contact UMB Veterinary Resources at 410-706-3540.

## Animal Purchase and Care

Animals must be purchased or otherwise acquired from an approved commercial supplier (as listed below). No animals may be purchased without an IACUC approved [animal use protocol](#). Investigators with specific requests for animals from non-approved sources must submit a justification for their use in the animal use protocol submission, or via a minor modification form for already approved protocols. All requested purchases of species must be placed in accordance with UMBC Department of Procurement procedures and must correspond to a current IACUC approved protocol.

Animals from non-approved vendors or other sources have a great potential for carrying pathogens. When dealing with commercial suppliers, who have multiple production colonies, it is often best to try to obtain animals from the same colony to prevent differences in biological response. The current health status of animals requested from these sources, must be reviewed by the VR staff and the animals must be quarantined and tested by UM,B Veterinary Resources before they are placed in the UMBC colonies to ensure that they are pathogen free.

Harlan - <http://www.harlan.com>

Charles River - <http://www.criver.com>

Taconic - <http://www.taconic.com>

Jackson Labs - <http://www.jax.org>

Carolina Biological - <http://www.carolina.com/>

Charles Sullivan Co. - <http://www.researchamphibians.com/>

Zebrafish International Resource Center - <http://zebrafish.org/zirc/home/guide.php>

## Facility Access and Security

Only authorized personnel are permitted entry into animal facilities. All animal facilities are sealed by locked doors and are accessible only by key or by key card access.

### Employees

Employees who work in a particular animal facility, research staff listed in an IACUC-approved animal protocol that involves animals housed in a particular animal facility, and specified service personnel who may require occasional access for routine services (e.g., Facilities Management, Environmental Health and Safety, IACUC staff) are permitted access to animal facilities.

Access may be suspended or revoked if the employee does not observe animal facility regulations and procedures. Examples of situations in which access could be suspended or revoked include: allowing unauthorized persons to gain access into an animal facility; leaving animals in distress without reporting their condition to animal care staff; repeated or serious deviations from IACUC-approval protocols; placing personnel and animals at risk of harm. Employees requiring access to centralized animal facilities must complete the online Collaborative Institutional Training Initiative (CITI) animal care and use training module and have an occupational health screening prior to obtaining the access required. New personnel must be added to an approved protocol, via the principal investigator's submission of a protocol amendment before, animal facility access will be approved.

### Approved Visitors

Occasionally, non-employees may require access to animal facilities. These individuals may involve research collaborators visiting from other institutions, regulatory or accreditation site visitors, equipment vendors or maintenance personnel. UMBC wants to protect research animals and minimize any possibility of disease transmission between animals and visitors. Access is granted to only one location to help prevent the transmission of adventitious pathogens between facilities.

The visitor's host must notify the veterinarian and the animal facility supervisor, in writing, at least three (3) business days the name of each visitor, his/her institution or agency and purpose of the animal facility visit, date(s) involved, and contact information for the host. An employee of the facility must escort all hosts and visitors the entire time they are in an animal facility. Visitors will be asked to sign a guest book and required to wear a visitor's badge before entering a facility. Unauthorized persons (including visitors, friends, and children) are not permitted in the facilities without the approval of the veterinarian and the animal facility supervisor.

## Sponsored Programs Review of Grants

The UMBC Office of Sponsored Programs (OSP) will review all grant applications involving vertebrate animals. When an application is being submitted, the OSP will review and confirm that all information (i.e., the protocol's latest approval date and the institution's assurance number) is correct. If a protocol is pending, the word "PENDING" should be written in the space asking for the protocol's latest approval date.

When research involving vertebrate animals will take place at collaborating site(s) or other performance site(s) that have their own IACUC, the UMBC Principal Investigator should provide this information in a cover letter that accompanies the application. In these cases, the protocol and IACUC approval from the collaborating site(s) will be acceptable, provided all supporting correspondence is also provided. The UMBC IACUC may ask additional questions of the UMBC investigator. Also, the UMBC investigator must complete the cover sheet and the assurance form for UMBC. Finally, any such approval cannot exceed the duration of the approval obtained from the other institution.

## Training and Education for Investigators and Staff

The training or instruction available to scientists, animal technicians, and other personnel involved in animal care, treatment, or use is as follows: The Human and Animal Research Protections Office coordinates and informs scientists, animal technicians, and other personnel involved in animal care, treatment, or use of training or instructional programs that are available for use. Individuals using animals for the first time or employing unfamiliar techniques are provided on the job training regarding these procedures by the faculty in charge of the animal facility and by the Veterinarian on a regular basis during his/her regular visits.

The training or instruction available to the IACUC, investigators, animal technicians, and other personnel involved in animal care, treatment, or use is as described below:

### 1. IACUC

Upon appointment, members are provided educational materials including the UMBC Animal Assurance; PHS Policy on Humane Care and Use of Laboratory Animals; the Guide; AVMA Guidelines on Euthanasia (2007); Animal Welfare Act, Regulations and Standards; IACUC Guidebook; and the UMBC IACUC Policy and Procedure Guidebook. They are periodically provided additional information such as reprints of relevant journal articles and guidance updates. Members are provided information about OLAW and Public Responsibility in Medicine and Research meetings and webinars. On the job training also occurs during facility walk through and

observation of the protocol review process. All members complete the online Collaborative Institutional Training Initiative (CITI) Laboratory Animal Welfare Course "Essentials for IACUC Members" training module. Supplementary training opportunities are identified and offered to members when available.

## 2. Animal Care Personnel

Animal caretakers receive on the job training during orientation. Caretakers also complete the online CITI Laboratory Animal Welfare Course "Working with the IACUC" training module as well as the appropriate specialized species or model specific course offered by CITI.

## 3. Investigators and Research Technicians

All personnel performing procedures using animals must be identified in the Institutional Animal Care and Use Protocol. A description of each individual's qualifications, experience and/or training with the specific animal species, model and procedures must be provided for IACUC review. Any person needing additional protocol-specific training will be identified during the review process and such required training will be a condition of approval of the protocol.

All investigators and key personnel who participate in the design and/or the conduct of animal use research must be appropriately trained in the care and humane use of animal subjects. The University uses the Collaborative Institutional Training Initiative (CITI) web-based courses to satisfy this requirement for UMBC researchers. The training includes training or instruction on research or testing methods that minimize the numbers of animals required to obtain valid results and limit animal pain or distress as well as other requirements delineated in 9 CFR, Part 2, Subpart C, Section 2.32(c).

Training and instruction of personnel includes guidance in the following areas:

1. Humane methods of animal maintenance and experimentation, including:
  - a. The basic needs of each species of animal;
  - b. Proper handling and care for the various species of animals used by the facility;
  - c. Proper pre-procedural and post-procedural care of animals; and
  - d. Aseptic surgical methods and procedures;
2. The concept, availability, and use of research or testing methods that limit the use of animals or minimize animal distress;
3. Proper use of anesthetics, analgesics, and tranquilizers for any species of animals used by the facility;
4. Methods whereby deficiencies in animal care and treatment are reported, including deficiencies in animal care and treatment reported by any employee of the facility. No facility employee, Committee member, or laboratory personnel shall be discriminated against or be subject to any reprisal for reporting violations of any regulation or standards under the Act;
5. Utilization of services (e.g., National Agricultural Library, National Library of Medicine) available to provide information:
  - a. On appropriate methods of animal care and use;
  - b. On alternatives to the use of live animals in research;
  - c. That could prevent unintended and unnecessary duplication of research involving animals; and
  - d. Regarding the intent and requirements of the Animal Welfare Act and USDA-APHIS Regulations

Specialized Training: Training in experimental methods, i.e., specific animal manipulations and techniques and in the care of new and nontraditional laboratory animal species, will be conducted based on the types of research being conducted and the species being used at the institution.

Additional training materials (i.e. videotapes describing basic and specialized laboratory animal

techniques, texts, journals) are available from the University of Maryland, Baltimore, Program of Comparative Medicine, Veterinary Resources are available for animal facility staff and faculty, students, and technicians to use for further training and educational opportunities.

## Occupational Health Program

The program is based on risk assessment and includes all personnel involved in the care and/or use of laboratory animals. The occupational health and safety program is supported by UHS and OESH, who are responsible for implementing and overseeing the program. Supervisors and Principal Investigators are tasked to ensure that their personnel are adequately trained. However, ultimately it is the responsibility of the Institution to ensure that the OH&S program is fully developed, implemented, and maintained.

### a. Hazard Identification and Risk Assessment

All animal care employees of the University are required to undergo a complete physical examination at the time of employment, including history of any animal allergies, and a current tetanus inoculation with a booster every ten years. Animal care employees are required to receive a follow up physical examination by a physician on an annual basis. Animal care employees are encouraged to inform their personal physician that they work with animals. A copy of physical examination form shall be provided to UHS.

### b. Personnel Training

Animal care employees are provided a copy of "Procedures for Serious and Life-Threatening Emergencies". This document is also posted within each facility and is available from the OESH. Where applicable, investigators are expected to submit a statement to the OESH indicating their responsibilities of obtaining pertinent training and in adhering to correct procedures in handling biohazardous substances (e.g., radioisotopes, chemical agents, infectious agents). Laboratory supervisors shall also provide all employees with information regarding hazards to health, such as zoonoses and allergies that may be caused by contact with animals. The opportunity to obtain further information and training in how to control such allergies will also be provided through UHS and OESH. Personnel are advised that if they are planning to become pregnant, are pregnant, are ill, or have impaired immunocompetence that they should consult a health care professional/physician regarding such conditions and how they might pertain to their working with laboratory animals.

### c. Personnel Hygiene and Protection

The most common risks present while working in the UMBC animal facilities include:

1. Animal bites and scratches
2. Animal allergens from saliva, urine, blood, dander or fur
3. Zoonotic diseases, i.e. Salmonellosis, Yersinia enterocolitica

The minimum procedures required, as applicable, to minimize those risks include:

1. Training on proper animal handling techniques;
2. Following posted personal protective clothing and equipment requirements;
3. Washing hands after handling animals or related equipment
4. Using disposable supplies whenever possible;
5. Sanitizing lab work areas after animal work.

Eating, drinking and smoking are not allowed in research labs or animal housing areas. Animal care employees are provided with protective equipment, where appropriate, when working in the animal facilities at UMBC. Protective equipment may include cloth overalls, disposable

coveralls, disposable gowns, plastic gowns, rubber gloves, heat insulated gloves, sterile gloves, rubber boots, foot covers, surgical masks, respirators, face shields, ear protectors, and hats, as appropriate to the circumstance.

Supervisors and principal investigators shall file annually a personnel risk assessment report to OESH. Any injuries occurring on the job will be reported immediately to the next highest supervisor. When a faculty, staff or paid student employee has incurred a work-related injury, the injured person is to be referred directly to: University Health Services, Erickson Hall, Center Road, (410) 455- 2542. When University Health Services is not open, employees should be referred to: Concentra Medical Center, 1419 Knecht Avenue, Arbutus, Maryland, 21227 (410) 247-9595 or Friends Medical Center, Inc., 5820 Southwestern Boulevard, Arbutus, Maryland 21227, (410) 247-1417.

All work-related injuries must be reported to the OESH. The employee who is injured must complete an Employee's First Report of Injury form (available from the laboratory supervisor or on-line from the OESH website). The supervisor or designee must complete a Supervisor's First Report of Injury form and submit it to the OESH within one business day following the injury.

## Experiments Involving Biohazards

No hazardous agents (infectious, oncogenic, radioactive or chemical) may be used in any animal facility without being cleared by the IACUC. The use of radioactive materials requires additional approval by UMBC radiation safety office. If special caging and care are required, Veterinary Resources (VR) must be contacted well in advance (prior to submitting an animal protocol is recommended). The VR faculty and facilities personnel of VR are available for consultation and advice on matters relevant to animal housing, care and use when biohazard agents are proposed.

UMBC's Office of Environmental Safety and Health provides guidance for biosafety and experimentation and use of biohazardous agents. See the Laboratory Safety Guide for further information – online version at <http://www.umbc.edu/safety/>.

If radioactive substances, infectious organisms, toxic chemicals, or chemical carcinogens are to be used in-vivo, the following points must be addressed in your protocol to the IACUC:

- Biosafety Level
- Concentration
- Route of administration
- Duration of exposure
- Length of time animals will be kept following exposure
- Room location where agent is administered
- Location of animal housing post exposure
- Method of animal disposal

## Survival Surgical Procedures

The Institutional Animal Care and Use Committee have set minimum standards for animal operating rooms and laboratories in which surgery is performed. The standards are based on the NIH Guide for the Care and Use of Laboratory Animals. The standards are meant to ensure that surgical procedures are performed in an appropriate environment using good surgical techniques. Aseptic technique (e.g., surgical gloves, mask and sterile instruments) should be used for surgical procedures on rodents such as rats and mice; however, the standards for the surgical facility are

not as rigid. Rodent surgical areas may be a separate room or portion of a room. The area should be clean and orderly and should not be used for any other purpose during the time of the surgical activity. Animal housing areas may not be used for surgical procedures.

Non-survival surgical procedures may be performed in general purpose laboratories. The surgical site should be clipped, the surgeon should wear gloves, and the instruments and surrounding area should be clean.

The use of a survival surgical area for non-survival surgery is satisfactory provided the rules regarding survival surgery are followed, and the room is properly sanitized following the procedure. Any other laboratory outside of those designated for survival surgery CANNOT be used for survival surgical procedures in animals other than rodents.

## Prolonged Restraint

Brief physical restraint of animals for examination, collection of samples, and a variety of other clinical and experimental manipulations can be accomplished manually or with devices such as restraint stocks or squeeze cages. It is important that such devices be suitable in size and design for the animal being held and operated properly to minimize stress and avoid injury to the animal.

Prolonged restraint of any animal should be avoided unless essential to research objectives. Less restrictive systems, such as the tether system or the pole and collar system, should be used when compatible with research objectives. The following are important guidelines for the use of restraint equipment:

Animals to be placed in restraint equipment should be conditioned to such equipment prior to initiation of the research. The period of restraint should be the minimum required to accomplish the research objectives. The IACUC must approve prolonged restraint for any reason

Attention must be paid to the possible development of lesions or illnesses associated with restraint, including contusions, decubital ulcers, dependent edema, and weight loss. If these or other problems occur, veterinary care must be provided to treat the animal, which if necessary must be temporarily or permanently removed from the restraint device.

## Euthanasia

The “Public Health Service Policy on Humane Care and Use of Laboratory Animals”, “Animal Welfare Act” and the Guide for the Care and Use of Laboratory Animals require the IACUC to review and approve the proposed methods of euthanasia. The proposed methods must be consistent with the recommendations of the [AVMA Guidelines on Euthanasia](#) (formerly Report of the AVMA Panel on Euthanasia), published in June 2007, unless there are scientific justifications for alternative methods. The AVMA categorizes each method of euthanasia as acceptable (methods which consistently produce a humane death when used as the sole means of euthanasia), conditionally acceptable (methods which by the nature of the technique or because of greater potential for operator error or safety hazards might not consistently produce humane death or are methods not well documented in the scientific literature) and unacceptable (methods deemed inhumane under any conditions or that the panel found posed a substantial risk to the human applying the technique). The Office of Laboratory Animal Welfare (OLAW) has issued [policy guidance](#) clarifying current requirements regarding the use of carbon dioxide (CO<sub>2</sub>) as a euthanasia agent for small laboratory animals. Protocol applications should reflect the methods and guidance provided by the AVMA and OLAW.

Euthanasia is the act of humanely killing animals by methods that induce rapid unconsciousness

and death without pain or distress. In evaluating the appropriateness of methods, some of the criteria that should be considered are ability to induce loss of consciousness and death while minimizing animal pain, distress, or anxiety; reliability; irreversibility; time required to induce unconsciousness; species and age limitations; compatibility with research objectives; and safety of and emotional effect on personnel.

Euthanasia should be carried out in a manner that avoids animal distress. Depending on the species involved, some animals being euthanized may vocalize, release pheromones or behave in a manner which may be distressing to other animals. For those reasons, animals should not be euthanized while crowded or in the presence of animals not being euthanized.

It is essential that euthanasia be performed by personnel who are skilled in methods for the species in question and that it is performed in a professional and compassionate manner. It is imperative that death be verified after euthanasia and before disposal of the animal. Animals in deep narcosis following exposure to euthanasia agents may appear dead, but may eventually recover. Death must be confirmed by examining the animal for cessation of vital signs with consideration given to the animal species and method of euthanasia when determining the criteria for confirming death. All remains will be disposed of in accordance with university procedure, state and Federal regulations.

### **Disposition**

UMBC committed to minimizing the number of animals needed to satisfactorily conduct its research and teaching activities while being in full compliance with applicable federal, state, and local regulations. No person, whether faculty, staff or student, may acquire animals for use in research or teaching, unless the species and numbers have been approved by the IACUC in its protocol review. As such, the university uses a procedure that indicates methods for the disposition of animals not requiring euthanasia and for the disposal of the remains of those which do.

The [UMBC Animal Research Protocol Form](#) indicates the intended final disposition for the animals involved in a research project or teaching activity. The disposition of animals should be suited to the particular species, as specified in the Guide for the Care and Use of Laboratory Animals (Guide). Animals remaining at the end of an approved protocol may be: 1) euthanized following current AVMA Guidelines on Euthanasia, 2) transferred from one active protocol to another active approved protocol or 3) transferred to an OLAW assured institution. All other animals, including most birds, reptiles, amphibians, and various groups of fishes may be disposed following the methods mentioned above or returned to the wild in accordance with State and Federal Wildlife regulations.

Animals which do not require euthanasia and are considered safe to be handled may be transferred to another IACUC approved project or teaching activity at the university or transferred for approved activities to other OLAW assured facilities. When not specifically approved in a protocol (i.e., either at original review or by amendment), transfer of animals from one approved protocol to another at UMBC following review and approval by the IACUC of a UMBC Animal Subjects Approval Form describing the activity. Any institution asking for the transfer of live animals must submit a written request for approval by the full IACUC.

Tissues or individual organs of euthanized animals not exposed to infectious agents or chemical contaminants may be used by other investigators.

Alternative methods of final disposition may be requested to and approved by the UMBC IACUC prior to final disposition.