

# Institutional Animal Care and Use Committee Protocol And Policy Guidebook

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

## 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

### Animal Care and Use Staff

Operation Staff-Biology	Mr. Robert Dietrich	410-455-3130
Operation Staff-Psychology	Ms. Rosemarie Mills	410-455-3111
Veterinary Resources-UM,B	Veterinarians	410-706-3540
Veterinary Services emergency pager contact		410-748-4569
Director, Biology	Dr. Suzanne Rosenberg	410-455-2237
Director, Psychology	Dr. Bernard Rabin	410-455-2430

### Other Campus Officials

Environmental Safety and Health	Mr. Michael Pound	410-455-2918
University Health Services	Ms. Jennifer Lepus	410-455-2542
Recombinant DNA Safety Officer	Dr. Charles Bieberich	410-455-3125
Radiation Safety	Environmental Safety & Health	410-455-2918
Human and Animal Research Protections Office	Mr. Timothy Sparklin	410-455-2737
Institutional Official	Dr. Geoff Summers	410-455-2199

## Animal Welfare Assurance

As specified in "PHS Policy" at IV.A.2, as Category 2, all of the 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. The report contains a description of the nature and extent of this institution's adherence to the [Guide for the Care and Use of Laboratory Animals](#). 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,
- follow the guidance of the "U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training,
- acknowledges and accepts responsibility for the care and use of animals involved in activities covered by this Assurance, and
- establish and maintain a program for activities involving animals in accordance with the [Guide](#).

# 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. On an annual basis, Vice President for Research appoints members to serve on the UMBC IACUC.

## **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.

## **Comparative Medicine/Veterinary Resources**

Via a service agreement with UMBC, the UM,B Program of Comparative Medicine, Veterinary Resources (VR) provides all veterinary services at UMBC. The oversight of the Animal Care Facilities is the responsibility of the Veterinarian. The Veterinarian is a voting member of the IACUC and is the designated member who is a Doctor of Veterinary Medicine with experience in laboratory animal science and medicine. The Veterinarian has 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.

## **Administrator of the Human and Animal Research Protections Office**

The Administrator of the Human and Animal Research Protections Office (HARPO) 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.

All scientists at UMBC must comply with the Animal Welfare Act. The Act covers nonhuman primates, dogs, cats, rabbits, guinea pigs, hamsters, and aquatic mammals and any other warm-blooded animal used for biomedical research (except laboratory mice, rats and birds at the present time).

Veterinary inspectors of the U.S. Department of Agriculture who make unannounced site visits carry out enforcement of federal law. Reports filed by these inspectors are available to the public under the Freedom of Information Act.

## Public Health Service - National Institutes of Health

The Office of Laboratory Animal Welfare (OLAW) "[Public Health Service Policy on Humane Care and Use of Laboratory Animals](#)" was promulgated in 1985 and most recently revised in March, 1996. Several significant changes occurred in this revision of the 1979 policy.

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](#), 1996. 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**

UMBC 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 "PHS Policy" at IV.A.3.b. The IACUC (Institutional Animal Care and Use Committee) is responsible for evaluating and monitoring the care and use of animals. Specific duties of the IACUC include:

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 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

The IACUC will ensure no member desiring to participate in any portion of the program reviews is involuntarily excluded. All meetings will be posted on the UMBC IACUC website by the Administrator of the Human and Animal Research Protections Office (HARPO) and reminder notices will be sent at least two weeks prior to members.

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 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

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

3. Prepare reports, with the assistance of the HARPO Administrator, of the evaluations conducted as required by "PHS Policy" at IV.B.3, and submit the reports to the Vice President for Research. 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.
- e. will be signed by a majority of the IACUC members.

4. Investigate all concerns regarding the care, treatment and use of animals for research or teaching on campus or off campus.

5. Make written recommendations to the IO regarding any aspect of the institution's animal program, facilities, or personnel training. Recommendations for change to the institution's animal program or facilities, however received, are forwarded to the IACUC Chair for review and discussion by the Committee. Revised recommendations are passed on to the IO for administrative review. The IO formulates an action plan in consultation with the IACUC, consistent with the merit of the recommendation and availability of resources.

6. Review and approve, require modifications in (to secure approval) or withhold approval of new animal use protocols as specified in "PHS Policy" at IV.C (1). All investigators wishing to use vertebrates as a part of their program must submit an animal use protocol to HARPO, no less than four weeks before the next scheduled meeting. Meetings are held four (4) times per year. Protocols not submitted within the stated timeframe may not be reviewed until the following scheduled Committee meeting. Appeals may be made to the IACUC Chair for his/her consideration.

7. Review and approve, require modification in (to secure approval), or withhold approval of proposed significant changes regarding the use of animals in ongoing activities as specified in "PHS Policy" at IV.C (1). A significant or major modification 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.

8. Conduct a 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 least once every three years. HARPO 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.

9. Be 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.

## Protocol Submission, Review and Approval

### Protocol Submission and Review

The IACUC reviews all protocols for research and teaching involving laboratory animals at UMBC. 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.

All investigators wishing to use vertebrates as a part of their program must submit an animal use protocol to HARPO, no less than four weeks before the next scheduled meeting. Meetings are held four (4) times per year. Protocols not submitted within the stated timeframe may not be reviewed until the following scheduled Committee meeting. Appeals may be made to the IACUC Chair for his/her consideration. See the [UMBC IACUC Forms](#) section of the web site for further guidance.

Upon receipt of the protocol, the Administrator of the Human and Animal Research Protections Office (HARPO) 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

During the review process, no member may participate in the IACUC review or approval of a research project in which the member has a conflicting interest (e.g., is personally involved in the project) except to provide information requested by the IACUC. Additionally, no member may contribute to the constitution of a quorum for the IACUC review or approval of a research project in which the member has a conflicting interest (e.g., is personally involved in the project).

Following presentation and discussion at the scheduled Committee meeting, the Committee members shall approve as submitted, request resubmission to address specified concerns, or disapprove. A quorum consisting of a majority of voting members is required for approval of protocols.

HARPO, 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 as set forth in "PHS Policy" at IV.C4. HARPO will electronically forward to investigators and instructors the IACUC's written decisions. HARPO will also provide a copy of the IACUC minutes to the IO. If the IACUC decides to withhold approval of an activity, written notification to the investigators and instructors will include the reasons for its decision and give the investigator or instructor an opportunity to respond in writing. Principal investigators of externally funded projects bear the responsibility of providing written notification to granting agencies requiring such notification of approval. A copy of this notification must be forwarded by the investigator to HARPO.

### **Types of Approval**

#### Approval

Approval is granted if all reviewing members provide approval.

#### Additional Information Requested

If additional information is requested by any member(s), then a letter is sent to the principal investigator detailing the information requested. Copies of the letter and the investigator's response are forwarded to all members on the committee. Approval is granted if all reviewing members provide approval.

#### 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), or perhaps changing the route of administration of drug. Minor modifications may be approved administratively by the IACUC Chair and the University Veterinarian without full review. Minor changes can be proposed through submission of a **Request for Minor Change/Amendment to an Animal Use Protocol** form. 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.

HARPO, 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 as set forth in “PHS Policy” at IV.C4. HARPO will electronically forward to investigators and instructors the IACUC’s written decisions. HARPO will also provide a copy of the IACUC minutes to the IO. If the IACUC decides to withhold approval of an activity, written notification to the investigators and instructors will include the reasons for its decision and give the investigator or instructor an opportunity to respond in writing. Principal investigators of externally funded projects bear the responsibility of providing written notification to granting agencies requiring such notification of approval. A copy of this notification must be forwarded by the investigator to HARPO.

## Annual Review Reports

The Human and Animal Research Protections Office (HARPO) 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 HARPO, 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. Changes that are minor will be approved administratively by the IACUC Chair. HARPO, on behalf of the IACUC Chair, will notify investigators of the Chair’s decision regarding the approval of the administrative review.

Substantive changes must be submitted and approved by the IACUC as indicated in Modifications section.

### 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). HARPO 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.

A protocol closure report must be submitted if the protocol **will not be renewed**. See the [UMBC IACUC Forms](#) section of the web site for further guidance.

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.

- 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.

<http://grants.nih.gov/grants/olaw/references/PHSPolicyLabAnimals.pdf>

- Section 13.** (a)(1) - (3) (B) that the principal investigator considers alternatives to any procedure likely to produce pain or distress in an experimental animal and (7) (B) In complying with subparagraph (A), such research facilities shall provide-
- (i) information on procedures likely to produce pain or distress in any animal and assurances demonstrating that the principal investigator considered alternatives to those procedures; <http://www.nal.usda.gov/awic/legislat/awa.htm>

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 Institutional Animal Care and Use Committee will investigate all concerns regarding the care, treatment and use of animals for research or teaching on campus or off campus. Concerns should first be discussed with the investigator, instructor or facility manager to 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.

Alternatively, persons may contact the HARPO Administrator as follows:

Administrator, Human and Animal Research Protections Office  
bwtech@UMBC  
5523 Research Park Drive, Suite 310

Baltimore, Maryland 21228  
Telephone: 410-455-2737  
Fax: 410-455-3868  
Email: [HARPO@umbc.edu](mailto:HARPO@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. 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.

All reports are treated seriously and are investigated. If the IACUC finds merit in the concern, it will be passed on to the IO. If the IO agrees with the IACUC assessment, he/she will take administrative action to effect an immediate correction, if this is feasible. If immediate action is not feasible, the IO will notify the OLAW and initiate a process to evaluate the concern and to effect appropriate and sufficient action to correct it. The IO will take appropriate steps during the review to prevent any retaliation and to protect, to the extent practicable under University policies, the positions and reputations of the persons who made the complaint.

**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 locked file cabinet within the Human and Animal Research Protections Office. These files are retained under a separate key from the rest of the 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 this 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.

HARPO 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.

All records shall be accessible for inspection and copying by authorized OLAW or other PHS representatives, during University business hours, at reasonable times and in a reasonable manner.

## Veterinary Medical Services

### Technical and Consultation Services for Research Procedures

The staff of Veterinary Resources (VR) provides technical training such as blood withdrawal, administration of anesthetics, animal transportation, 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. Through pre-research consultations, budgeting for these services can be included in research grant applications.

### **Pre-Research Consultation**

The VR's Comparative Medicine Program at UM,B, through its faculty, provides information and advice regarding:

- Special caging or experimental techniques
- Selection of appropriate animal species to carry out specific animal techniques
- Animal models of human diseases
- Anatomical and physiological peculiarities of animals used in research
- Techniques of anesthesia, analgesia, chemical restraint, and dosages
- Techniques of blood and other sampling and drug or chemical administration
- Pathological and clinical effects of intercurrent animal disease
- Estimates of animal purchase prices

The UMBC IACUC encourages such consultations prior to the preparation of grant and contract applications.

### **Clinical Medicine**

When an investigator, research staff member, student, technician or any other person associated with institutional animal use believes an animal is abnormal, sick, in discomfort, or otherwise requiring aid, a call should be placed to VR. A staff veterinarian will respond and take appropriate action in consultation with the investigator. It is essential that the investigator, student, fellow or technician initiate clinical calls at the earliest sign of the abnormality. VR maintains complete animal diagnostic laboratories, two aseptic surgical suites, treatment and radiographic facilities.

### **Pathology**

VR provides diagnostic pathology service to investigators using animals in their research. The purpose of this service is to identify intercurrent disease in the animal population and to assist investigators in identifying protocol related problems, which affect animal health and impact on successful research endeavors. Inquiries should be directed to VR designated representatives. Carcasses must not be frozen but refrigerated instead. A complete description of the animal's history should be included. A preliminary diagnosis will be available following the examination. A final diagnosis will follow as soon as possible after histopathology, microbiology, and other diagnostic procedure results are available.

### **Sources of Research Animals**

Animals used at UMBC are purchased from pre-approved commercial suppliers and dealers. Approval of sources is based on the health status, genetic quality, costs, vendor reputation and reliability. A pre-approved list of vendors can be obtained from the Administrator for Human and Animal Research Protections. Investigators with specific requests for animals from commercial sources not currently approved must contact the IACUC Chair who will ensure that a proper investigation of the source is obtained. No animals may be brought onto UMBC property without prior consultation and approval of the IACUC. 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.

Animals from other sources, such as other universities, have a great potential for carrying pathogens. 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.

No animal may be housed in UMBC facilities unless a protocol is approved and the animal ordering procedures are followed. The introduction of animals without authorization by the IACUC places the facility and the research of other investigators at great risk for loss of animals and data, which could jeopardize the results of research endeavors, publication and funding.

## Animal Acquisition

Animals used at UMBC are purchased from pre-approved commercial suppliers and dealers. Approval of sources is based on the health status, genetic quality, costs, vendor reputation and reliability. A pre-approved list of vendors can be obtained from the Human and Animal Research Protections Office. Investigators with specific requests for animals from commercial sources not currently approved must contact the IACUC Chair who will ensure that a proper investigation of the source is obtained. No animals may be brought onto UMBC property without prior consultation and approval of the IACUC. 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.

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## Animal Care Cost

All procurements for UMBC research animals, under approved protocols must be placed in accordance with UMBC Department Procurement Manual. The Director of the animal care facility handles all arrangements for the acquisition, transportation and receipt of animals.

All animal-based research requires prior approval by IACUC. To assure this, all investigators will provide a current protocol number to their procurement representative at the time an order is placed. Investigators must make sure that the protocol number used is correct for the procedure and species to be used.

Animal orders up to \$2500 will be placed using the small procurement (SP) procedure set forth on the UMBC Department Procurement Manual. Designated department representatives have also been authorized to use VISA cards to facilitate procurement at this level. For orders over \$2500 a formal competitive bid process is required through the Department of Procurement unless a sole source determination is justified. Blanket purchase orders have been established with key vendors to facilitate periodic ordering. Detailed information regarding this process can be obtained from the designated department representative, the Department Procurement Manual or the Department of Procurement at phone 410-455-2071, <http://www.umbc.edu/adminaffairs/procurement/>

The Director of the animal facility must approve all Animal requisition requests. The following information must also be included with any animal requisition request:

- The number of the protocol approved by the Institutional Animal Care and Use Committee
- Complete information on type, source, and numbers of animals
- Number of animals to be used with appropriate anesthetic, analgesic, or tranquilizer administered to avoid pain or distress
- Number of animals to be used involving pain or distress without the administration of anesthesia, analgesics, or tranquilizers (requires specific justification and approval)

The animal care facility staff will coordinate animal deliveries with the suppliers and the Principal Investigator will be contacted when the animals are accepted or if there are any problems. The animals are delivered to the facility designated on the request form. Housing for the animals is assigned after the animals have been checked for accuracy of species and type and examined to ensure they are in good condition. Animals arriving without a UMBC purchase order number must be pre-approved by UM,B VR. Animals arriving without pre-approval will not be accepted or allowed to enter the facility.

Arrangements for animals from private sources or other institutions must be done through the Director of the Facility who will contact UM,B for procedures. Only pathogen-free animals can be accepted, and the known health status is reviewed by UM,B veterinary staff. UM,B will arrange shipping, place animals in quarantined facilities at UMB and test each animal (4-6 weeks). If animals test negative, they are released from quarantine and transported to UMBC.

Investigators must provide to the animal care facility department a UMBC PeopleSoft project number(s) to authorize the transfer funds from the investigator's account to cover the cost of special animal care supplies and services. Investigators will be responsible for notifying the facility of any changes in funding or expiration dates.

## Animal Housing

### Location

The facility selected for housing animals will generally be the most convenient to the investigators' laboratories, with regard to available space, PHS requirements regarding species separation, and with other needs of the investigator.

### Access to Facilities

Access to the animal housing facilities for investigators and their staff can be granted only after a UMBC I.D. badge has been issued.

Once an approved I.D. badge has been obtained, a memorandum on the investigator's department stationery should be sent to the Director of the appropriate animal care facility containing the following information:

- Name of the person requiring access
- The facility to which the person requires access
- Social security number
- Number on the University I.D. badge

Investigators are granted access to only one location to help prevent the transmission of adventitious pathogens between facilities.

Unauthorized persons (including visitors, friends, and children) are not permitted in the facilities without the approval of the facility Director. They shall be restricted to the caretaker's office unless approved by the facility Director.

## **Amphibian and Fish Holding Areas**

Sites for housing of fish outside the centralized facilities must meet minimum standards. In general these areas must conform to the guidelines written by the Canadian Council on Animal Care as such guidelines are recognized by the Association for the Assessment and Accreditation of Laboratory Animal Care, International (AAALAC). The guidelines include monitoring of water quality, appropriate husbandry and handling practices, and appropriate use of anesthetic and euthanasia methods for various species.

Written standard operating procedures, prepared by the investigator, should be available in all fish holding areas. Records of water monitoring, treatments, and husbandry procedures should also be maintained. Guidelines and reference materials are available through the IACUC.

## **Management of animal facilities**

The *Guide for the Care and Use of Laboratory Animals* states "Proper management of animal facilities is essential to the welfare of animals, validity of research data, and health and safety of the animal care staff". A good husbandry program provides a system of housing and care that permits animals to grow, mature, reproduce, and maintain good health and minimizes variations that can modify an animal's response to experimentation. Animal housing must conform to NIH Guide standards and Animal Welfare Act requirements while meeting research needs.

Environmental factors can have a profound effect on the health and well-being of animals as well as the outcome of experimental manipulation. Temperature, humidity, air pressure and rate of turnover and noise levels all may affect animal well-being and research results.

### **Housing**

The primary enclosure provides the limits of an animal's immediate environment.

Acceptable enclosures:

- Allow for the normal physiologic and behavioral needs of the animals
- Allow social interaction and development of hierarchies
- Make it possible for the animals to remain clean and dry (as consistent with the requirements of the species).
- Allow adequate ventilation.
- Allow the animals access to food and water and permit easy filling, refilling, changing, servicing, and cleaning of food and water utensils.
- Provide a secure environment that does not allow escape of or accidental entrapment of animals or their appendages between opposing surfaces or by structural openings.
- Are free of sharp edges or projections that could cause injury to the animals.
- Allow observation of the animals with minimal disturbance of them.

### **Temperature and Humidity**

Environmental temperature and relative humidity can depend on husbandry and housing design and can differ considerably between primary and secondary enclosures. The temperature must be constant and adapted to the species. The recommended temperature for commonly used laboratory animals, such as mice, rats, hamsters, gerbils, guinea pigs is 18-26 °C or 64-79 °F.

Animals can tolerate humidity variations more easily than temperature variations. Abrupt change, during a short period of time, can cause stress and induce health issues. Relative humidity should also be controlled, but not nearly as narrowly as temperature; the acceptable range of relative humidity is 30 to 70%.

### **Ventilation**

The purposes of ventilation are to supply adequate oxygen; remove thermal loads caused by animal respiration, lights, and equipment; dilute gaseous and particulate contaminants; adjust the moisture content of room air; The animal depends on it for its oxygen provision. That is why in animal facilities the ventilation system provides 100% fresh air. While supplying oxygen to the animal, a ventilation system must also eliminate the CO<sub>2</sub> produced by the animals as well as the ammonia generated by the bacterial degradation of urine, and the allergens and the odors.

### **Lighting**

The intensity and duration of the photoperiod must be adapted to the species and to the needs of the experiment. Rodents, which are mainly nocturnal, benefit from a low level of lighting during the day. The photoperiod is usually 12 hours of light and 12 hours of darkness. The reproduction of many animals is influenced by the photoperiod.

### **Noise**

Animals are sensitive to sudden noise. The noise level in a facility must be kept constant and as low as possible. The animals can hear noise at frequencies inaudible to humans, for instance, noise from the vibration of a blower.

### **Bedding**

Often contact bedding is used for animal housing. The bedding is used to provide a clean, dry and comfortable environment to the animal. It must be replaced on a regular basis to keep the animal dry and clean, and to prevent the build up of ammonia. For some species, or protocols, the bedding may be a source of hazardous biological, chemical or radioactive agents. Appropriate measures for disposal of the bedding must be applied.

### **Animal Care Procedures**

#### **Quarantine and Stabilization of Animals**

All newly received animals must be allowed a stabilization period of **at least 48 hours** prior to their use. This permits the animals to adapt to their surroundings resulting in a more stable physiological and behavioral state. Studies indicate that mice have altered immune functions and elevated corticosterone levels for 48 hours following shipment.

**Incubator Facilities** – Investigators at these facilities using animals must comply with all requirements for animal use and submit protocols for all use of vertebrate animals in research or teaching to the UMBC IACUC.

#### **Animal Transport Between Building**

Animals should not be transported from one research building to another. Exceptional circumstances require approval of the IACUC. Under no circumstances should animals other than rodents be transported in a public elevator (freight elevators should be used). All animals that are transported should be covered in a manner to obscure public view and prevent exposure of others to animal allergens.

### **Breeding of Animals**

Breeding of animals is permitted only in special circumstances, such as when animals are not readily available through normal sources. Any proposed breeding requires specific approval by the IACUC.

Breeding of animals, any species, is generally not cost effective in the research environment and requires excessive space. Also young, naive neonatal animals make control of adventitious rodent disease difficult. Control over genetic purity is another problem. For these reasons, it is best to leave the breeding of animals to the commercial suppliers. If it is necessary to work with fetal or neonatal animals, pregnant animals can be purchased.

### **Pets**

Research animals are not pets and should not be removed from the facilities. Concerns have to do with public perception of an animal removed from a research setting, the fact that these animals have generally been procured with grant monies, liability of the University, and the need to document the disposition of research animals in accordance with federal law.

Conversely, personal pets should not be brought onto campus for treatment, or otherwise. The IACUC does not operate a clinic or provide service for pet animals. In addition, certain pet animals (especially mammals) can harbor and spread infectious diseases to animals within the research facility.

### **Pathogen Testing of Rodent Biologics**

Rodent origin cell lines, tumor lines or any other biologics (e.g., body fluids) passed through live rodents have the potential to transmit a wide range of rodent pathogens. One example is mouse hepatitis virus (MHV), which can be devastating even as a subclinical infection as it can confound experimental results, especially in immunological studies. Another example is lymphocytic choriomeningitis virus (LCM) that can interfere with experimental data and result in rodent morbidity and mortality and is also zoonotic (i.e., may cause disease in personnel).

All animal biologics (any tissues, sera, cells, tumors, or other animal passaged materials) must be adventitious pathogen free prior to introduction into any animal. Veterinary Resources will test these biologics at no cost to the investigator. This usually involves a serological evaluation (e.g. rodent cell line injected into a naive mouse, which is subsequently assayed for antibodies to a panel of murine viral antigens).

## **Media Coverage Policy**

It is understood that publicity for research is important at UMBC and therefore should be supported and encouraged. Media coverage of animal-based research must be conducted in a socially sensitive fashion and meet all federal regulations and guidelines regarding the humane care and use of animals. It is important that media coverage be presented in a positive light and is not prone to misrepresentation. Also, it should be determined if it is truly necessary to exhibit the animals or demonstrate their use.

Any investigator who is contacted by the media to provide information on any animal-based

research should contact the IACUC Chair and the Vice President for Research without delay. If it is anticipated that animals will be exhibited to the media or if a portion of the media coverage includes specific use and/or care of animals, then the IACUC Chair may solicit recommendations from the IACUC members.

The media event should not proceed until these persons (or their designees) are satisfied that all has been done to ensure that media coverage will be conducted appropriately.

A representative from the IACUC should be present during the event and have authority to make any necessary changes to protect the investigator and UMBC from misrepresentation.

### **Protests Against Animal Research / Animal Activist Threat**

Scheduled protests must be approved by UMBC Administration via the Director of Public Affairs. The Director determines which university officials must approve the event and determines the final approval for the event. Any events involving protest against animal research must be approved by the University Police and Departmental Animal Care Committees. The Vice President for Research will be notified of all protest against animal research.

If an unscheduled protest, notice of an unapproved protest, or an animal activist threat occurs, the University Police Department will be immediately notified. The University Police Department will determine what action will be taken in the event of a protest / animal activist threat and will determine whether to initiate the Rapid Communication System.

## **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. The NIH currently allows a 60-day grace period for the institutional approval letter to be submitted. If the application is being submitted to another funding source, which requires a special letter indicating protocol status, the Human and Animal Research Protections Office (HARPO) will issue these letters.

The IACUC Chair or the Administrator, Human and Animal Research Protections Office are the only individuals authorized by the IO to verify that the activities described in PHS Applications, PHS Form 398, are congruent with those approved by the IACUC-or visa versa. These individuals will work in concert with the Office of Sponsored Programs to review those sections of applications and proposals related to the care and use of animals.

HARPO, 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 as set forth in "PHS Policy" at IV.C4. Principal investigators of externally funded projects bear the responsibility of providing written notification to granting agencies requiring such notification of approval. A copy of this notification must be forwarded by the investigator to HARPO.

### Collaborations

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.

### **Public Health Service (PHS) 398 Grant Applications**

#### Requirements for Institutional Review of Section 2F - Vertebrate Animals

Section 2F in PHS grants must be completed for all new and competitive renewal applications. Section 2F should contain all of the information which the NIH has specified shall be included in this section:

Provide a detailed description of the proposed use of the animals in the work previously outlined in the experimental design and methods section. Identify the species, strain, age, sex, and number of animals to be used in the proposed work

Justify the use of animals, the choice of species, and the numbers used. If animals are in short supply, costly, or to be used in large numbers, provide an additional rationale for their selection and their numbers

Provide information on the veterinary care of the animals involved. Include the following statement:

*Animals are maintained in the centralized animal facilities of the University of Maryland Baltimore County (UMBC) Animals are housed, cared for, and used strictly in accordance with the NIH Guide for the Care and Use of Laboratory Animals, 1996. UMBC has a category 2 approved program assurance on file with NIH. Veterinary care is provided by specialty-trained laboratory animal veterinarians at UM. This institution has an Animal Welfare Assurance on file with the NIH Office for Laboratory Animal Welfare (OLAW), Assurance Number A3784-01.*

Describe the procedures for ensuring that discomfort, distress, pain, and injury will be limited to that which is unavoidable in the conduct of scientifically sound research. Describe the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices where appropriate to minimize discomfort, distress, pain, and injury

Describe any euthanasia method to be used and the reasons for its selection. State whether this method is consistent with the recommendations of the Panel on Euthanasia of the American Veterinary Medical Association. If not, present a justification for not following the recommendations

Although no specific page limitation applies to this section of the application, be succinct.

## **Training and Education for Investigators and Staff**

Federal regulations require institutions to ensure that individuals caring for or using animals for research or educational purposes are qualified to do so.

Personnel caring for animals shall be appropriately trained. Training of individuals is provided as needed in several ways. Investigators (including faculty and students), technical personnel, and trainees who perform animal anesthesia, surgery, or other experimental manipulations must be

qualified through training or experience to accomplish these tasks in a humane and scientifically acceptable manner and as applicable to the specific species and procedures to be used.

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.

### **Informal or “On-The-Job” training**

Individuals using animals for the first time or employing unfamiliar techniques are provided on the job training these procedures by the faculty in charge of the animal facility and by the Veterinarian on a regular basis during his/her regular visits.

### **UMBC Animal Use and Care On-line Training**

Any person using animals in a research or teaching project, IACUC members and animal care staff are required to participate in an on-line education module, accessed through the [Collaborative Institutional Training Initiative \(CITI\)](#).

This education program is divided into two modules:

**Working with the IACUC** – the basic course required for investigators and research staff who plan to use laboratory animals or plan to supervise such work at UMBC. Investigators and research staff are also required to choose appropriate species-specific module.

**Essentials for IACUC Members** - This module is designed for new IACUC or current IACUC members.

A completion certification will be provided by HARPO to each participant and is valid for 3 years; opportunities for continuing education will be provided on an annual basis.

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. HARPO will obtain and make available these materials at any time upon request.

## **Occupational Health Program**

The occupational health and safety program for personnel involved in the care and use of laboratory animal 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 University Health Services (UHS) and Office of Environmental Safety and Health (OESH), who are responsible for implementing and overseeing the program.

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.

The health program for personnel who work in the animal facilities is as follows:

1. 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.
2. Laboratory supervisors shall provide all employees a copy of "Procedures for Serious and Life-Threatening Emergencies" (see the Appendices). 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).
3. Laboratory supervisors shall 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.
4. Laboratory supervisors shall provide all employees 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.
5. Supervisors/Principal Investigators shall file annually a personnel risk assessment report to OESH.
6. 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.

Both off-campus facilities specialize in work-related illnesses and injuries in addition to offering physicals, special testing and vaccinations. They are approximately a seven-minute drive from campus. During normal business hours an Authorization for Treatment form may be obtained from the OESH in the Physical Plant Building, room 105.

When both facilities are closed (usually Saturday after noon, Sunday and some holidays), injured employees should be referred to: St. Agnes Hospital, 900 Caton Avenue, Baltimore, Maryland 21229. General (410-368-6000) and Emergency Room (410-368-2000)

In cases of severe work-related injuries which necessitate the use of an ambulance to transport the injured person, the emergency room facilities at St. Agnes Hospital are to be utilized. When an employee is sent to St. Agnes, the OESH must be notified by the

appropriate supervisor..

All work-related injuries must be reported to the OESH via the following OESH procedure:

- a. 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 [UMBC Safety website](#)) and submit it to his/her immediate supervisor. The form must be submitted within 24 hours after the injury has occurred.
- b. 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.
- c. Once the forms have been submitted, they are reviewed by the OESH. The campus Safety Officer will investigate, if necessary, and notify the Injured Workers' Insurance Fund and the Human Resources Office.
- d. Failure to submit injury reports in a timely manner may result in the rejection of a claim by the Injured Workers' Insurance Fund.

## 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

We must protect the health of our employees and others. Those who attend to the care and housing of your animals may not be familiar with the nature of hazards being used. Therefore, we require the necessary information on the agent to best safeguard those who work with the animals.

## 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.

### Rodents

These standards apply to all mammalian species. 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 Procedure

Non-survival surgical procedures may be performed in general purpose laboratories provided the rules outlined below are followed:

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.

### Aseptic Technique

Aseptic technique, including aseptic preparation of the skin, sterilization of instruments, and wearing sterile gloves and masks (gowns and caps when appropriate), is necessary when performing survival surgery on all animals. Operating suites should not be used for eating, drinking or smoking. Personnel performing the surgery should have formal training in operative procedures and aseptic technique or have acceptable career experience approved by the IACUC.

### Anesthetics and Analgesics

Information concerning types, dosages and routes of administration of anesthetics and analgesics is available from members of the Program.

Anesthetic techniques and use of post-operative analgesia should be in accordance with current methods in the literature and approved by the IACUC. Inquiries may be directed to Veterinary Resources. Records must be maintained of the anesthetics used, amounts, dates, procedures and animal species.

If volatile anesthetic gases are used, a gas evacuation and scavenging system is necessary.

Analgesic- If any particular procedure performed on animals would cause pain or discomfort if performed on a human then the animal should receive similar consideration in the form of analgesics.

### Post-Operative Care

The investigator is primarily responsible for postoperative care and record keeping for animals until the animal is eating, drinking, and behaving normally. Immediate postoperative care should be provided in a dedicated recovery area with close observation and the animal should not be left until it can reach sternal recumbency. In the days following the procedure, the animal should be monitored and observed, as necessary, to insure the animal is recovering normally. Analgesics should be administered if there is any question of pain; incisions should be checked daily;

bandages should be changed when wet, soiled, or coming off; supportive treatment should be provided when indicated (parenteral fluids, antibiotics); and sutures should be removed (7-14 days generally). For all species (except rodent), individual surgical records and post procedural records must be made and kept by the investigator.

#### Multiple Major Surgical Procedure

Major surgery is defined as surgery, which penetrates and exposes a body cavity or produces substantial impairment of physical or physiologic function.

Multiple major survival surgery is described as more than one major survival surgical procedure performed on a single animal.

Multiple major survival surgical procedures may be performed on the same animal only if they are related components of a project and have been reviewed and approved by the IACUC. Multiple major survival surgery on animals for economic purposes alone is not acceptable according to the NIH Guide.

#### Euthanasia

Proper methods of euthanasia should be used at the termination of the experiment. The methods used should be documented. A record must be kept of the amounts, date, and animal species when restricted drugs such as sodium pentobarbital are used for euthanasia.

## Prolonged Restraint Policy

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.

## Suggested Readings

#### General

Andrews, E.J., Ward, B.C. and Altman, N.N. (eds.): Spontaneous Animal Models of Human Disease, two volumes, New York, Academic Press, 1979.

AVMA Panel on Euthanasia, Report of the AVMA Panel on Euthanasia. J. Am. Vet. Med. Assoc. 218:669-696, 2001.

Baker, H.J., Lindsey, J.R. and Weisbroth, S.N. (eds.): The Laboratory Rat, two volumes, New York, Academic Press, 1980.

Benirschke, K., Garner, F.M. and Jones, T.C. (eds.): Pathology of Laboratory Animals, two volumes, New York, Springer-Verlag, 1978.

Cornelius, C.E. (1969). Animal Models - Neglected Medical Resource. New England Journal of Medicine 281:934-944.

Foster, H.C., Small, J.D., and Fox, J.G. The Mouse in Biomedical Research, volumes 1-4, New York, Academic Press, 1981-1982.

Gay, W.I. Health Benefits of Animal Research, Foundation for Biomedical Research, 1986.

Jones, L.M., Booth, N.H., and McDonald, L.E. Veterinary Pharmacology and Therapeutics, Ames, Iowa, The Iowa State University Press, 1977.

Jones, T.C. (1969). Mammalian and avian models of disease in man. Federation Proceedings 28:162-169.

Lang, C.M. (1976). Animal physiologic surgery. Springer-Verlag, New York, 1976.

Lang, C.M. and Vesell, E.S. (1976). Environmental and genetic factors affecting laboratory animals: impact on biomedical research. Federation Proceedings 35:1123-1165.

Lindsey, J.R. and Capen, C.C. (1976). Animal models for biomedical research - metabolic disease. Federation Proceedings 35:1192-1236.

Melby, E.C. and Altman, N.H. (eds.): Handbook of Laboratory Animal Science, three volumes, Cleveland, Chemical Rubber Company Press, 1974.

Wagner, J.C. and Manning, P.J. (eds.): The Biology of the Guinea Pig, New York, Academic Press, 1976,

U.S. Congress, Office of Technology Assessment, Alternatives to Animal Use in Research, Testing and Education (Washington, DC: U.S. Government Printing Office, OTA-BA-273, February 1986.)

U.S. Department of Health and Human Services, PHS, NIH, National Symposium on Imperatives in Research Animal Use: Scientific Needs and Animal Welfare, NIH Publication No. 85-2746, 1984.

Weisbroth, S.H., Flatt, R.E. and Kraus, A.L.: The Biology of the Laboratory Rabbit, New York, Academic Press, 1974.

Surgery, Anesthesiology

Bojrab, M.J. Current Techniques in Small Animal Surgery, Philadelphia: Lea and Febiger, 1975, 585 pp.

Hughes, H.C. Anesthesia of Laboratory Animals. Lab Animal. 10:40-56, 1981.

Lumb, W.V., Jones, E.W. Veterinary Anesthesia. Philadelphia: Lea and Febiger, 1973, 680 pp.

Piermattei, D.L., Greeley, R.G. An Atlas of Surgical Approaches to the Bones of the Dog and Cat, 2nd ed., Philadelphia: W.B. Saunders Co., 1979, 202 pp.

Sawyer, D.C., Ed., The Practice of Small Animal Anesthesia, Philadelphia: W.B. Saunders Co., 1982, 154 pp.

Soma, L.R., Ed., Textbook of Veterinary Anesthesia. Baltimore: Williams and Wilkins, 1971, 621 pp.

Stimpfel, T.A., and Gershey, E.L. Selecting Anesthetic Agents for Human Safety and Animal Recovery Surgery, The FASEB Journal, 5:2099-2104, 1991.

Swindle, M.M., Basic Surgical Exercises Using Swine, NY: Praeger Scientific, 1983, 237 pp.

Waynforth, H.B., Ed. Experimental and Surgical Technique in the Rat, NY: Academic Press, 1980, 186 pp.

## Relevant Journals

[American Journal of Veterinary Research](#)

[Comparative Pathology](#)

[Journal of the American Veterinary Medical Association](#)

[Lab Animal](#)

[Laboratory Animals](#)

[Veterinary Pathology](#)

[Comparative Medicine](#)

## Video Tapes-VHS

(Available through UM,B Veterinary Resources)

<http://medschool.umaryland.edu/orags/acuo/reqtraining.asp>

1. Alzet Osmotic Pumps Surgical Transplantation Techniques. - Alza Corp. (23:15)
2. Use of the Microisolator Caging System - Lab Products
3. Surgical Procedures on Swine - Charles River (36.:30)

4. Fundamentals of Blood Gas Analysis: Collection, Measurement and Interpretation - UC Davis
5. Endotracheal Intubation of the Rat and Hamster - UC Davis (10:30)
6. Endotracheal Intubation of the Guinea Pig - UC Davis (12:30)
7. Endotracheal Intubation of the Rabbit - UC Davis (13:00)
8. Practical Methodology: Humane Handling and Lab Techniques for the Hamster - UC Davis (22:00)
9. Practical Methodology: Humane Handling and Lab Techniques for the Mouse - UC Davis (19:00)
10. Practical Methodology: Humane Handling and Lab Techniques for the Rat - UC Davis (21:00)
11. Practical Methodology: Humane Handling and Lab Techniques for the Guinea Pig - UC Davis (18:00)
12. Practical Methodology: Humane Handling and Lab Techniques for the Rabbit - UC Davis (25:00)
13. Practical Methodology: Reptiles, Part I Humane Handling, Restraint and Husbandry, UC Davis (17:00)
14. Practical Methodology: Reptiles, Part II Special Laboratory Techniques, UC Davis (17:40)
15. Practical Methodology: Non-human Primates - Part I - Personal Safety, Primate Handling and Restraint - UC Davis (18:40)
16. Practical Methodology: Non-human Primates Part II - Special Laboratory Techniques - UC Davis (15:22)
17. The New Research Environment - FBR
  - Tape 1
    - Part One: The Animal Care and Use Committee (30:28)
    - Part Two: Common Procedures and Techniques
    - Part Three: Survival Surgery
  - Tape 2 Animal Rights: The Threat to Research (14:00)
18. "Will I Be All Right Doctor?" - FBR (25:00)
19. Caring for Life - FBR (10:30)
20. Using Animals in Research: Guidelines for Investigators
  - Three tape series produced by Animal Welfare Information Center - National Agricultural Library - USDA, 1986 (5 hours)
21. "Hope" - FBR (17:02)

22. Dr. C. Everett Koop - Public Service Announcements - FBR (0:30 each)
23. Thoren Caging Systems, Inc. - The Ultimate System (11:00)
24. Surgical Instruments and Their Use, Dr. P. Vasseur, UC Davis (0:33)
25. Knot Tying-Hand and Instrument, Dr. I. Gourley, UC Davis
26. Antiarrhythmic Drugs, Dr. S.N. Giri, UC Davis (0:24)
27. Orientation to Small Animal Intensive Care Unit, Dr. S. Haskins, UC Davis
28. Restraint and Handling of the Bird-Special Groups, Dr. M. Fowler, UC Davis (0:34)
29. Neuromuscular Blocking Agents, Dr. Robert Joy, UC Davis (0:52)
30. Catheterization Techniques - Venous and Arterial, Dr. Haskins and Dr. Parker, UC Davis (0:42)
31. Bone Marrow Aspiration - Bovine and Canine, Dr. N. Jain, UC Davis (0:16)
32. Surgical Instruments and Their Use, Dr. P. Vasseur, UC Davis
33. Knot Tying-Hand and Instrument, Dr. I. Gourley, UC Davis
34. Antiarrhythmic Drugs, Dr. S.N. Giri, UC Davis
35. Orientation to Small Animal Intensive Care Unit, Dr. S. Haskins, UC Davis
36. Restraint and Handling of the Bird-Special Groups, Dr. M. Fowler, UC Davis
37. Neuromuscular Blocking Agents, Dr. Robert Joy, UC Davis
38. Catheterization Techniques - Venous and Arterial, Dr. Haskins and Dr. Parker, UC Davis
39. Bone Marrow Aspiration - Bovine and Canine, Dr. N. Jain, UC Davis
40. Why I Should Stay Awake in Science Class - FBR
41. Michael Carey, M.D. - 60 Minutes, Ambrose Video (15:00)
42. Avian Diseases, Dr. A. Mutalib, Charles Louis Davis, DVM Foundation for Advancement of Veterinary & Comparative Pathology
43. Gross Pathology Tapes, Charles Louis Davis, DVM Foundation for Advancement of Veterinary Pathology (24 - 29)
44. Diseases of Nonhuman Primates, Dr. Linda Lowinstine, University of California
45. Laboratory Animal Diseases, Dr. R. H. Brunner, Wright-Patterson AFB, vol 26, tape 1
46. Canine & Feline Diseases, Dr. T. J. VanWinkle, University of Pennsylvania, vol. 27, 28, tape 1 - 2
47. Poikilotherm & Lab Animal Disease, Dr. Miriam Anver, Clement Association, Inc., vol. 30, tape 1

48. Laboratory Animal Diseases, Dr. P. C. Stromberg, Ohio State University, vol. 34 35, 36, tapes 1-3
49. Laboratory Rodent Diseases, Dr. S. W. Barthold, Yale University, vol 42, 43, 44, tapes 1-3
50. Saving Inky, National Aquarium in Baltimore (15:50)
51. Surgical Implantation of Whiffle Golf Ball in Rabbits, 9/29/93
52. Animal Research, Channel 45, 10/9/92
53. Bench to Bedside: Creating Tomorrow Today, AMA (8/93)
54. Use of TiterMax adjuvant
55. Into the Danger Zone, Inf. Dis., 48 hours
56. TechnoPolitics - Paris vs. Matthews
57. Respiratory Fit Tests - 6100 series, Willson Safety Products
58. Documentation on Practical Parasitology: The Species Entamebae, Ed U Quest
59. Procedures for Handling Monkeys Infected with Immunodeficiency Viruses - General Precautions for Handling Human Blood, Body Fluids and Tissues, Billie Davison & Jeff Falkenstein