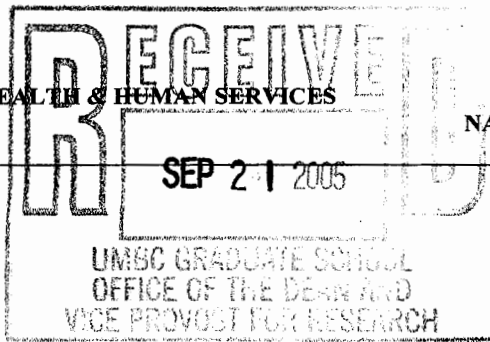




DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH



FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare
Division of Assurances
6705 Rockledge Drive
RKL 1, Suite 360, MSC 7982
Bethesda, Maryland 20892-7982
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare
Division of Assurances
6705 Rockledge Drive, Suite 360
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 402-7065

September 14, 2005

Reference: Renewal Assurance #**A3784-01**

Scott Bass, Ph.D.
Vice President for Research and Dean of the Graduate School
University of Maryland, Baltimore County
1000 Hilltop Circle
Baltimore, Maryland 21250

Dear Dr. Bass:

I am pleased to inform you that The Office of Laboratory Animal Welfare (OLAW) reviewed and approved the renewal of your institution's Animal Welfare Assurance (Assurance) that was submitted in compliance with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy), as revised August 2002.

Your Assurance renewal, number **A3784-01**, became effective on **September 14, 2005** and expires on **September 30, 2009**. This Assurance supersedes all previously issued Assurances. Please include the Assurance number in all correspondence to OLAW. A copy of the Assurance signature page is enclosed.

The Assurance is a key document in defining the relationship of your Institution to the PHS. It sets forth the responsibilities and procedures of your Institution regarding the care and use of laboratory animals. Among the important elements of the Assurance, I would especially call your attention to the reporting requirements that are essential for continued compliance with the PHS Policy. Please note that a Report to OLAW is required at least once every 12 months. The reporting period, unless requested otherwise in writing, is the calendar year. Reports, for the previous calendar year, are due **January 31**.

If I may be of further assistance, please do not hesitate to contact me.

Sincerely,

William R. Parlett, Jr., DVM, DACLAM
Assurance Officer (Contractor)
Office of Laboratory Animal Welfare

Enclosure:
As stated

cc:
Dr. Ostrand-Rosenberg
David Gleason, Esq.

VII. INSTITUTIONAL ENDORSEMENT AND PHS APPROVAL

A. Authorized Institutional Official

Name: Scott Bass, Ph.D.
Title: Vice President for Research
Address: University of Maryland, Baltimore County
1000 Hilltop Circle
Baltimore, Maryland 21250
Phone: 410-455-2199
Fax: 410-455-1092

Signature: Scott Bass
Date: 9/12/05

B. PHS Approving Official

Name: Denis Doyle
Director, Division of Assurances
Office of Laboratory Animal Welfare
National Institutes of Health
6705 Rockledge Drive
Address: RKL1, Suite 360, MSC 7982
Bethesda, MD 20892-7982

Phone:

Fax:

Signature: Denis J. Doyle
Date: 9/14/05

C. Effective Date of Assurance: 9/14/05

D. Expiration Date of Assurance: 9/30/09

**University of Maryland, Baltimore County
ASSURANCE OF COMPLIANCE
WITH
PUBLIC HEALTH SERVICE
POLICY ON HUMANE CARE AND
USE OF LABORATORY ANIMALS**

The University of Maryland, Baltimore County (UMBC) hereinafter referred to as "Institution," hereby gives assurance that it will comply with the Public Health Service Policy on Humane Care and Use of Laboratory Animals, hereinafter referred to as "PHS Policy."

I. APPLICABILITY

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

"Institution" includes all Departments and components of the University of Maryland, Baltimore County. Specific departments with most intensive animal use as of the effective date of this Assurance are Biological Sciences and Psychology.

II. INSTITUTIONAL POLICY

A. UMBC will comply with all applicable provisions of the "Animal Welfare Act" and other Federal statutes and regulations relating to animals.

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

C. UMBC acknowledges and accepts responsibility for the care and use of animals involved in activities covered by this Assurance. As partial fulfillment of this responsibility, this institution will make a reasonable effort to ensure that all individuals involved in the care and use of laboratory animals understand their individual and collective responsibilities for compliance with this Assurance as

well as all other applicable laws and regulations pertaining to animal care and use.

D. UMBC has established and will maintain a program for activities involving animals in accordance with the Guide for the Care and Use of Laboratory Animals.

III. INSTITUTIONAL PROGRAM FOR ANIMAL CARE AND USE

A. The lines of authority and responsibility for administering the program and ensuring compliance with this Policy are (see Figure 1):

1. 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.

2. The Chair of the IACUC and the Veterinarian report directly to the IO on all matters relating to animal care and use. The Assistant/Associate Vice President for Research also reports directly to the IO and serves as a non-voting ex officio member of the IACUC.

3. 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.

4. 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.

5. 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.

6. 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.

7. 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.

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

Name: Louis J. DeTolla, Jr.

Degrees: V.M.D, Ph.D.,M.S., A.B

Training: Fellow in Immunology, NSF, (1974-81) University of Pennsylvania: Post Doctoral Research in Genetics, Rutgers (1978). Immunobiology Fellowship, NIH, Sloan-Kettering Institute, (1982), Cancer Biology Fellowship, NIH, Institute for Cancer Research (Philadelphia), 1983-84.

Experience: Chairman of Comparative Medicine and Chief, UMB Veterinary Resources; Associate Professor, Departments of Medicine, Pathology and Comparative Medicine; The University of Maryland, Baltimore, Maryland; Research Veterinarian and Immunologist, Merck Sharp and Dohme Research Laboratories, Merck Institute for Therapeutic Research, Rahway, N.J.(1986-1989); Research Veterinarian and Cancer Biologist, Chairman, Animal Care Committee, Institute for Cancer Research, Fox Chase Cancer Center, Philadelphia, PA. (1983-1986); Research Veterinarian and Immunochemist, Sloan-Kettering Institute for Cancer Research (1982-1983).

Membership: AA VPT, AAAS, ASZ, ASM, A VMA, Pennsylvania VMA, Maryland VMA, IPS.

Name: Krishnan Kolappaswamy

Degrees: BVSc (DVM), M.S, PhD.(Molecular Epidemiology, 2004-current)

Training: Resident in Comparative Medicine, 2003-Current

Experience: Resident Intern, State Government of Kerala, India; Veterinary Surgeon, State Government of Kerala, India; Graduate Research Assistant, Department of Veterinary and Biomedical Sciences, University of Nebraska; Faculty Research Assistant, Program in Comparative Medicine, University of Maryland, Baltimore

Membership: ASM, Sigma Xi, Anarero Society of Americas, AALAS, American Society for Laboratory Animal Practitioners, American VMA, Maryland VMA, Association of Primate Veterinarians

Delegated program authority:

The Veterinarians have responsibility to oversee the program for animal care and use at UMBC and reports directly to the Vice President for Research, who implements the Guide and secures necessary resources and administrative support for the programs 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.

Percentage of time contributed to the program:

The participating veterinarians spend approximately 10% of their time on the animal care and use program at UMBC. In the event that Dr. DeTolla is unable to perform these program services, a licensed qualified veterinarian from the University of Maryland, Baltimore, Program of Comparative Medicine, Veterinary Resources will be available on call.

C. This institution has established an Institutional Animal Care and Use Committee (IACUC), which is qualified through the experience and expertise of its members to oversee the institution's animal program, facilities, and procedures. The IACUC consists of at least five members, and its membership meets the composition requirements set forth in "PHS Policy" at IV.A.3.b.

D. The IACUC will:

1. Review at least once every six months the institution's program for humane care and use of animals, using the Guide as a basis for evaluation. The 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 HARPO and reminder notices will be sent at least two weeks prior to members. UMBC has developed the IACUC Semi-Annual Review Form for use in evaluation of this activity.

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. UMBC has developed the IACUC Semi-Annual Review Form for use in evaluation of this activity.

The IACUC uses the UMBC Animal Care and Maintenance Procedures during the course of the program and facility evaluations.

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. 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
Administration Building, Room 205
1000 Hilltop Circle
Baltimore, Maryland 21250
Telephone: 410-455-2737
Fax: 410-455-3868
Email: 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.

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.

The Administrator of 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.

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.

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).

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.

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.

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.

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 section D.7 above.

All protocols expire at three years following the original protocol approval date and must be resubmitted for complete review. 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.

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.

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.

E. 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.

F. 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". 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 Safety at UMBC 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.

G. 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 these procedures by the faculty in charge of the animal facility and by the Veterinarian on a regular basis during his/her regular visits.

Additionally, 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 the UMBC Blackboard web server.

This education program is divided into several modules, including:

- 1) Animal Use, Ethics and the IACUC
- 2) Essentials for IACUC Members
- 3) Regulatory coverage housing requirements, biological features, anesthetic doses, biomethodologies and the zoonotic hazards of animal species – species specific
- 4) Minimizing pain and distress in animal species during and after experimental procedures – species specific

Principal investigators, graduate students and research staff are to complete and successfully pass a competency exam for modules 1 and 2 before beginning new or continuing current animal experimentation protocols. Laboratory supervisors will have the responsibility of ensuring that research staff complete the appropriate modules (3 and 4), as it relates to the species involved in the research protocol, within three months of completing the first two modules.

IACUC members must complete "Essentials for IACUC Members" module.

A completion certification will be provided by HARPO to each participant and is valid for 5 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.

The Administrator of HARPO will maintain membership in related professional societies and will attend relevant professional conferences in order to ensure regulatory compliance and to provide guidance and training for researchers.

IV. INSTITUTIONAL STATUS

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. 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.

V. RECORD KEEPING REQUIREMENTS

A. This institution will maintain, through HARPO, 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.

B. This institution, through 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.

C. 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.

VI. ANNUAL REPORTING REQUIREMENTS

A. At least once every 12 months, beginning January 1, the IACUC, through HARPO and the Institutional Official, will report in writing to the Office of Laboratory Animal Welfare (OLAW):

1. Any change in the status of the institution, any change in the description of the institution's program for animal care and use as described in this Assurance, or any changes in IACUC membership. If there are no changes to report, the IACUC, through HARPO and the Institutional Official, will submit a letter to OLAW stating that there are no changes.

2. Notification of the date that the IACUC conducted its semiannual evaluations of the institution's program and facilities (including satellite facilities) and submitted the evaluations to the Institutional Official.

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

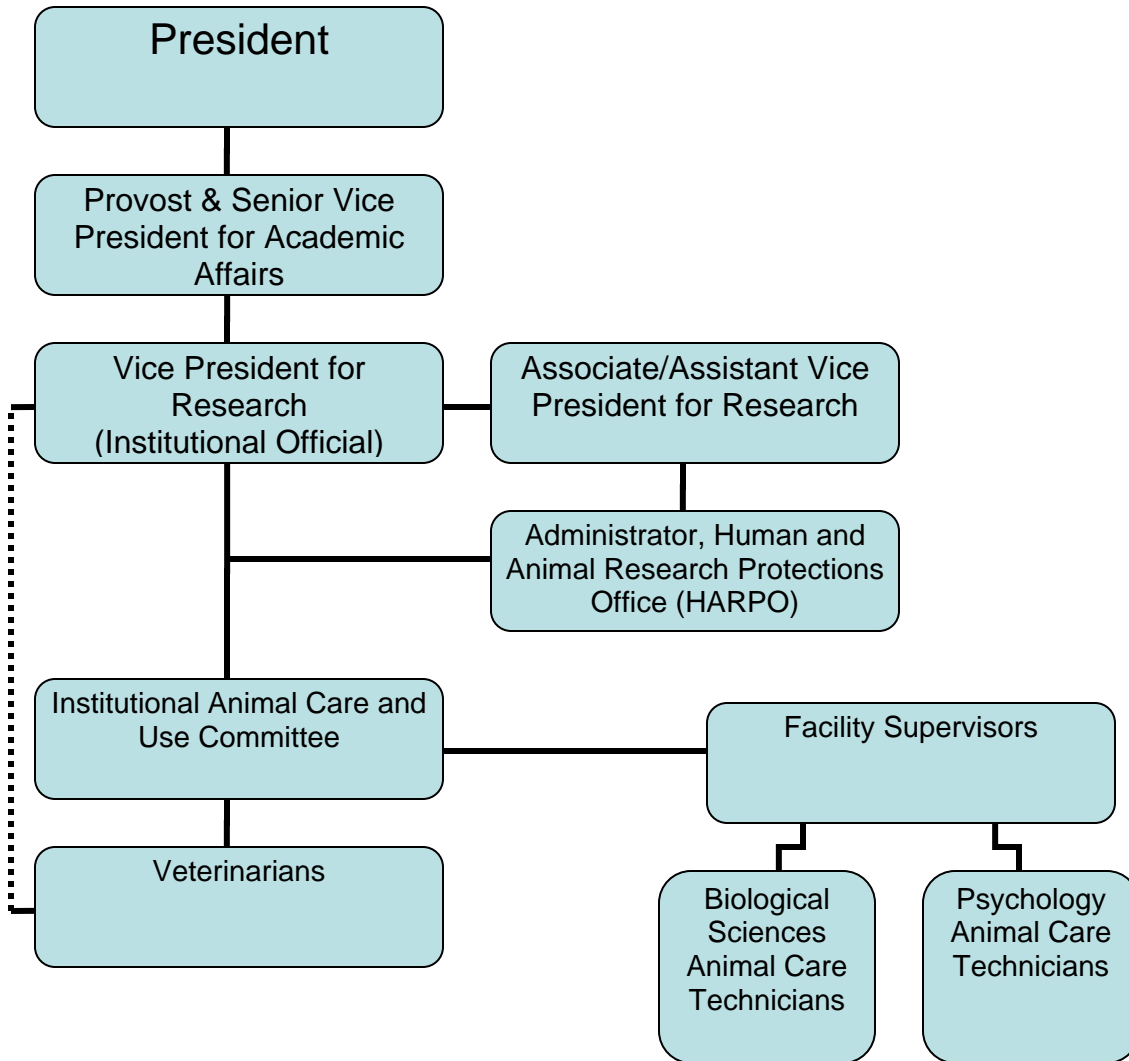
1. Any serious or continuing noncompliance with the "PHS Policy".

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

3. Any suspension of an activity by the IACUC.

C. Reports filed under VI.A.2. and VI.B above shall include any minority views filed by members of the IACUC.

Figure 1
Lines of authority and responsibility for administering the UMBC Institutional Animal Care and Use Program



UMBC IACUC Semi-Annual Review Form

Important Regulatory Notes

What must be covered by the semi-annual IACUC review?

Institutions are required by the PHS Policy on Humane Care and Use of Laboratory Animals "PHS Policy" to conduct adequate semiannual reviews of institutional programs and facilities for the care and use of animals. This "PHS Policy" requirement, found at IV.B.1.&2., states that, at least once every six months, the Institutional Animal Care and Use Committee (IACUC) will review the institution's program for humane care and use of animals and inspect all of the institution's animal facilities. The Guide for the Care and Use of Laboratory Animals (*Guide*) contains the standards and benchmarks to be used as a basis for evaluation. Each member of the IACUC will complete the attached forms during the semi-annual review. All forms will be collected and collated into a report format by the Administrator, Human and Animal Research Protections (HARPO) for inclusion in the IACUC's semi-annual report to the IO.

What is a significant deficiency?

Nearly identical definitions of a significant deficiency are found in the AWA Regulations and PHS Policy is found below:

1. USDA Animal Welfare Act Regulations, 9 CFR Part 2, Subpart C, Section 2.31, par. (c)(3): "A significant deficiency is one which, with reference to Subchapter A, and, in the judgment of the IACUC and the Institutional Official, is or may be a threat to the health or safety of the animals."
2. Public Health Service Policy on Humane Care and Use of Laboratory Animals, IV. Implementation by Institutions, paragraph B.3: "...A significant deficiency is one which, consistent with this Policy, and, in the judgment of the IACUC and the Institutional Official, is or may be a threat to the health or safety of the animals. If program or facility deficiencies are noted, the reports must contain a reasonable and specific plan and schedule for correcting each deficiency..."

Does the IACUC have to report significant deficiencies?

If the plan to correct a significant deficiency is not completed according to the schedule set by the IACUC in Program and Facilities Deficiencies Report and approved by a majority of a quorum, the USDA AWA Regulations state that the failure to correct must be reported in writing within 15 business days by the IACUC, through the Institutional Official, to USDA and any Federal agency funding that activity (USDA AWA Regs, 9 CFR Part 2, Subpart C, Section 2.31, par (c)(3)). PHS Policy does not have the same requirement to report a failure to adhere to the correction schedule for a significant deficiency, but PHS Policy does require that the following be reported by the IACUC through the IO to PHS, regardless of whether a corrective plan is completed according to schedule:

- any serious or continuing noncompliance with PHS Policy (including the Guide for the Care and Use of Laboratory Animals).
- any suspension of an activity by the IACUC.

UMBC IACUC Semi-Annual Review Form

Instructions: For each deficiency noted on this form, fill out a row in Part 3, Program and Facilities Deficiencies Report

Part 1: Program Review

Date of Review:

Reviewers Name:

Reviewer's Signature: _____

Key: NA = Not applicable, A = Acceptable, M = Minor Deficiency, S = Significant Deficiency
The superscript numbers on this form correspond to selected USDA regulatory requirements that differ from the PHS Policy (see notes following the end of Part 3).

Item description	NA	A	M	S	
I. IACUC POLICIES AND RESPONSIBILITIES					
At least 5 members, appointed by the UMBC Institutional Official (IO) in writing for renewable terms responsible for oversight and evaluation of UMBC's program					1
Members include veterinarian, scientist, non-scientist, and non-affiliated non-lab animal user ¹					2
Conducts semiannual evaluations of the UMBC animal care and use program and animal facilities, using the <u>Guide</u> as a basis for evaluation					3
Procedures in place to review and investigate internal or external concerns or allegations about animal care and use ²					4
Procedures in place for review, approval of animal activities not less than annually, with a complete new review every 3 years utilizing all the criteria for initial review ³					5
Procedures in place for review and approval of significant changes to protocols before work begins					6
Policies in place for special procedures (e.g. restraint, multiple survival surgery, fluid restriction)					7
Procedures in place for suspension of animal activities if warranted by findings and after majority vote of quorum					8
II. IACUC REPORTING REQUIREMENTS					
Departures from <u>Guide</u> or "PHS Policy" are detailed and reasons for departure are reported to IO ⁴ and includes a plan and schedule with dates for correction of all deficiencies ⁵					9
Significant deficiencies are distinguished from minor deficiencies					10
IACUC meetings, documents, semi-annual, annual reports and correspondence related to the animal care and use program are maintained at least three years, and IACUC records of individual protocols are kept at least 3 years					11

III. VETERINARY CARE					
Institutional arrangement is present with a veterinarian with appropriate lab animal qualifications					12
Backup veterinary care has been arranged					13
Veterinarian can access all animals and animal procedure areas as needed, including emergency/weekend/holiday					14
Veterinarian oversees daily care of animals					15
Veterinarian oversees disease prevention and control/quarantine program					16
Veterinarian provides oversight/guidance for treatment of disease, surgery, anesthesia, analgesia, euthanasia procedures and programs and pre/post-surgical care					17
IV. INSTITUTIONAL TRAINING PROGRAMS, HEALTH & SAFETY					18
Institutional program for a safe and healthy workplace is established and implemented and covers all personnel who work in laboratory animal facilities ⁶					19
Training program covers ensure the humane treatment of animals and focus on the 3 R's (Replacement, Reduction, and Refinement) ⁶					20
Training program covers use of hazardous agents and proper use, storage, and disposal of hazardous materials ⁶					21
Program in place for medical evaluation and preventive medicine					22
A pre-employment evaluation is offered to employees to make sure the workplace does not pose unnecessary risks					23
Immunizations offered are appropriate (e.g. rabies, tetanus)					24
Zoonosis surveillance is appropriate for species housed (e.g. LCM, Hantavirus, etc.)					25
Procedures are in place for reporting and treating injuries, including bites, etc.					26

UMBC IACUC Semi-Annual Review Form

Part 2: Facilities Review

Instructions: For each deficiency noted on this form, fill out a row in Part 3, Program and Facilities Deficiencies Report

Date of Review:

Reviewers Name:

Reviewer's Signature: _____

Key: NA = Not applicable, A = Acceptable, M = Minor Deficiency, S = Significant Deficiency
The superscript numbers on this form correspond to selected USDA regulatory requirements that differ from the PHS Policy (see notes following the end of Part 3).

Item description	NA	A	M	S	
V. FACILITY POLICIES AND RESPONSIBILITIES					
Animal procurement from authorized vendors only					27
Primary enclosures, cage, or shelters are appropriate for species housed					28
Social environment- appropriate for species housed					29
Special procedure policies (e.g. diet restriction, prolonged restraint) are conducted per IACUC approval					30
Use of specialized housing (e.g. barrier, isolation when appropriate) is utilized as approved by the IACUC					31
Food/water/bedding is appropriate for species housed					32
Animal handling is appropriate for species housed					33
Cage/room sanitation is appropriate for species housed					34
Waste disposal meets facility, municipal, and federal policies and regulations					35
Animal identification is appropriate for species housed					36
Medical/surgical records are accessible and appropriate for species housed					37
Program of surveillance, diagnosis, treatment and control of disease in place					38
Animal transportation is appropriate and compliant with institutional policy					39
Emergency/holiday/weekend husbandry care of animals is provided and appropriate					40
VI. PHYSICAL FACILITIES					
Specialized space (e.g. barrier, surgery, quarantine, necropsy) is maintained properly and safely utilized					41
Cold storage is properly maintained and safely utilized					42
Facility maintenance problems are reported and corrected in a timely fashion					43
Ventilation is monitored to ensure adequate air changes and					44

proper directional air flow					
Wall, ceiling and floor finishes allow appropriate sanitation					45
Paint on animal housing services is intact and not chipped or cracked					46
Ceiling tiles and plaster ceilings that experience water damage are replaced in a timely fashion to prevent mold growth					47
Requests for emergency facility repairs are addressed in a timely fashion by institutional personnel to prevent distress to animals and personnel					48
Temperature and humidity in animal rooms are monitored to ensure they stay within acceptable ranges					49
Facility cage, equipment and sanitation methods meet standards in Guide					50
Cage wash temperatures are monitored to meet applicable standards in the Guide					51
Room care records document that laboratory staff observe animals on a daily basis and clean and water animals as is appropriate					52
Soiled bedding disposal procedures are appropriate					53
Vermin control measures are adequate, and do not unnecessarily compromise animal and human health or scientific studies					54
VII. SURGERY, PAIN/DISTRESS, EUTHANASIA					
Procedures in place for monitoring surgical anesthesia and analgesia					55
Pre-surgical plans approved by the IACUC (e.g. identify space, supplies, conduct pre-op exam, define post-op care)					56
Appropriate training or experience of personnel in surgery & anesthesia					57
Major procedures distinguished from minor					58
Procedures include use of effective aseptic procedures for survival surgery					59
Procedures documented for use of surgical facility					60
Documentation of post-operative monitoring and care					61
Guidelines used for assessment and categorization of pain					62
IACUC guidelines used for avoiding unnecessary pain and distress					63
Appropriate anesthetics, analgesics, tranquilizers used for each species					64
Veterinary input in the choice of drugs					65
Euthanasia procedures compliant with current AVMA Panel on Euthanasia unless approved by the IACUC					66
Guidance provided on appropriate methods for each species					67
Training available for personnel in humane methods of euthanasia					68

UMBC IACUC Semi-Annual Review Form

Part 3: PROGRAM AND FACILITIES DEFICIENCIES REPORT

Date of Review: _____

Reviewers Name: _____

Reviewer's Signature: _____

Instructions: For each deficiency noted on the checklist, enter the checklist number in the first column, and provide the information requested on this form. This form can also be used to track corrections afterwards (see last column).

Line # from last column of checklist	Facility	Description of Deficiency, Reason(s) for the Deficiency, and Plan for Correction	Type of Deficiency ¹		Timetable For Correction (e.g. 30, 60, 90 days)	Date of Correction
			Minor	Sig		

1: Minor = Minor Deficiency, Sig = Significant Deficiency (which is a or may be a threat to animal health or safety)

NOTES FOR PARTS 1, 2 and 3

¹ Committee membership should include the following: The committee shall consist of not less than five members, and shall include at least:

- (1) one Doctor of Veterinary Medicine, with training or experience in laboratory animal science and medicine, who has direct or delegated program authority and responsibility for activities involving animals at the institution (see IV.A.1.c.);
- (2) one practicing scientist experienced in research involving animals;
- (3) one member whose primary concerns are in a nonscientific area (for example, ethicist, lawyer, member of the clergy); and
- (4) one individual who is not affiliated with the institution in any way other than as a member of the IACUC, and is not a member of the immediate family of a person who is affiliated with the institution. IV.B.3.b.

PHS Policy on Humane Care and Use of Laboratory Animals <http://grants.nih.gov/grants/olaw/references/phspol.htm>

² The PHS Policy requires the IACUC to "review concerns involving the care and use of animals at the institution," and the Guide states that the IACUC is responsible for "establishment of a mechanism for receipt and review of concerns involving the care and use of animals."

³ The IACUC shall conduct continuing review of each previously approved, ongoing activity covered by this Policy at appropriate intervals as determined by the IACUC, including a complete review in accordance with IV.C.1.-4. at least once every three years.

PHS Policy on Humane Care and Use of Laboratory Animals <http://grants.nih.gov/grants/olaw/references/phspol.htm>

⁴ The reports must distinguish significant deficiencies from minor deficiencies. A significant deficiency is one which, consistent with this Policy, and, in the judgment of the IACUC and the Institutional Official, is or may be a threat to the health or safety of the animals. IV.B.1

PHS Policy on Humane Care and Use of Laboratory Animals <http://grants.nih.gov/grants/olaw/references/phspol.htm>

⁵ If program or facility deficiencies are noted, the reports must contain a reasonable and specific plan and schedule for correcting each deficiency. IV.B.1

PHS Policy on Humane Care and Use of Laboratory Animals <http://grants.nih.gov/grants/olaw/references/phspol.htm>

⁶ The Animal Welfare Regulation, in Sec. 2.32 (a) and (b), specify:

It shall be the responsibility of the research facility to ensure that all scientists, research technicians, animal technicians, and other personnel involved in animal care, treatment, and use are qualified to perform their duties. This responsibility shall be fulfilled in part through the provision of training and instruction to those personnel. Training and instruction shall be made available, and the qualifications of personnel reviewed, with sufficient frequency to fulfill the research facility's responsibilities....

The PHS Policy, Section IV.C.1.f. places responsibility specifically with the IACUC to ensure that personnel conducting procedures on research animals are appropriately qualified and trained in those procedures.

UMBC Animal Care and Maintenance Procedures

All animal care personnel will function under the direct supervision of the veterinarian who will establish and implement necessary policies and procedures in accord with the "PHS Policy," the Guide and the "Animal Welfare Act."

GENERAL REQUIREMENTS FOR THE ANIMAL CARETAKER

1. The general duty of animal caretakers is to provide care for laboratory animals and the maintenance of sanitary conditions in the animal care facilities.
2. Animal caretakers should be available in the facilities at all times or leave a message as to where they can be reached.
3. Animal caretakers must be able to follow specific instructions from investigators as to exact requirements for their animals.
4. Animal caretakers must become familiar with regulations pertaining to animal care. These regulations include the "PHS Policy," the Guide and the "Animal Welfare Act" and any other federal and state requirements which pertain to the care and the use of animals. Animal caretakers will be encouraged to attend the annual National Capital Area Branch of the American Association for Laboratory Animal Science (NCAB) meeting and are encouraged to obtain AALAS certification.
5. Animal Caretakers will implement policies and procedures established by the Veterinarian.

GENERAL REQUIREMENTS FOR THE ANIMAL FACILITY

1. All rooms of the animal facility are to be maintained broom clean and tidy at all times. Floors are to be mopped daily with fresh disinfectant solution and scrubbed as necessary.
2. A schedule, including the room number, maintenance function (such as: water bottles washed, cages washed, etc.) shall be maintained in a facilities log. As a maintenance function is performed, the caretaker will date and initial its completion.
3. All supplies pertaining to the animal facility (especially feed and bedding) shall be ordered in ample time such that the animal facility does not run short. A month's supply of food and bedding should be on hand at all times. Other supplies to be kept in reasonable inventory should include but not be limited to:
 - A. Maintenance items such as:
 1. Trash bags
 2. Brooms, mops, hand soap, paper goods
 3. Detergents and treatments for cage washing machine
 - B. Filters for watering system and laminar flow cage systems

- C. Label cards for cages
- D. Gloves and animal discard bags
- E. CO2 tank for disposal of animals.
- F. Any medications, anesthesia, or related items as directed by the investigators

Water system pressure station and in-line filters should be checked daily and filters replaced at least once every month.

Doors and adjacent corridors are to be kept locked at all times.

MAINTENANCE OF RATS AND MICE IN PLASTIC BOTTOM CAGES

Note: Mice in the Biology facility are on an automatic watering system. Water bottles are used on rare occasions if mice require medication or other additives in their drinking water as per an IACUC approved experimental protocol. Water bottles are used solely in the Psychology facility.

A.DAILY DUTIES

1. Inspect all animals to determine their general condition and health. Treat or arrange for treatment any animals which appear to be sick or diseased.
2. Remove any wet or soiled food from feeders. Make sure food supply is adequate.
3. Remove animals from soiled cages and place into cages with fresh litter.
4. Empty soiled litter from cages and place of rack for cleaning and sanitizing.
5. Check all water bottles for adequate supply; replace with fresh bottles.
6. Check to make sure that no cages have flooded from a water bottle or water system. Change any cages that have flooded.
7. Check all mating cages for new litters. Enter the date of the litter on the cage card.
8. Check all cages for dead animals. Any dead animals in experimental cages (i.e., cages with an experiment number in the experiment room on the cage card) are to be bagged in plastic. All of the cage card information is to be copied onto a new card and the dead animal and the card placed on the table or in a conspicuous spot in the room so the investigators can recover them. The date of the death and the number of animal dead that day will be neatly noted on the cage card remaining on the cage.
9. Sweep and/or wash floors.
10. Keep a written record of room temperature, feeding and maintenance of the animals in the "LOG SHEET" as they are accomplished.

B. OTHER THAN DAILY DUTIES

1. Cage racks are to be cleaned twice a week: on Mondays or Tuesdays and Thursdays or Fridays.
2. Water bottles are to be changed, sanitized at least once per week.
3. Solid waste will be removed from the shelves of all racks by flushing with water from a hose or by scraping at least once every two days.
4. In advance of need, order feed and bedding. Keep at least a one month supply on hand at all times. Maintain an adequate supply of experimental items as requested by the investigator.
5. Record on the "LOG SHEET" each of the above events when accomplished.
6. Arrange for weekend and holiday coverage of all daily duties listed above for Saturday and for Sunday.

PROCEDURES for SERIOUS and LIFE-THREATENING EMERGENCIES

In the event of any of the following emergencies, CALL CAMPUS POLICE (5-5555) as quickly as possible.

AMBULANCE

Call CAMPUS POLICE (5-5555)

CHEMICAL ACCIDENT

1. Call CAMPUS POLICE (5-5555)
2. Restrict contamination area: close windows and doors
3. Vacate space and post RESTRICTED DO NOT ENTER SIGNS
4. Vacate building and pull fire alarms

EXPLOSION

1. Pull fire alarm
2. Call CAMPUS POLICE (5-5555)
3. Vacate building

FIRE

1. Pull fire alarm
2. Call CAMPUS POLICE (5-5555)
3. Vacate building

RADIATION ACCIDENT

1. Call CAMPUS POLICE (5-5555)
2. Make no attempt to clean up spill
3. Close windows and doors
4. Vacate room and post RESTRICTED DO NOT ENTER signs

PROCEDURES FOR OTHER EMERGENCES

AMBULANCE

Call CAMPUS POLICE (5-5555)

ACCIDENT OR ILLNESS-JOB RELATED

1. If ambulance needed:
 - a. Call CAMPUS POLICE (5-5555)
 - b. Notify Concentra Medical Center (410) 274-9595 that injured person will be taken to St. Agnes Hospital (Wilkins Avenue-East)
2. Otherwise, take person to the Concentra Medical Center with UMBC
Personnel Department authorization form (available in departmental offices)

Concentra Medical Center	Open Monday-Friday
1419 Knecht Avenue	8:30am - 4:30pm
Arbutus, Maryland 21227	

ACCIDENT OR ILLNESS--NON JOB RELATED

1. Employees should be referred to their personal physician
2. Students should be referred to University Health Services. If UHS is closed, student should be transported to St. Agnes Hospital (Wilkins Avenue-East) and call CAMPUS POLICE (5-5555)

ELECTRICAL OUTRAGE

Call Work Control (5-2550)

ELEVATOR STUCK

Call Work Control (5-2550)

GAS LEAK

Call Work Control (5-2550)

WATER PIPE BREAK

Call Work Control (5-2550)