THE INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE

ABOUT THE INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC)

The IACUC (Institutional Animal Care and Use Committee is the institutional review board that oversees research involving the use of animals. IACUC is charged with the duty to protect animals used in research, ensure proper care, and oversee animal research facilities. IACUC reviews all research protocols where animals are considered for use.

The IACUC Committee is comprised of faculty members from various academic units throughout the University, the University Veterinarian, and non-affiliated community members. The IACUC is chaired by: Emmanuel Akala, PhD, Professor, Pharmaceutical Sciences Department. Please contact the Office of Regulatory Research Compliance if you have any questions regarding the Howard University IACUC at 202-865-8597 or via email at theorrc@howard.edu.

LEGAL MANDATE:

Public law 99-158 and 99-198 require each institution to appoint an Institutional Animal Care and Use Committee (IACUC) qualified through the experience and expertise of its members to oversee the institutional animal programs, facilities and procedures.

The Assurance Statement of HU (No. A-3742-01) to the Public Health Service includes the names, position titles and credentials of the IACUC chairperson and the members.

The number of members required to fully constitute the IACUC is 3 for the United States Department of Agriculture (USDA) and 5 for the Public Health Service (PHS).

PHS IACUC Membership Requirements:

- A Doctor of Veterinary Medicine either certified (e.g., by ACLAM, ECLAM, JCLAM, KCLAM) or with training and experience in laboratory animal science and medicine or in the use of the species at the institution

- At least one practicing scientist experienced in research involving animals

- At least one member from a nonscientific background, drawn from inside or outside the institution

- At least one public member to represent general community interests in the proper care and use of animals (Public members should not be laboratory animal users, affiliated in any way with the institution, or members of the immediate family of a person who is affiliated with the institution)..

USDA IACUC Membership Requirements:

UNDER USDA POLICY MANUAL POLICY # 15, the regulations requirethat the IACUC be composed, at a minimum, of an IACUC Chairperson, an Attending Veterinarian and an Nonaffiliated Member. The policy goes on to state that the the nonaffiliated member of the Institutional Animal Care and Use Committee (IACUC) is to "provide representation for general community interests in the proper care and treatment of animals." The person filling this position is intended to represent society's "less specialized" nonscientific concerns regarding the welfare of the animal subjects. APHIS has determined the nonaffiliated member should not be a laboratory animal user at any research facility.

TRAINING & EDUCATION

On-line Animal Care and Use Training Program

Effective March 1, 2013, the LATA will no longer be the required training for animal research. The CITI courses, "Animal Care and Use," will replace the LATA as the required training for persons involved in the conduct of research that uses non-human vertebrate animals. Registration for the CITI Animal Care and Use courses can be located at http://www.citiprogram.org. New users should select **Howard University Medical Center** as the participating institution.

LINKS & RESOURCES

USDA Policy Manual: This manual addresses frequently asked questions regarding compliance to federal USDA animal welfare regulations.

USDA National Agricultural Library (NAL): All researchers are required to be knowledgeable about this library.

The Animal Welfare Information Center (AWIC): a repository of information on animal welfare information resources. As such, AWIC provides vital information resources for those using animals in research, testing and teaching. Federal regulations for animal welfare can also be found on the AWIC website.

Essentials for Animal Research: A Primer for Research Personnel, a primer for animal research staff

Institute for Laboratory Animal Research (ILAR): operates under the auspices of the National Academy of Sciences. ILAR prepares authoritative documents for the animal research community.

Drug Enforcement Administration (DEA): University laboratory animal facilities and University personnel must comply with these regulations. A District of Columbia controlled substance license must be acquired before one can apply for a DEA federal license. Contact the District of Columbia Consumer and Regulatory Affairs Bureau of Food, Drug and Radiation Protection at (202) 535-2076 for licensing information.

NetVet Veterinary Resources and its indexed site the Electronic Zoo is one of the best sites on the web for information on anything and everything you want to know about animals, animal care and research.

Federal Regulations and Standards governing animal care and use training and procedural resources for university research facilities can be accessed through the National Institutes of Health Office of Animal Care and Use (OACU).:

United States Department of Agriculture Animal Welfare Act

The Guide for the Care and Use of Laboratory Animals

The PHS Policy on Humane Care and Use of Laboratory Animals

The Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC)

The Office of Laboratory Animal Welfare (OLAW)

FUNCTIONS OF THE INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE

1. Review at least twice annually the institutional program for humane care and use of animals.

2. Inspect at least twice annually all of the animal facilities, including satellite facilities and sites of rodent surgery.

3. Review concerns involving the care and use of animals at the institution.

4. Make recommendations to the institutional official regarding any aspect of the institutional animal program, facilities or personnel training.

5. Review and approve, require modifications in (to secure approval) or withhold approval of all proposals for research or teaching involving the use of animals. The animal use protocol is a detailed description of the proposed use of laboratory animals. The following topics should be considered in the preparation of the protocol by the researcher and its review by the IACUC (Excerpts from the Guide):

   - rationale and purpose of the proposed use of animals
   - a clear and concise sequential description of the procedures involving the use of animals that is easily understood by all members of the committee
   - availability or appropriateness of the use of less invasive procedures, other species, isolated organ preparation, cell or tissue culture, or computer simulation (i.e., alternatives)
   - justification of the species and number of animals proposed; whenever possible, the number of animals and experimental group sizes should be statistically justified (e.g., provision of a power analysis; see Appendix A, Experimental Design and Statistics)
   - unnecessary duplication of experiments
   - nonstandard housing and husbandry requirements
   - impact of the proposed procedures on the animals' well-being
   - appropriate sedation, analgesia, and anesthesia (indices of pain or invasiveness might aid in the preparation and review of protocols; see Appendix A, Anesthesia, Pain, and Surgery)
   - conduct of surgical procedures, including multiple operative procedures
   - postprocedural care and observation (e.g., inclusion of post-treatment or postsurgical animal assessment forms)
   - description and rationale for anticipated or selected endpoints
   - criteria and process for timely intervention, removal of animals from a study, or euthanasia if painful or stressful outcomes are anticipated
   - method of euthanasia or disposition of animals, including planning for care of long-lived species after study completion
   - adequacy of training and experience of personnel in the procedures used, and roles and responsibilities of the personnel involved
   - use of hazardous materials and provision of a safe working environment.

6. Review and approve, require modifications in (to secure approval) or withhold approval of proposed significant changes regarding the use of animals in ongoing activities.

7. Suspend any activity that deviates significantly from procedures as described in the research proposal that may have an adverse effect on experimental animals.

ROADMAP TO IACUC APPROVAL OF ANIMAL USE
Completing the Paperwork

1) *No animal use in research or teaching can proceed without an IACUC approved proposal (See attached IACUC A, B, C Proposal Forms).* IACUC Forms are available on the Office of Research Website at http://www.huiacuc.howard.edu. Please visit this IACUC website for forms, their use and to obtain instructions on how to fill them out).

2) All forms must be typed, signed by the Principal Investigator (PI) and contain all supporting documents (i.e., a copy of the grant application if external funding is sought; a copy of the faculty advisor-endorsed (signed) research plan for student submissions, curriculum vitae and roles of personnel who will be working on the project and letters from collaborators affirming their participation and roles on the project). For external grant proposal submissions the Howard University OLAW Assurance Number is A-3742-01.

3) Each funding source requires a separate proposal submission no matter how similar the proposal may be to others already approved, submitted or being submitted.

4) Student researchers cannot be listed as the PI. A fulltime faculty member must agree to accept responsibility for the project and serve as the PI. The student researcher must then be identified as the Co-PI. As stated under item 2 above the approved research plan signed by the PI and faculty advisor must accompany the application.

5) *Each* research or teaching project requires the submission of a separate IACUC proposal.

   a) *Form IACUC-A:* Use Form A for new, renewal, revised grant applications and for ongoing projects extending beyond three years (i.e., de novo review) and ongoing projects with substantial changes. In the case of 3 year review (de novo), submit Form A prior to the start of year 4.

   b) *Form IACUC-B:* Use Form B for non-competing annual continuation proposals when there are no significant changes in the number or species of animals used, procedures performed on animals, procedures designed to limit discomfort or injury to animals or methods of euthanasia. One can also report an imminent anticipated change in animal handling personnel (i.e., within 30 days or less) and not have to simultaneously submit an additional addendum IACUC-C Form

   c) *Form IACUC-C:* Use Form C to request minor changes in animal use or care on approved ongoing studies.

6) Changes in animal use for research, teaching or testing for ongoing approved animal use proposals, whether or not they are perceived to have an impact (or no impact) on the care and use of animals, shall not be initiated without prior approval of the IACUC. To this end, a change in venue, personnel, animal numbers, animal species, proposal scope, method of euthanasia or agents administered to animals (such as antibiotics, test agents, analgesics, etc.) must be granted prior approval prior to use in approved animal use proposals.

7) Use of hazardous agents or materials [hazardous chemicals\biochemical agents, biohazardous agents, recombinant DNA, radioisotopes, physical agents (lasers, etc.)] in animal research must be approved by the relevant Safety Committee (SC): IBC or RSC. A copy of the SC letter of approval and stipulations for safe use of hazardous material /agent(s) must be received by the IACUC prior to approval of animal research. The PI must assure that these SC approval documents are received by the IACUC and is advised to send the Safety Application to the relevant SC at the same time the proposal is submitted to the IACUC. The IACUC Safe Use Form must also be completed.

8) IACUC Forms and supporting documents should be sent electronically to the IACUC at http://www.huiacuc.howard.edu .

9) The IACUC meets routinely ***monthly.*** Submission deadlines are posted on the IACUC website.

10) The Howard University OLAW Assurance Number is A3742-01.

Anticipated timeframe for IACUC actions on ***complete*** proposals is appended.

11) Most Common Mistakes That Delay IACUC Action:

a) Incomplete IACUC Forms

b) Lack of statistical justification or justification of animal numbers

c) Lack of plan to minimize pain, stress or distress

d) Lack of a letter of approval from the relevant Safety Committee (IBC and/or RSC)

e) Lack of adequate search for alternatives

HOWARD UNIVERSITY
OFFICE of REGULATORY RESEARCH COMPLIANCE (ORRC)
IACUC Protocol Development Process (Rev 11/17)

- **Pre-application Consultation**
- **Application Pre-review**
- **Initial Application Submission and Review by the IACUC**
  - Prior to the IACUC meeting, we strongly encourage reviewers to engage the investigators, clarify minor issues, and request correction of errors or modifications as appropriate.
  - This communication can be channeled through the ORRC for proper documentation
- **Resubmission**:
  - **Designated Member Review (DMR)**
  - **Full Committee Review (FCR)**
- **Approval Letter from the ORRC**

IACUC Pre-Application Checklist to Expedite the Application Process			
Please, respond "YES" or "NO" to the following questions/items			
I. Institutional Biosafety Committee (IBC) Review: Assessment for IBC review requirement Note: A "YES" response in this section means your protocol requires IBC review.		**YES**	**NO**
1	Are you using body fluid, tissue or cells of any kind or established or created cell lines?	O	O
2	Are you using viruses, viral vectors or potentially infectious materials?	O	O
3	Does your protocol involve recombinant DNA/RNA?	O	O
4	Does your protocol involve toxins or pathogenic microorganisms?	O	O
5	Does your protocol require a material transfer agreement (MTA)?	O	O
6	Does your protocol require IBC review/approval?	O	O
7	If IBC Review is required, have you submitted the protocol to the IBC?	O	O
8	If your protocol was submitted to the IBC, has it received IBC approval?	O	O
II. Other Assessments Required:		**YES**	**NO**
9	Have you completed occupation health and safety assessment?	O	O
10	Has your laboratory undergone a laboratory safety inspection? (Contact Dr. Nandedkar)	O	O
11	Do you need a Biological Safety Cabinet (BSC) to carry out your work?	O	O
12	If you respond "YES" to item 11 (need BSC) above, is the BSC currently certified?	O	O
13	Do you need a Chemical Fume Hood (CFH) to carry out your work	O	O
14	If you respond "YES" to item 13 (need CFH), is the CFH currently certified?	O	O
15	Do you need a Radiation Safety Cabinet (RSC) to carry out your work?	O	O
16	If you respond "YES" to item 15 (need RSC), is the RSC currently certified?	O	O
III Training/Certification Requirements (M = mandatory)		**YES**	**NO**
17	Completed Responsible conduct of research training (RCR) **M**	O	O
18	Completed IACUC Collaborative Institutional Training Initiative (CITI) Online Training **M**	O	O
19	Completed Conflict of Interest (COI) Training **M**	O	O
20	Completed Biosafety/ Biosecurity (B&B) training required for IBC-approval	O	O
21	Completed Veterinary Services hands-on training if research role is to handle animals	O	O

HOWARD UNIVERSITY
OFFICE of REGULATORY RESEARCH COMPLIANCE (ORRC)
INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC) Protocol Development Process (Revised Nov 2017)

Pre-Application Consultation (Complete within one week of initiation.

Investigators (PI) may directly contact the following or go to "b)"

- Veterinary Services (strongly recommended)
- Institutional Biosafety Committee (IBC) Chair
- IACUC Chair
- Laboratory Safety Officer
- The ORRC

b) The Investigator contacts the ORRC

ORRC provides programmatic orientation and information to the PI along with a new investigator package including contact for the following:

- Veterinarian and Veterinary Services Manager (consul)
- IACUC Chair
- IBC Chair (consult regarding IBC approval if required)
- Laboratory Safety Officer (consul and scheduler for laboratory inspection)
- ORRC Staff (also provides regulatory documents and contact information and details for CITI Training and Occupational Health Program enrollment)

PI One-on-One meeting with Veterinarian (Strongly recommended) and/or IACUC Chair or Designated Expert

Pre-Review (Complete estimate: 1 – 3 weeks

PI submits application to the ORRC

Veterinary Pre-Review (Estimated Time: 1 – 2 weeks)

IACUC Chair or Designated Expert Pre-Review (Estimated Time: 1 – 2 weeks)

Veterinarian/IACUC Chair or Designated Expert Pre-Review comments are returned to ORRC

PI makes necessary revisions based on pre-review comments and submits application for IACUC Review
(Estimated Time: 1 week allotted but revision time exceeding 1 week must be added to the total Pre-Review Time)

IACUC Review (Complete estimate: 1 – 3 weeks

PI officially submits protocol to the IACUC

IACUC reviews protocol (FCR/DMR)

Protocol is approved **

Protocol requires revision for FCR or DMR

PI revises/ returns protocol for FCR

PI revises/ returns protocol for DMR

Protocol is approved**

Protocol is approved **

**Approval letter is issued to the PI by the ORRC (within 48 hours) **