Instructions for Submission of a Proposal for Laboratory Vertebrate Use in Research, Teaching or Testing Forms IACUC A, B and C

Proposals may only be submitted by a HU Faculty member who will serve as the Principal Investigator (PI) and Responsible Faculty Member in the case of student research proposals. The PI bears direct accountability and responsibility for the proper conduct of the project or activity described in the proposal and approved by the IACUC.

Research or teaching that uses vertebrate animals may not be initiated until **(1)** A Proposal for Laboratory Vertebrate Use has been submitted and is approved by the Institutional Animal Care and Use Committee (IACUC), **(2)** Training in the care and use of laboratory animals (of the species named in the proposal) is received (see V below), and **(3)** The use of hazardous agents or materials in animals has been approved by the relevant safety committee [Radiation Safety Committee (RSC) and/or Institutional BioSafety Committee (IBC)] as appropriate. It is the responsibility of the Principal Investigator to submit his or her application to the relevant safety committee for the work to be carried out in the parallel animal protocol and to assure that copies of the [RSC or IBC] Safety Committee Letter of Approval are submitted to the IACUC.

Three proposal forms are currently in use: **IACUC-A**, a comprehensive form ; **IACUC-B**, an abbreviated form for continuations; and **IACUC-C**, a form for addenda with minor changes.

Directions for the use of each form are as follows: Forms are modified over time in order to reflect changing regulatory requirements. Please refer to the IACUC Home Page to assure you are using the most recent form. All three forms may be downloaded in Word for Windows from the IACUC Home Page at http://www.huiacuc.edu.

Filling out and signing the form: New formats are designed to be opened in Word and the information entered directly into the response space provided. ***Applicants are asked not to add or delete items on any form. Altered or Incomplete forms will be returned without committee action.*** Print, sign and submit the original and four (4) copies to the IACUC application, ***along with five (5) copies of the grant, thesis or dissertation. THESIS and DISSERTATIONS MUST HAVE THE SIGNATURES OF ALL COMMITTEE MEMBERS, THE FACULTY ADVISOR, THE DEPARTMENT CHAIR and THE DEAN OF THE GRADUATE SCHOOL, PRIOR TO SUBMISSION. Submit the entire package*** to the IACUC Office located in suite 137 of the C.B. Powell building at 525 Bryant street, N.W.

I. RESEARCH

For New, Renewal, and Revised Grant Applications and for ongoing projects extending beyond three years complete IACUC Form A.

Investigators are urged to submit applications to the IACUC at the time of grant submission to prevent delay in the onset of research. Except National Institutes of Health (NIH), Department of Defense (DOD) etc. funded research which allows just-in-time approvals. Items 1-5 of this form are in a standardized format for submission to extramural sponsors. You may duplicate these items on the appropriate continuation pages and include them in your grant application,

e.g., under item F in NIH proposals.

For Non-Competing Continuation Proposals complete IACUC Form B, when there are no significant changes in the number of animals request or species to be used, procedures performed on animals, procedures designed to limit discomfort or injury to animals, or methods of euthanasia. In your continuation application under the heading, **Vertebrate Animals** - a statement that there are no changes in the above listed items is required. If there are significant changes in any of the items listed above; or if the project is continuing beyond three years, complete IACUC Form A. ***A de novo review of continuing projects is required every three years).***

For minor changes in ongoing animal care and use studies complete IACUC Form C.

II. TEACHING

For New Teaching Projects complete IACUC Form A.

For Continuing Teaching Projects complete IACUC Form B; this is for proposals that have been previously approved by the IACUC and there are no significant changes in number animals and species to be used, in procedures performed on animals, in procedures designed to limit discomfort or injury to animals, or in methods of euthanasia.

For minor changes in ongoing animal care and use studies complete ACUC Form C.

III. ANNUAL CONTINUATION

IACUC approval for all research and teaching projects must be renewed yearly dating from the annual effective approval date for each proposal.

IV. INFORMATION NEEDED FOR NIH PROPOSALS

A. The Howard University Animal Welfare Assurance number is A3742-01

B. A suggested description of the Animal Research Facility for the resources and environment section of PHS 398 follows:

The Veterinary Services (VS) core laboratory animal facility is fully accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC). The satellite Biology Laboratory Animal Facility is overseen by the University Veterinarian but has not yet applied for accreditation with the core facility. The Veterinary Services Staff is qualified in veterinary medicine and laboratory animal care and management. TheVS core facility is located on the 5th floor of the Numa P.G. Adams Building and features administrative offices, refrigerated diets storage, quarantine, examination and treatment room, necropsy, cage sanitation, storage rooms, procedure rooms, a diagnostic laboratory and a surgery suite. Conventional animal holding rooms are equipped with sinks, seamless floors, automatic watering, light cycle timers, and HVAC (Heating, Ventilation and Air Conditioning) support stipulated by the Guide in accordance with all facets of applicable laboratory animal research industry standards. Animal care and management practices also comply with the Guide, the Animal Welfare Act, and other applicable local and federal regulatory requirements and meet AAALAC quality standards.

C. Information on the Veterinary Care of the Animals Used:

All animals used in this study will receive care under the direction of a trained and experienced staff veterinarian. The attending veterinarian has devised programs to insure daily observation of animals; use of appropriate methods to prevent, control, diagnose, and treat diseases and injuries; monitor surgery, post-surgical and postprocedural care; and provide guidance regarding handling, anesthesia, analgesia, and euthanasia.

V. TRAINING REQUIREMENTS

All animal handling personnel (except Principal Investigators on research projects or Professors on teaching projects who are experienced with the animal species and the procedures to be performed) must view videotapes relevant to the animal species to be used. Once approval for use of an animal species is obtained, there is no present requirement for updating training for use of that species. All animal handling personnel must be certified by the Laboratory Animal Training Association (LATA) for the species to be used. To become LATA-certified contact the IACUC Office. In addition, the PI of all research and teaching projects are required to procure and have available to animal handling personnel training manuals including the IACUC Guide and the Animal Welfare Act. All animal handing personnel are encouraged to attend the IACUC lectures on animal care and use, which are announced in advance. Training requirements must be met before access is given to animal rooms; prior to initiating any studies employing animals; and before animals can be ordered. Call 202 806 5340 to schedule training and to obtain the latest version of the IACUC Guidelines.

VI. SURGERY

For IACUC purposes, major surgery is defined as an incision that penetrates and exposes a body cavity or the central nervous system (CNS), or that produces a permanent impairment. Multiple major survival surgeries on a single animal are discouraged and must be fully justified. All survival surgery must be conducted aseptically in all species of warm blooded animals. For all animals, except rodents, such surgery must be conducted aseptically in the surgical suite of the VS. For rodents, use of sterile instruments and supplies, skin prep, gloves, clean lab coat or coverall and mask are minimal requirements. Removal of tissue or fluid after death or under anesthesia followed immediately by death constitutes a non-surgical procedure, though personnel must comply with the use of proper attire and personal protective equipment needed to address occupational safety concerns. An incision for subcutaneous placement of a drug or drug-containing pump is considered a minor surgical procedure, sterility and analgesia must be assured in such instances.

VII. NON-SURGICAL PROCEDURES

Some non-surgical procedures produce permanent impairment of the physical or physiological functions of an animal, i.e., reduce its normal range of motion, abilities, functions or produce permanent impairment or result in a handicap (e.g., impact tests, burns, prolonged immobilization, deprivation and drug tumor, toxicology or disease models). Multiple procedures producing impairment on a single animal are discouraged and must be fully justified. Researchers must also be aware of the time course of disease progression for various genetically engineered or natural disease models and the impact of disease progression on animal health and well-being; the level of pain, stress or distress experienced by the animal during any given

period.

VIII. PAIN

Pain, stress or distress that is experienced is defined in hum an standards. (If a procedure would be painful for you, it is considered similarly painful to animals.) Pain is estimated on a 0-4 scale.

Category

0 (Non-painful or no pain perception)	Non-living vertebrate anim als, use of eggs or embryos, tissue culture, invertebrates without complex CNS, slaughterhouse tissues, necropsy tissues
1 (little or no discomfort)	Non-survival procedure under general anesthetic. Injections of non-irritant, non-toxic materials. Euthanasia (AVMA-approved). Short term restraint (<15 minutes). Blood sampling not re quiring sedation or anesthesia. Use of invertebrates with com plex CNS (unless proven otherwise).
2 (minor stress/ short duration pain)	Minor procedure or small\first degree burn under anesthetic. Blood vessel catheterization or infusion pum p implantation. Use of Freund's Adjuvant once per animal. Moderate restraint (15-60 minutes). Food/Water deprivation (a few hours).
3 (significant, but unavoidable pain/stress)	Major procedure or burn under general anesthesia with surv ival but with out use of post-op analgesia. Moderate to severe restraint (>1 hour). Use of Freund's Complete Adjuvant (m ore than once per animal). Whole body radiation (causing G-I or CNS syndromes). Death as end point (w ith little appa rent suffering, e.g., hemorrhagic or septic shock). Decapitation or cerv ical dislocation without prior sedation. Behavioral stress (cold exposure, shaker stress). ***(Investigators must explore alternative designs to minimize or eliminate animal distress; and must develop an assessment and intervention tool that calls for the***

	earliest possible euthanasia of animals).
4 (severe pain near, at or above pain tolerance threshold)	Major survival surgery, burn, or traum a infliction without general anesthesia, or without post-op analgesia. Use of muscle relaxants or paralytic drugs alone for surgical restraint. Death as en d point acc ompanied by suffering (e.g., som e toxicity test ing, disease production models). Euthanasia accom panied by su ffering and unapproved by the AVMA. Any procedure accompanied by severe and pro longed stress or pain, not relieved by anal gesia, tranquilizers, or anesthetics. ***(Highly questionable irrespective of significance and could result in loss of federal funds)***

IX. FOR PROPOSALS THAT ARE NOT PEER-REVIEWED FOR SCIENTIFIC MERIT BUT ARE FUNDED BY DEPARTMENTAL, COMMERCIAL, OR PRIVATE SOURCES, PROVIDE A DESCRIPTION OF THE PROJECT FORMATED AS BELOW:

I. RESEARCH PLAN

A. Specific Aim(s) (Include in this section what new information is expected.)
B. Method of Procedure
C. Significance of this Research
D. Facilities Available

II. SUPPORT DATA

A. Previous Work Done on the Project
B. Results Obtained by Others
C. Personal Publications
D. Curriculum Vitae

Optionally investigators m ay provide a copy of th e entire grant proposal, to include tim e and effort from all sources i.e. teaching and other research project to include Co-PI status.

X. ADDITIONAL REQUIREMENTS FOR USDA COVERED SPECIES:

ALTERNATIVES

A literature search for alternatives is required for all **potentially** painful procedures on all warm blooded species covered by the Anim al W elfare Act (A WA), whic h currently excludes rats, mice, and birds. Our in stitution requires an alte rnative search for all ve rtebrate animal use, and therefore does not exempt rat, mice and birds in this regard. **Potentially** painful procedures are defined as those pro cedures that cause m ore th an m omentary or slight pa in, stress or distress.

(**Note:** A procedure in which pain /distress/suffering is relieved, is defined in the AWA as a potentially painful procedure, e.g., collection of tissues under general anesthesia is still a potentially painful procedure). Such procedures are categorized by USDA based on whether or not anesthesia/ analgesia/ sedation/ tranquilization are given to alleviate or minimize pain, stress or distress. Alternatives (reduction, refinement or replacement) must be considered for animals subjected to potentially painful procedures.

Alternatives are defined as the three "R's": **Replacement** -- use of non-vertebrate animals, tissue culture, other models; **Refinement** -- use of less invasive, less painful procedures; and **Reduction** -- using the minimum number of animals consistent with statistical reliability. A literature search is the most often utilized method of fulfilling this requirement (though other methods are accepted but must be fully documented). An alternative search requires identification of the **search databases** (*Medline, BIOSIS Previews, TOXLINE, EMBASE, AGRICOLA, PASCAL, CAB Extracts, Altweb, etc.),* the **period searched** *(a minimum of 10 years to present is recommended),* procedural and alternatives **words** used (*Be sure to first use study aim, species, etc. and then filter the results using applicable alternative-finding- words such as in vitro, ex vivo, mathematical model, cell culture, computer simulation, reduction, refinement, replacement, etc*.), the **number and types of alternatives found** (*Ex.: 2 cell culture methods, 3 non-vertebrate models, etc*.) and **a statement of conclusions** *[indicating whether the alternatives found were suitable (and incorporable) or unsuitable based on study objectives).* Those using non-covered species are urged to conduct this exercise on their own as a means of seeking alternatives to procedures that cause more than momentary pain, stress and distress.

Researchers are referred to the IACUC Guidelines for additional information on searching for alternatives. The Stokes Library and the Animal Welfare Information Center (AWIC) are also prepared to assist in your search of databases for alternatives to painful procedures.

XI. ENDANGERED ANIMALS

A variety of federal and international laws and agreements exist to protect animals. Statutes such as the Endangered Species Act prohibit or control acquisition of wild or captive-bred, domestic and non-domestic animals classified as "endangered" or "threatened." Applicants are referred to the applicable federal and State regulations for further information.

XII. HAZARDOUS AGENTS OR MATERIALS AND SELECT AGENTS

Researchers are required to designate the Animal BioSafety Level (ABSL) of work to be carried out in animals (Definitions of ABSL categories are presented in the BMBL SECTION IV VERTEBRATE ANIMAL BIOSAFETY LEVEL CRITERIA.). It is recommended that the latest edition of the CDC BioSafety in Microbiological and Biological Laboratories manual be consulted if applicable to make the designation (The Health Canada MSDS website listing for infectious agents is also a good supplemental source of information.). The designation of ABSL based on use of recombinant DNA should be made according to recommendations of the *NIH Guidelines for Research Involving Recombinant DNA Molecules*.

If substances in the diet, air (dust or aerosol), water, research or caging equipm ent or by living or d ead anim als or their tissues , secretio ns or ex crement poses a risk to VS or research personnel, anim als on other experiments or the environm ent, the IACUC safety form (entitled *IACUC Safety Form for In vivo Use of Hazardous Materials/Agents in Animals)* attached to the end of the IACUC A Form, must be completed.

Note: All new proposals or proposals am ended with new safety concerns m ust be submitted to the re levant Saf ety Comm ittee [Radiation Saf ety Comm ittee (RSC) or Institutional BioSafety Committee (IBC) for approval.

It is the responsibility of the Principal Investigator to as sure that copies of the IBC and RSC Comm ittee Letter of Appr oval a re su bmitted to the IACUC. It is als o the responsibility of the Prin cipal Investigator to assure that applications are submitted to the appropriate safety committee for work to be carried out under this proposal.

Note: While the IACUC is primarily concerned with in vivo use and safety issues related to that use, Safety Committees (SC) require approval of both in vivo and ex vivo (in vitro) use of hazardous agents or materials. The use of radioisotopes or irradiating devices requires RSC approval. Use of biological, chemical, recombinant DNA or other hazards requires IBC approval.

Select Agents: Select Agents (SA) are a group of bi ological agents or their toxic byproducts deemed to represent a potential risk for use in ca rrying out acts of terrorism or with potential for catastrophic acciden tal release. Based on these potential risks th e federal governm ent has promulgated strict regulations regarding SA tr ansport, transfer, acqui sition, storage, use and disposal and a stringent SA registration process. Listed agents represent potential health risks for humans, anim als, plants and the environm ent. Researchers are respo nsible for assuring they have the most updated list by accessing the Centers for Diseas e C ontrol (CDC) website at http://www.cdc.gov/od/sap/ria.htm and by contacting the IBC.