**OBJECTIVE:**
To provide a detailed guide of the format to be used in the writing of Written Policies and Procedures (WPPs), to outline the procedures for making changes and how the WPPs are distributed for the Virginia Commonwealth University Institutional Animal Care and Use Committee (IACUC).

**DESCRIPTION:**
The WPPs described in this manual cover the operations of the VCU IACUC and were generated by the Office of Research Subjects Protection (ORSP) in consultation with a subcommittee of the IACUC. These procedures are described in detail to help ensure efficient and consistent functioning of the VCU IACUC.

Minor deviations from steps described within this manual are permitted as long as deviations remain in accordance with Federal, State, and local regulations (including VCU institutional policies). As the protection of animal subjects remains paramount to the VCU IACUC, the IACUC subcommittee and the Office of Research Subjects Protection (ORSP) may take alternative actions (as long as actions do not conflict with federal, state, and local regulations) to those described within or not addressed by these Written Policies and Procedures.

All official WPPs are produced by computer following this standard WPP format. The following information is required for all WPP:

A. Table of Contents: A complete Table of Contents (no required format, but should exclude page numbers) will appear at the beginning of this document. A cover page may or may not precede the Table of Contents.

B. Section: The name of the section heading within the WPP document and section identifier (Roman numeral or letter).

C. WPP #: The number is a combination of the Section identifier, a hyphen, and the Title placement within that section (e.g. Title 1 in Section I is written as WPP #: I-1).

D. Title: A concise description of the subject of the WPP and number of title.

E. Effective Date: This date indicates the date on which the content of the WPP became official. This date is the IACUC meeting that the WPP is approved.

F. Revision History: These dates record the history of revisions to this WPP.

G. Approvals: The WPP is approved by the IACUC.

Procedures are written in an outline form using the topics in the following order:

A. “OBJECTIVE”: This section states the intent of the WPP.

B. “DESCRIPTION”: This section provides an overview of the WPP and describes related procedures.
C. “RESPONSIBILITY”: This section specifically designates who is assigned to perform and/or review the work performed as outlined.

D. “REFERENCE”: This section lists any reference materials that may be consulted for additional information. This section may be completed as ‘none listed,’ if appropriate.

The currently approved version of the WPP manual is maintained electronically on the VCU Animal Care and Use Program website. An historical WPP manual (hard copy or electronic file) must be maintained with originals of previously approved WPP documents and dates of periodic review.

After a WPP has been written and approved, the original is saved in the original WPP file. A copy of the WPP will be distributed to all IACUC staff and provided to all members/Chairpersons/alternates of the IACUC. In addition, the WPP will be posted on the VCU Animal Care and Use Program (ACUP) website for investigators. A table of contents, including the title and effective date, should be maintained and updated by ORSP.

**RESPONSIBILITY:**
It is the responsibility of the ORSP to ensure that the new or revised WPP are clearly prepared; follow the required format; and are compliant with federal, state, and local regulations and other ORSP procedures. The IACUC approves WPPs. The ORSP is responsible for ensuring the development of necessary educational / training programs for investigators, committee members, staff, and administration. ORSP is responsible for the distribution of new or modified WPP material.

**REFERENCE:**
None listed
OBJECTIVE:
The purpose of this section is to describe the responsibility and institutional authority under which the VCU IACUC is established and operates.

DESCRIPTION:
All VCU animal facilities research projects and programs are operated in accordance with the requirements and recommendations of the:


And as required by the following:
A. American Association for Accreditation of Laboratory Animal Care International (VCU represents AAALAC unit #000036)
B. USDA/APHIS Registration #52-R-0124
C. PHS Assurance A3281-01.

VCU has adopted the IACUC Written Policies and Procedures to ensure compliance with the PHS Policy, ‘The Guide’, and the Animal Welfare Regulations (AWR) in research conducted under the authority of the VCU.

RESPONSIBILITY:
The Health Research Extension Act (HREA) of 1985 and the AWR require the VCU Institutional Official (IO), whose responsibilities are delineated in the law and federal policy and regulations, to appoint the IACUC. At VCU, the IO is currently the Vice President for Research and Innovation.

REFERENCE:
1. USDA-AWR: Title 9, Subchapter A, Parts 1-3
2. PHS Policy on the Humane Care and Use of Laboratory Animals
3. Guide for the Care and Use of Laboratory Animals, Eighth Edition
OBJECTIVE:
The purpose of this policy and procedure is to describe authority of the IACUC.

DESCRIPTION:
The VCU IACUC derives its authority from the Health Research Extension Act (HREA) of 1985 and the Federal Animal Welfare Regulations (AWR). The VCU IACUC has the following responsibilities and authority:

A. Review, at least once every six months, the research facility’s program
B. Inspect, at least once every six months, all of the animal facilities including animal study areas/satellite facilities
C. Prepare reports of IACUC evaluations and submit the reports to the Institutional Official (IO)
D. Review and investigate legitimate concerns involving the care and use of animals at the VCU research facility resulting from public complaints and from reports of noncompliance received from the University community
E. Make recommendations to the IO regarding any aspect of the research facility’s animal program, facilities, or personnel training
F. Review and approve, require modifications in, or withhold approval of those components of proposed activities related to the care and use of animals
G. Review and approve, require modifications in, withhold approval of, or table proposed significant changes regarding the care and use of animals in ongoing activities
H. Suspend an activity involving animals when necessary, take corrective action, and report to the funding agency and the USDA/OLAW, if required.

RESPONSIBILITY:
It is the responsibility of Animal Care and Use Program (ACUP) leadership to ensure that adequate resources, including facilities, are provided to the IACUC for the purpose of ensuring the protection of animal research subjects.

REFERENCE:
1. USDA-AWR: Title 9, Subchapter A, Parts 1-3
2. PHS Policy on the Humane Care and Use of Laboratory Animals
3. Guide for the Care and Use of Laboratory Animals, Eighth Edition
OBJECTIVE:
The purpose of this policy and procedure is to describe the membership of the IACUC, including composition and requirements, membership diversity, alternate members, nonvoting members, the use of consultants, confidentiality, liability indemnification, conflict of interest policy, and quorum requirements.

DESCRIPTION:
VCU 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 VCU IACUC consists of a minimum of five members with one Chairperson, who has direct access to the Vice President for Research and Innovation on IACUC issues.

A. Membership Composition and Requirements:
The VCU IACUC consists of at least five members, and its membership meets the composition requirements set forth in the PHS Policy at IV.A.3.a., b. and USDA Regulations 9 CFR, 2.31(a)(b), including chair, veterinarian, scientist, nonscientist and nonaffiliated member. The president of VCU (Chief Executive Officer) delegates authority to the Vice President for Research and Innovation as VCU's Institutional Official (IO) to appoint the IACUC members.

Veterinarian: At least 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 VCU.

Scientist: At least one practicing scientist experienced in research involving animals.

Nonscientist: At least one member whose primary concerns is in a nonscientific area: examples include, but are not limited to, ethicist, lawyer, member of the clergy, or librarian.

Nonaffiliated member: One member not affiliated in any way with VCU and is not a member of the immediate family of a person who is affiliated with VCU. The nonaffiliated member is intended to represent general community interests in the proper care and use of animals and can bring significant value to the committee by bringing a non-institutional perspective to the research endeavor. This member has equal status to every other committee member and should be provided the opportunity to participate in all aspects of IACUC functions.

Restriction: Not more than three members can be from the same administrative unit (e.g., department) within VCU. (USDA-AWRs 9 CFR, 2.31(a)(b))
Attendance Requirements:
1. **Voting Members:** Three consecutive absences by the member may result in removal from the IACUC. The IACUC Chair together with the IACUC coordinator will review members’ attendance on a regular basis to make a suggestion to the Director of ORSP.
2. **Alternate Members:** In order to maintain familiarity with IACUC procedures and applicable regulations, Alternate Members are required to attend at least 2 protocol meetings per calendar year at which animal protocols are considered. Attendance as a replacement for a voting member counts towards this total. In addition, Alternate Members are required to attend at least 1 administrative meeting per calendar year, which includes inspection of facilities and program review.

Removal / Resignation:
Recommendations of the IACUC Chairperson, Vice Chairperson, other members of the IACUC, investigators, and/or other university officials will be considered. Resigning members must notify the IACUC Chairperson, and the Director of ORSP of their intentions in writing.

B. **Membership Diversity:**
Membership is selected to assure appropriate diversity, including representation by multiple departments, multiple scientists who use different types of animals and both genders, and to include both scientific and non-scientific members. Scientific expertise of the IACUC should reflect the types of animal protocols reviewed and approved.

C. **Alternate Members:**
An alternate member may be appointed to the IACUC by the authority of the Institutional Official, with a specific one-to-one role designation of IACUC members and alternates. An IACUC member and his/her alternate may not count toward a quorum at the same time or act in an official member capacity at the same time. Alternates will receive training similar or identical to the training provided to regular IACUC members.

D. **Nonvoting Members (Ex Officio Members):**
Nonvoting members may be appointed to the IACUC and serve as ex officio members of the VCU IACUC. There is no limit to the number of nonvoting members that may be affiliated with the VCU IACUC.

E. **Use of Consultants:**
The VCU IACUC may, at its discretion, invite individuals with competence in special areas to assist in the review of complex issues that require expertise beyond or in addition to that available on the IACUC. These individuals may not approve or withhold approval of an activity or vote with the IACUC.

F. **Confidentiality:**
All VCU IACUC members agree that they will not use any confidential information received from VCU during the period of their participation on the IACUC for any purpose other than to fulfill their obligation to VCU in accordance with their service on the IACUC. They will not disclose such confidential information to any third party. “Confidential Information” shall include, but is not limited to, knowledge
or data regarding products, processes, operating procedures and/or research, and animal care and use
protocol information. All materials, papers, records and other similar documents furnished or made
available to them during their participation on the IACUC that are not destroyed will be returned when
requested or at the end of the period of their participation on the IACUC. Under AWA, section 2157, it is
unlawful for any member of an IACUC to release to the public any confidential information of the
research facility, including any information concerning or relating to trade secrets or confidential
statistical data. Penalties for violation of this law include a fine of up to $10,000 and imprisonment of up
to 3 years, as well as removal from the IACUC.

G. Liability Indemnification for IACUC Members:
VCU will indemnify and hold all IACUC members harmless from any third party claims against them, or
the IACUC, or VCU to the extent that such claims arise from the performance of their official duties as a
member of the VCU IACUC. VCU will not indemnify or hold members harmless from any third party
claims against them, the IACUC or VCU which arise from any negligence in performance of duties as a
member of the VCU IACUC or for any activities which are outside of the scope of their official duties as
set forth in the WPPs, the PHS Policy on Humane Care and Use of Laboratory Animals, the “Guide for
the Care and Use of Laboratory Animals” and the Animal Welfare Act as set forth in the USDA Animal
Welfare Regulations.

H. Conflict of Interest:
No IACUC member, alternate, or consultant may participate in the IACUC review or approval of an
activity in which that individual has a conflicting interest, (e.g., is personally involved in the activity or
policy) except to provide information requested by the IACUC. If the investigator submitting a protocol
believes that an IACUC member has a potential conflict, the investigator may request that the member be
excluded. When a member has a conflict of interest, the member should notify the IACUC Chairperson
and may not participate in the IACUC review or approval except to provide information on request.
Persons identified in this section shall leave the meeting during the discussion and the vote on any motion
to approve or disapprove the protocol in question. Members who have a conflict of interest may not be
counted toward a quorum and may not vote.

I. Quorum Requirements:
Certain official IACUC actions require a quorum: full committee review of a research project (Policy
IV.C.2. and AWR 2.31(d)(2)) and suspension of an activity (Policy IV.C.6. and AWR 2.31(d)(6)).
“Quorum” is defined as a majority (>50%) of the voting members of the IACUC. Therefore, protocols
requiring full committee review are approved only if a quorum is present, and if more than 50% of the
members constituting that quorum vote in favor.

RESPONSIBILITY:
The Director of ORSP and IACUC Chair are responsible for working with the VCU Institutional Official
to ensure adequate membership and support for the operation of the IACUC and for ensuring that the
policies noted above are reasonable, effective, and followed.

REFERENCE:
1. USDA-AWR: Title 9, Subchapter A, Parts 1-3
2. PHS Policy on the Humane Care and Use of Laboratory Animals
3. Guide for the Care and Use of Laboratory Animals, Eighth Edition
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<td><strong>Scheduling of Meetings</strong></td>
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**OBJECTIVE:**
The purpose of this policy and procedure is to document standard practices for scheduling VCU IACUC meetings.

**DESCRIPTION:**
Regularly scheduled meetings of the VCU IACUC are held at least once per month. Currently the IACUC meeting for “protocol review” is held on the 2nd Wednesday each month and for “institutional policies – administrative meeting” is held on the 3rd Wednesday of each month.

**RESPONSIBILITY:**
It is the responsibility of the Director of the ORSP to ensure that IACUC meetings are planned and scheduled, allowing for sufficient time for IACUC members to review materials prior to the meeting.

**REFERENCE:**
None listed.
OBJECTIVE:
The purpose of this policy and procedure is to describe standards for submission of protocols to the IACUC, including:

A. Protocol Electronic Submission  
B. Submission Deadlines  
C. Approval Period  
D. Department Chairperson Approval  
E. Principal Investigator Criteria  
F. Humane Treatment / Procedures  
G. Euthanasia  
H. Surgery  
I. Training  
J. Replacement, Reduction and Refinement of animal use  
K. Animal Husbandry  
L. Occupational Health  
M. Animal handlers  
N. Exposure / Bite Policy  

DESCRIPTION:
A. Protocol Electronic Submission:
The VCU Office of Research and Innovation has implemented a module of the VCUeRA (VCU electronic Research Administration) – Click Commerce System for electronic submission of IACUC protocols. The protocol must be submitted by the principal investigator using lay language (allowing all members of the IACUC to thoroughly understand the proposed use of the animals). All pertinent questions must be answered and all applicable sections of the protocol form must be completed. In addition, all procedures, drugs and/or devices must be fully described. Ambiguous, incomplete, or insufficiently explained procedures may require the return of the protocol to the investigator for clarification, which would result in a delay in the review process. Upon submission of an IACUC protocol, the PI is required to designate any research personnel who meet the definition of a Conflict of Interest (COI) Investigator (A ‘COI Investigator’ is an individual, regardless of position, title or role, who is responsible for the design, conduct, or reporting of the research, and is designated by the PI. The PI should consider a person’s independence relative to the research in determining whether they should be so designated. The PI is always a ‘COI Investigator’. Others with responsibility and independence fairly comparable to the PI are also ‘COI investigators’). All designated COI investigators must complete an initial Financial Interest Report (FIR) in the AIRS (Activity and Interest Reporting System) (https://airs.research.vcu.edu). When a protocol submission is received in Click Commerce, an IACUC
coordinator will verify that all required FIRs are complete and/or current. The PI will be notified of any incomplete FIRs. Once the required FIRs are complete, a COI review will occur and a disposition will be made. More information about “Conflict of Interests”, visit the VCU Policy on Conflicts of Interest in Research.

The IACUC requires that principal investigators make use of the electronic pre-review process for an initial review (new protocol) and a three year renewal. The pre-review is defined as a review between PI and reviewers to clarify questions or request additional information to prepare for an initial submission or a three year renewal. Two IACUC members will conduct the pre-review and contact the principal investigator regarding any clarifications, additional information needed, and/or questions that the IACUC may raise. After pre-review, the principal investigator is responsible for submitting the completed protocol through the electronic system so that it may be reviewed by the convened IACUC.

Protocols involving hazardous materials used in vivo or in tissues disposed of in DAR facilities will be pre-reviewed by the VCU Office of Environmental Health and Safety (OEHS. OEHS approval should be obtained before IACUC’s final approval will be granted. The OEHS provides guidance on use of hazards in protocols. The OEHS also provides “a guide for developing IACUC protocols involving hazardous chemicals” at the following web site: http://www.vcu.edu/oehs/chemical/biosafe/IACUCHazguide.pdf

If the protocol is a three-year renewal, a brief progress report of research completed to date and an updated database search within 6 months of the IACUC submission date should be included. Additional protocol details, such as employee health letters, and IBC approval letter, are to be uploaded and included in the submission.

The VCU IACUC provides Animal Care and Use Program (ACUP) policy and guideline documents (posted at ACUP website: https://www.vcu.edu/research/acup/policies/) that may be useful for investigators in completing the protocol. Investigators and all personnel involving animal research are encouraged to review these documents for familiarity.

**B. Submission Deadlines:**
The IACUC requires that principal investigators use the electronic pre-review process for an initial review (new protocol) and a three year renewal. The pre-review submission must be received by the 15th of each month prior to full committee review.

After pre-review, the principal investigator is responsible for submitting the completed protocol through the electronic system for receipt by the IACUC no later than the last day of the month preceding the meeting. The protocol then will be reviewed at the next full committee meeting, generally held the second Wednesday of the month.

**C. Approval Period:**
The IACUC requires an annual review of every protocol, which is completed via the annual renewal submission. A complete re-review is required within three years after the initial submission (3 year renewal). Annual reviews and 3-year renewals must be sought well in advance by the principal
investigator, in order to ensure that adequate time is available for making any necessary revisions as required by the IACUC prior to final approval and protocol expiration.

If the 3-year renewal protocol is not approved before the protocol expires, the IACUC Chairperson or the Attending Veterinarian (AV) will authorize the Division of Animal Resources (DAR) to block new animal orders associated with said protocol and will secure any research animals present (animals will be placed on a holding protocol status) until an approved protocol is in place. The DAR is responsible for placing the holding cards on all cages to cease animal activities on the date the protocol expires. If the annual review form is not submitted and approved before the first or second-year protocol expiration date, the IACUC Chairperson or the AV will authorize the DAR to block new animal orders associated with said protocol and the holding protocol will be enacted. If the annual review submission still has not been submitted by the investigator after 90 days, the protocol may be administratively closed.

D. Department Chairperson Approval:
The Department Chairperson’s approval for scientific review is required on all protocols that have not received funding or notice of funding from a recognized extramural body (i.e. NIH Study Section, VAMC Review Board, NSF Review Board, American Heart Association, etc.) The Chairperson’s approval indicates that he/she takes responsibility for scientific review of the protocol. A list of the IACUC accepted extramural fund agencies is posted at
https://www.vcu.edu/veuera/IACUCAcceptedExtramuralFundAgencies.pdf

E. Principal Investigator Criteria:
The Principal Investigator is usually a VCU faculty member. Individuals who have a contractual relationship with VCU may serve as a PI with approval of the IO after demonstrating adequate training to carry out the proposed research, including specific IACUC-required training (see section below ‘Training’). Pre or postdoctoral trainees may serve as a PI when required by certain granting agencies. In such cases, the co-investigator must be a faculty member of VCU (who may be referred to as a sponsor or mentor in the grant proposal) and is ultimately responsible to VCU for the supervision of the protocol. If the project is directed by a student in the course of his or her academic responsibilities at VCU, the academic advisor/thesis advisor must assume the responsibility for the student’s study and must, therefore, be listed as the Principal Investigator. Some exceptions might be allowed and details are described in the University Policy on Principal Investigator Eligibility posted at
http://www.assurance.vcu.edu/Policy%20Library/Principal%20Investigator%20Eligibility.pdf

F. Humane Treatment / Procedures:
A primary concern of the IACUC is the humane treatment of the animals. Procedures will avoid or minimize discomfort, distress and pain, consistent with sound research design. When pain and discomfort are anticipated, the investigator must explain completely how these will be alleviated. If pain and discomfort cannot be eliminated, the methods used to minimize discomfort must be described. Procedures that may cause more than momentary or slight pain or distress to the animals will (1) be performed with appropriate sedation, analgesia, or anesthesia, unless the procedures are justified for scientific reasons in writing by the investigator and approved by the IACUC, (2) involve, in the protocol's planning, consultation with the attending veterinarian or his or her designee, and (3) not include the use of paralytics without anesthesia. The definitions and examples of USDA Pain Categories are available at
ACUP Policy on Categories of Potential Pain or Distress. Certain animal use protocols include procedures that require special consideration during the IACUC review process due to their potential for unrelieved pain or distress. These special considerations are (1) experimental and humane endpoints, (2) unexpected outcomes (such as, genetically modified animals-GMAs), (3) physical restraint, (4) multiple survival surgical procedures (more information described in H. below) and (4) food and fluid regulation.

G. Euthanasia:
Animals that would otherwise experience severe distress that cannot be relieved will be painlessly sacrificed at the end of the procedure, or, if appropriate, during the procedure. Methods of euthanasia will be consistent with the recommendations of the American Veterinary Medical Association (AVMA) Guidelines on Euthanasia (currently approved version) unless a deviation is justified for scientific reasons in writing by the investigator and approved by the IACUC.

H. Surgery:
Activities that involve surgery must include appropriate provision for pre-operative and post-operative care of the animals in accordance with established veterinary medical and nursing practices. In general, surgical procedures are categorized as major or minor and in the laboratory setting can be further divided into survival and non-survival. Whether a procedure is major or minor should be evaluated on a case-by-case basis, as determined by the veterinarian and IACUC. As a general guideline, major survival surgery penetrates and exposes a body cavity or produces substantial impairment of physical or physiologic functions (such as laparotomy, thoracotomy, joint replacement, and limb amputation) or involves extensive tissue dissection or transection. Minor survival surgery does not expose a body cavity and causes little or no physical impairment (such as wound suturing; peripheral-vessel cannulation, percutaneous biopsy, and routine agricultural animal procedures). All survival surgery should be performed using aseptic procedures, including surgical gloves, masks, sterile instruments, and aseptic techniques. Major operative procedures on USDA regulated animals (https://www.vcu.edu/vcuera/USDARegulatedAnimals.pdf) will be conducted only in facilities (e.g., surgical suite) intended for that purpose which shall be operated and maintained under aseptic conditions. Any exceptions will be justified and approved by the IACUC. Non-major survival operative procedures and all surgery on rodents do not require a dedicated facility, but must be performed using aseptic procedures. Survival operative procedures conducted at field sites need not be performed in dedicated facilities, but must be performed using aseptic procedures. All protocols involving survival surgeries, surgical non-survival lasting more than 30 minutes, or pain category E are required to have a veterinary observation every three years, unless waived by the Attending Veterinarian (or designee). Any deviations from above require a written approval, submitted to the IACUC, from a DAR veterinarian. The IACUC may request additional veterinary observations on any protocol and will specify details at the meeting.

Multiple major surgical procedures on a single animal are acceptable only if they are (1) included in and essential components of a single research project or protocol, (2) scientifically justified by the PI, or (3) necessary for clinical reasons determined by the veterinarians. Conservation of scarce animal resources may justify the conduct of multiple major surgeries on a single animal, but the application of such a practice on a single animal used in separate protocols is discouraged and should be reviewed critically by the IACUC.
To allow a regulated animal to undergo multiple major survival surgical procedures in separate unrelated research protocols, the IO must submit a request to the USDA/APHIS and receive approval prior to the protocol’s final approval. Cost savings alone is not an adequate reason for performing multiple major survival surgical procedures.

I. Training:
Personnel conducting procedures on animals will be appropriately qualified and trained to perform those procedures. The principal investigator must indicate personnel who will be performing the animal procedures and indicate the training and recent experience of each person with the types of animal procedures proposed and with the species of animal proposed (including surgery and provision of anesthesia). All personnel are required to take the appropriate mandatory VCU on-line training courses and exams outlined at the following URL https://www.vcu.edu/research/acup/iacuc/training.pdf or other IACUC-approved training and exam as indicated. Personnel who will be irradiating experimental animals must be trained and have approval from the Radiation Safety Section of the Office of Environmental Health & Safety. The PI and other personnel included on the study should have taken required training before IACUC approval.

J. Replacement, Reduction and Refinement of animal use:
The animals selected for the procedure should be an appropriate species and quality, and the minimum number of animals required to obtain valid results (including statistical or other criteria for animal numbers) should be used. Alternatives should be considered in the planning phase of the animal use protocol. Alternative methods such as mathematical models, computer simulation, and in vitro biological systems should be considered and reasons provided for their non-selection. Written documentation must be provided that alternatives were not available. For example, the principal investigator should document the databases or services that have been used to determine that alternative methods would not be acceptable. The database search should be updated every three years at a minimum and the date search conducted should be within 6 months of IACUC submission. The database search should include (1) the name(s) of the databases searched (due to the variation in subject coverage and sources used, one database is seldom adequate), (2) the date the search performed, (3) the time period covered by the search, and (4) the search strategy (including scientifically relevant terminology) used. For this section, an alternative is defined as any procedure that results in the reduction of the numbers of animals used, refinement of techniques, or replacement of animals. If the project involves teaching, the principal investigator must explain why films, videotaped demonstrations, etc. would not be acceptable. See VCU databases for the database search to be completed for each protocol. The IACUC will make the final approval of the database or search engine. Two research & education librarians, who are IACUC members, are available for consultation on database searches.

K. Animal Husbandry:
The living conditions of animals will be appropriate for their species and contribute to their health and comfort. The housing, feeding, and non-medical care of the animals will be directed by the attending veterinarian or designee or other scientist trained and experienced in the proper care, handling, and use of the species being maintained or studied. Medical care for the animals will be available and provided as necessary by a qualified veterinarian in consultation with investigators.
L. Occupational Health:
The Guide for the Care and Use of Animals (‘The Guide’) states “An occupational health program is mandatory for personnel who work in laboratory animal facilities or have substantial animal contact.”

VCU has in place the Occupational Health and Safety Program for Animal Handlers (OHSPAH). OHSPAH is an educational tool to help ensure that all persons who have contact with animals are aware of the potential hazards of working with animals and the procedures available at the University to prevent and treat such hazards. It is the responsibility of the principal investigator (PI) of each IACUC approved protocol to assure the IACUC that all workers under their supervision (co-investigators, staff, students, and volunteers) who have contact with animals have read the OHSPAH and have been informed of the potential dangers involved in their laboratory and are aware of the procedures available to prevent and treat such hazards.

An IACUC protocol will not be approved before all the requirements of OHSPAH are fulfilled, and thus, no animals may be ordered for use with the protocol until the PI is in full compliance with the provisions of the program.

M. Animal Handlers:
All animal handlers must be informed of the requirement that they register as an animal handler with either Employee Health Services (EHS) or Student Health Services (SHS). Animal handlers will receive appropriate counseling about the availability of pre-exposure vaccines, have routine tuberculosis testing where appropriate, and receive treatment for exposure to animal allergens, bites, scratches, etc. The animal handler will take the EHS/SHS Registration Letter to the EHS/SHS appointment for signature by a health service representative and return the signed copy to the principal investigator. For initial, three-year renewal and amendment submissions, the employee health letters should be uploaded in the electronic system or sent to the IACUC office (by mail, email or fax) when adding new personnel.

It is not required to include on the protocol personnel (with the exception of the PI) who are not handling whole animals (live or dead). If such personnel are included on the protocol, they must meet all of the occupational health and training requirements for animal handlers, and the PI must maintain these records with those of all other animal handlers.

Certain categories of individuals that are handling animals for a short period of time (i.e., students performing lab rotations or educational lab tutorials or volunteers for up to 12 weeks) may have the training requirements (Mandatory on-line training courses and exams) waived if they are under “Close Supervision” (defined as the presence of the trainer(s) with the animal handler at all times [within visual contact] when working with live or dead whole animals on the protocol. Animal room access is not needed and will not be granted for these individuals since the trainers will be with the animal handler at all times.

Principal investigators desiring to train individuals for short periods of time (not to exceed 12 weeks, such as, student lab rotation or volunteers) under close supervision are required to notify IACUC in writing (by mail: PO Box 980568 or fax to 827-1448) or by email (IACUC@VCU.EDU). Such notification should contain the following information or download a copy of the notification form at https://www.vcu.edu/research/acup/forms.htm:
(a) Protocol number;
(b) Name of PI;
(c) Individuals who will receive supervised training;
(d) Individuals listed in protocol who will closely supervise trainees;
(e) Describe the extent and duration of training (not to exceed 12 weeks);
(f) Purpose of training (i.e., lab rotation, educational experience, or volunteers);
(g) A copy of completed health form (for VCU employees or VCU students, submit the Employee/Student Health Service Registration Letter; for volunteers, submit VCU Health Form for Volunteers Forms – VCU Human Resources);
(h) Maintain a copy of the notification on file in your lab as long as the person named is working with your lab animals; these individuals are still required to have health registration letters completed before working with animals. Although they do not need to be added to the IACUC protocol, a copy of their health letter is still required to send to the IACUC office for verification. For placing volunteers, see VCU Human Resources at http://www.hr.vcu.edu/about/forms.html.

N. Exposure / Bite Policy:
Any individual who has been bitten or scratched while working with an animal, or who has a known exposure to a zoonotic disease must immediately report the incident to his/her supervisor (or instructor) and to the appropriate health officials. As with any occupational injury, employees should report to Employee Health Service (EHS) or Student Health Service (SHS) and complete a VCU Accident Report of Workers’ Compensation Claim (Form P-100). Volunteers should use “VCU volunteer injury report form” posted at http://www.hr.vcu.edu/worklife-and-wellness/forms/. On evenings, holidays or weekends employees/students should report to the VCU Health System, Emergency department.

RESPONSIBILITY:
It is the responsibility of Principal Investigators, Animal Handlers, The Division of Animal Resources, and the IACUC to ensure that the above policies and procedures are accurate and followed as standard practice.

REFERENCE:
1. USDA-AWR: Title 9, Subchapter A, Parts 1-3
2. PHS Policy on the Humane Care and Use of Laboratory Animals
3. Guide for the Care and Use of Laboratory Animals, Eighth Edition
OBJECTIVE:
The purpose of this policy and procedure is to describe the standards for protocol review by the IACUC, including:

A. IACUC Actions (Motions)
B. Protocol Review Procedures
C. Procedure for Full Committee Review
D. Procedure for Subcommittee (Designated Member) Review
E. IACUC Protocol Review Criteria

DESCRIPTION:
A. IACUC Actions (Motions): Depending upon the findings of the Committee as a result of their review of a protocol, a convened quorum of the IACUC may vote on one of the following different actions:

3. Approval: when the IACUC has determined that the investigator has adequately addressed all review criteria, the IACUC may approve the protocol, thus providing the investigator permission to perform the experiments or procedures as described. If a study is unusually complex or involves untried or controversial procedures the IACUC may impose restrictions (for example, require veterinary observations). The approval date for the protocol will be the date of the IACUC Full Committee Review meeting.

4. Modifications Required to Secure Approval: there are three methods that IACUC uses to follow up the modifications required to secure approval:

   a) Administrative modifications: if the IACUC determines that a protocol is approvable contingent upon receipt of specific modifications, or clarification of a specific point, the IACUC may handle these modifications or clarifications as administrative details (such as specific room change, spelling error, grant number, etc.; all other modifications related to animal welfare issues are not considered administrative details and will be verified by the Chairperson or designee. As soon as the requested specific modifications to the protocol have been made, submitted to the IACUC (no later than three months after the receipt of the original request for modifications letter), and verified by the Chairperson or designee, the protocol may be activated. Animal work cannot be initiated until all modifications have been verified and approved. The approval date for the protocol will be the date the IACUC Chair or designee completes the verification of modifications.
Refer to Designated Member Review (DMR) subsequent to full committee review: when substantive information is lacking from a protocol, the IACUC may have questions requiring a response from the PI. All IACUC members agree by unanimous vote to use DMR subsequent to FCR when modification is required to secure approval. This has been approved in advance indicating that the quorum of members attending any given meeting has the authority to refer requested modifications to DMR. Thus, the committee vote will determine whether modifications required to secure approval return for future FCR (see below “table for FCR”) or are referred to DMR.

Table for Full Committee Re-Review: if (a) the protocol requires clarification in order for the IACUC to make a judgment, (b) committee members with certain expertise are not present, (c) the IACUC needs to seek external consultation, or (d) any other reasons that prevent the IACUC from conducting its review, then the IACUC may table the protocol. If the IACUC requires additional information and /or has a serious concern, the designated or primary/secondary reviewer is encouraged to discuss the protocol with the investigator. The protocol will then be re-reviewed at another IACUC meeting.

5. Withhold Approval: when the IACUC determines that a protocol has not adequately addressed all of the requirements of the PHS Policy and AWR (Animal Welfare Regulation) as applicable, the Committee may withhold approval. This action may only be taken if the review is conducted using the full committee review method.

B. Protocol Review Procedures:
Review procedures apply to:
1. Initial review,
2. Triennial renewal (three year renewal), and
3. IACUC review of proposed significant changes to the use of animals in ongoing activities.

The Committee may use one of the following two methods for review:
1. Full Committee Review
2. Subcommittee (Designated Member) Review.

C. Procedure for Full Committee Review:
1. The Principal Investigator submits the protocol to IACUC for pre-review (see WPP IV-2 for the definition of pre-review) through the electronic system by the 15th of the month for consideration at the IACUC protocol review meeting the following month.
2. The Chairperson or designee assigns each protocol to a primary and, a secondary reviewer (chosen based on their expertise in the subject matter of the protocol). The assigned reviewer(s) will a) receive an email with a link to VCUeRA, b) receive instructions for protocol review and c) have the principal responsibility for conducting an in-depth review. Reviewer related information for animal protocol submissions are posted at https://www.vcu.edu/vcuera/lab_animals.htm
3. Reviewers are expected to enter all pre-review comments by the 24th of the month. If the pre-review will be prolonged beyond the 24th of the month, the reviewer must enter feedback as a
Public Comment through the electronic system. Pre-review is intended to elicit clarifications and additional information in anticipation of questions the IACUC may raise.

4. After pre-review, the investigator is responsible for making changes according to pre-review feedback and submitting the completed protocol through the electronic system so that it is received by the IACUC for an initial review or a three year renewal review no later than the last day of the month preceding the meeting.

5. At least 5 calendar days (3 business days) prior to the meeting, IACUC members receive an agenda, prepared by the IACUC coordinator (ORSP staff), which lists (a) review of previous meeting minutes, (b) protocols to be reviewed, (c) the type of review to be performed (three-year renewals, significant changes or new protocols), (d) the names of two reviewers (primary and secondary reviewers) for Full Committee Review protocols, (e) a list of upcoming annual reviews (f) a report of Post Approval Compliance Monitoring (PACM), (g) a report of veterinary observation, and (h) adverse event reports if any, and others.

6. Both the primary and secondary reviewers will present the protocol to the Committee, answer questions about the protocols during review by the Committee and make suggestions for modifications to the protocol where appropriate to secure approval.

7. No member may participate in the review of or vote on a research protocol in which the member has a conflict of interest (e.g., is personally involved in the project or has financial involvement) except to provide information requested by the IACUC; a member who has a conflict of interest is excused from the meeting during the discussion and vote and does not contribute to the constitution of a quorum.

8. After discussion, the IACUC may take one of the following motions: (a) approval, (b) modifications required to secure approval (including administrative modifications, refer to Designated Member Review (DMR), or table for full committee re-review) or (c) withhold approval.

9. Following Full Committee Review, the IACUC notifies the investigator in writing of the decision. The notification will indicate the action taken. The approval letter also will note the approval date and expiration date.

10. For motion of "Approval." The protocol approval date is the date of the IACUC meeting that conducted the review.

11. For motion of “Modifications required to secure approval” – Administrative Modifications:
The investigator is prompted to respond to the requested specific modifications through the electronic system to the IACUC no later than 90 calendar days (three months) after the receipt of the original letter requesting modifications. The Chairperson or designee will verify that the modifications are satisfactory, and upon such verification, the investigator will be notified that the protocol has been approved.

12. For motion of “Modifications required to secure approval” - “Refer to DMR”. If DMR is approved by all IACUC members at the meeting, the procedures followed are described in section, D. Procedure for Designated Member Review. An exception to the 4 day waiting period occurs, when FCR has previously voted that required modifications can subsequently be reviewed by designated member review. This exception is based on the fact that all members have accepted the policy granting authority to the quorum of members present at any given meeting to vote to have requested changes reviewed by DMR. However, any members of the IACUC still may request FCR of the protocol at any time.
13. For motion of “Modifications required to secure approval” - "Table for full committee re-review." If the protocol is tabled, the IACUC will request additional information from the investigator, and the protocol will be re-reviewed by IACUC using the full committee method after the information is received. The investigator is prompted to submit the requested specific modifications to the IACUC no later than 90 calendar days (three months) after the receipt of the original request for modifications letter. The procedure then follows the full committee method again.

14. For motion of "Withhold Approval." If the IACUC withholds approval of a protocol, it will include in its written notification to the investigator a statement of the reasons for its decision and give the investigator an opportunity to appeal. The appeal will consist of a written response and/or a presentation in person before the IACUC. Although the IACUC may re-consider its decision based on additional information, the IACUC’s decision to withhold approval is final. According to OLAW and USDA regulations, the Institutional Official does not have the authority to approve a protocol for which approval has been withheld by IACUC.

D. Procedure for Subcommittee (Designated Member) Review:
Subcommittee (Designated Member) Review is a method of review that can be elected by IACUC. If IACUC elects to conduct a Subcommittee (Designated Member) Review, the following procedures will apply. The chairperson or designee appoints a subcommittee of one or more members to review the protocol.

Subcommittee (Designated Member) Review Process:
1. The Principal Investigator submits the protocol through the electronic system to IACUC for consideration, unless the protocol was previously tabled by the IACUC. DMR may also be assigned by the IACUC.
2. The Chairperson or designee recommends protocols for Designated Member Review and assigns each recommended protocol at least one reviewer (chosen based on their expertise in the subject matter of the protocol).
3. All members of the IACUC will receive an email "IACUC significant amendment selected for DMR" including the name of PI, title of the protocol. All IACUC members can access the details of the protocol through the electronic system. IACUC members have 4 calendar days to consider the protocol and request full committee review, if deemed appropriate. Protocols will be reviewed by the full committee review process if any IACUC member so requests.
4. If no IACUC member calls for a full committee review, then the designated reviewer(s) will follow the review instructions and enter all reviewer notes through the electronic system. Reviewer related instructions for animal protocol submissions are posted at http://wp.vcu.edu/iacucmembers/.
5. The Designated Member Reviewer(s) may (a) approve the protocol, (b) require modifications to secure approval, or (c) require Full Committee Review. If any Designated Member Reviewer requests Full Committee Review, the protocol will be subjected to review by the Full Committee method.
6. If the Designated Member Reviewer(s) requires “modifications”, the investigator is responsible for making any necessary changes to the protocol and submitting them through the electronic system for approval. The Designated Reviewer(s) will verify the modifications adequately to
address DMR concerns. The recommendations of each of the Designated Member Reviewers must be satisfied before approval is granted.

7. Once the Designated Member Reviewer(s) is prepared to approve the protocol, the reviewer will complete his review in the Click Commerce. The IACUC coordinator will be notified of approval and is responsible for finalizing approval and preparing the approval letter.

8. The approval date for the protocol will be the date of the last Designated Member Reviewer’s approval in the Click Commerce. Following Designated Member Review, the IACUC formally notifies investigators in writing of the decision. The notification will indicate the action taken. The approval letter will also note the approval date, expiration date and any restrictions (for example, veterinary observation requirements).

E. IACUC Protocol Review Criteria:
The following criteria, modified from the OLAW IACUC Guidebook (2nd Edition, 2002), are used by the VCU IACUC in the review of protocols:

1. **Alternatives: Replacement, Reduction and Refinement – 3 Rs**
   ([http://awic.nal.usda.gov/alternatives/3rs](http://awic.nal.usda.gov/alternatives/3rs))
   The IACUC must ensure that investigators have appropriately considered alternatives to procedures that can cause more than slight or momentary pain or distress in animals, consistent with sound research design, and have provided a written narrative description of the methods and sources consulted to determine availability of alternatives [in accordance with USDA-AWR Policy #12 – “Alternatives to Painful Procedures” at [http://www.aphis.usda.gov/animal_welfare/policy.php](http://www.aphis.usda.gov/animal_welfare/policy.php)].
   Two database searches or one database and one other source are required every three years at a minimum and the date the search is conducted should be with 6 months of the IACUC meeting review date.

2. **Euthanasia**
   “Euthanasia means the humane destruction of an animal accomplished by a method that produces rapid unconsciousness and subsequent death without evidence of pain or distress, or a method that utilizes anesthesia produced by an agent that causes painless loss of consciousness and subsequent death” ([Animal Welfare Act and Regulations](http://animalwelfarestateguidelines.org/pdfs/animal_welfare_act_and_regulations.pdf), p19). The IACUC reviews and approves methods of euthanasia that will be consistent with the current recommendations of the American Veterinary Medical Association (AVMA) Guidelines for Euthanasia of Animals (2013 Edition), unless scientific justifications for alternative methods are presented in writing by the investigator and approved by the IACUC.

   The criteria used as the basis for the AVMA Guidelines for Euthanasia’s recommendations include: (a) minimum pain, distress, anxiety or apprehension; (b) minimum delay until unconsciousness; (c) reliability and irreversibility; (d) safety of personnel; emotional effect on personnel; (e) compatibility with requirement and purpose, including subsequent use of tissue; (f) compatibility with species, age and health status; and (g) drug availability and human abuse potential.
3. **Endpoints**
The IACUC will determine that discomfort to animals will be limited to that which is unavoidable for the conduct of scientifically valuable research, and that unrelieved pain and distress will only continue for the duration necessary to accomplish the scientific objectives. Criteria used to end experimental studies earlier in order to avoid or terminate unrelieved pain and/or distress is referred to as humane endpoints. If pain and distress are anticipated, the IACUC must ensure a detailed plan for when and how pain and distress will be alleviated. The Principal Investigator must include this plan within the protocol.

Specifically, the plan must include detailed written criteria for the endpoints that will be used to determine when animals can be removed from the study, treated, or euthanized. Such endpoints are particularly important in the case of survival surgery that will take place without post-operative analgesia. The Principal Investigator should provide clear directions concerning who can make the decision to euthanize or treat animals, including procedures to follow if a situation arises on weekends, holidays, or in the absence of the responsible study investigator.

4. **Minimization of Pain and Distress**
As required by the PHS Policy and the AWR, and reiterated in ‘The Guide’, the IACUC is mandated to review protocols to ensure that pain and distress are minimized/avoided in laboratory animals. If pain/distress is caused, appropriate sedation, analgesia or anesthesia will be used unless contraindicated by the scientific justification. The Attending Veterinarian or designee will be involved in planning and be consulted for any procedure that has the potential to cause more than momentary pain or distress. Animals with chronic/severe unrelieved pain will be humanely euthanized. About specific requirements on survival surgeries, please visit ACUP Policies on “Non-Rodent Postoperative Surgical Care” or/and “Rodent Survival Surgery”.

5. **Personnel Qualifications**
The PHS Policy and the AWR require the IACUC to assess whether personnel conducting procedures are appropriately qualified and trained in those procedures (IV.C.1.f and 2.31(d)(1)(viii)). The VCU mandatory on-line training program (https://www.vcu.edu/research/acup/training.htm) provides VCU staff who is working with animals with appropriate training as required by regulations. All individuals who have contact with animals must take the appropriate mandatory on-line modules before protocol approval is granted.

Personnel conducting procedures on animals will be appropriately qualified and trained to perform those procedures. The principal investigator must indicate personnel who will be performing the animal procedures and indicate the training and number of years of experience of each person for the types of animal procedures proposed and with the species of animal proposed (including surgery and provision of anesthesia). All personnel are required to take the appropriate mandatory VCU on-line training courses and exams outlined at the following URL: https://www.vcu.edu/research/acup/training.htm or other IACUC-approved training and exam as indicated. Personnel who will be irradiating experimental animals must be trained and have approval from the Radiation Safety Section of the Office of Environmental Health & Safety. It is
not required to include personnel involved in the study (with the exception of the PI) who are not handling whole animals. If the PI chooses to include them in the “personnel qualifications” of the protocol, they must meet all of the occupational health and training requirements for animal handlers, and must maintain these records with records of all other animal handlers. The PI and other personnel included on the study should have a completed health letter on file with the IACUC and taken required training before IACUC review.

Certain categories of individuals that are handling animals for a short period of time may have the training requirements waived. More details see WPP #: IV-2, M. Animal Handlers.

6. **Veterinary Review and Consultation**  
Contact the Attending Veterinarian at the time of protocol submission to consult in regards to “animal housing.” During protocol development and review, the Attending Veterinarian or his/her designee will assist the IACUC in reviewing the following activities and provide the investigators consultation for:

(a) Choice and use of appropriate analgesics/anesthetics;
(b) Verification of appropriate drug dosages, route of administration and choice of agent;
(c) Assistance in selection of appropriate animal model;
(d) Identification of refinement initiatives to ensure that manipulations have a minimal impact on animal welfare;
(e) Oversight of aseptic surgery and peri-operative care;
(f) Oversight of animal health and husbandry pertinent to the protocol and the entire colony;
(g) Identification of possible iatrogenic complications of model and procedures selected;
(h) Ensuring there are appropriate remediation efforts for iatrogenic complications;
(i) Serving as an occupational health and safety (including zoonoses) resource; and,
(j) Assistance in identifying appropriate endpoints and in ensuring humane euthanasia.

7. **Veterinary Observations**  
During IACUC protocol full committee meeting, for certain protocol classes (USDA Pain Category E, survival surgery, non-survival surgery with anesthesia period(s) greater than 30 min. duration, and others as deemed appropriate by the IACUC), the IACUC requires a veterinary observation of the animal procedure in question. The Attending Veterinarian or his/her designee will visit the PI’s laboratory after protocol approval to observe the animal procedure(s). The PI is responsible for scheduling observations through VCUeRA before initiating such procedures. Following the visit, a report will be generated and sent to the IACUC approving the procedure or requiring changes that may involve a repeat visit. While the veterinary observation is imposed as a part of post-approval monitoring by the IACUC, the responsibility for the veterinary observation then falls within DAR (Division of Animal Resources). Therefore, any request for exemptions, appeal of findings, etc. should be made first to DAR, and be forwarded to the IACUC (generally the Veterinary Care subcommittee) only if agreement cannot be reached.

**RESPONSIBILITY:**  
It is the responsibility of the Chairperson of the IACUC and the protocol reviewers/members to ensure that proper review procedures are followed in the review of all protocols that come before the IACUC. It
is the responsibility of the ORSP to ensure that IACUC members receive all necessary protocol materials and to maintain appropriate documentation.

**REFERENCE:**

1. USDA-AWR: Title 9, Subchapter A, Parts 1-3
2. PHS Policy on the Humane Care and Use of Laboratory Animals
3. Guide for the Care and Use of Laboratory Animals, Eighth Edition
5. Guidance to IACUCs Regarding Use of Designated Member Review (DMR) for Animal Study Proposal Review Subsequent to Full Committee Review (FCR), OLAW, Notice Number: NOT-OD-09-035, January 8, 2009
OBJECTIVE:
The purpose of this section is to describe the procedures for monitoring approved protocols, including:

A. **Periodic Review (Annual/Continuing Review)**
B. **Review of Changes to Approved Protocols**
C. **Review and assurance of protocol - proposal congruence:**
D. **Frequency of Review of Approved Protocols**
E. **Post-approval compliance monitoring (PACM)**

DESCRIPTION:

A. **Periodic Review (Annual/Continuing Review):**
Federal regulations (AWR) and VCU policy require that all activities involving the care and use of animals be reviewed at least annually. To this end, each principal investigator of an approved IACUC protocol must complete and submit an annual review submission through the electronic system each year prior to the anniversary date of the initial IACUC approval.

The ORSP has instituted a standard practice of sending an annual review notice to each principal investigator one month prior to the expiration anniversary date. Nevertheless, it remains the responsibility of the principal investigator to monitor his/her approval periods and respond to an annual review notice.

PIs should submit the annual review no later than one month prior to the anniversary date. If the annual review is not approved before the due date, the holding protocol (see WPP# IV-10) may be enacted. If the investigator still has not submitted the annual review after 90 calendar days, the protocol may be administratively closed.

The annual review is reviewed by the Designated Member Review process (see WPP#: IV-3, D). All IACUC members receive a list of upcoming annual reviews each month to have an opportunity to call for a Full Committee Review.

B. **Review of Changes to Approved Protocols:**
Changes to an approved protocol may be Significant or Minor.

1. **Significant changes:** significant changes to an IACUC-approved protocol must be reviewed and approved before they occur (PHS Policy IV.C.1., and AWR 2.31[d][1]). For Full Committee Review, the committee can approve, require modifications to secure approval, Refer to DMR, table for full committee re-review, or withhold approval of proposed significant changes in ongoing research protocols. Prior to review, each IACUC member is provided a copy of the entire revised research protocol and a cover letter describing all changes made since the last review. For
those protocols eligible and recommended for Designated Member Review, IACUC members will have an opportunity to request Full Committee Review.

1) Significant changes requiring IACUC approval include, but are not limited to the following:
   a) Changes in purpose or aim of study, or study objectives or design
   b) Change of principal investigator
   c) Change/addition of the new vertebrate species.
   d) A major increase in the number of animals used, defined as more than 10% for non-USDA regulated species (e.g., rodents, birds, etc.) or more than 5% of USDA-regulated species (such as dogs, cats, pigs, guinea pigs, ferrets, hamsters, rabbits, non-human primates, etc. (the rationale for an increase must be included in the amendment)
   e) Addition of painful procedures (USDA Pain Category D or E)
   f) Unanticipated marked increase in clinical signs or proportion of animal deaths requiring increased numbers of animals
   g) Change in surgical plans: e.g., non-survival to survival surgery, multiple survival surgeries, and major alteration of surgical procedures
   h) Changes in procedures resulting in greater pain, distress, or degree of invasiveness to the animal
   i) Changes in experimental substances
   j) Changes in duration, frequency, type, or number of procedures performed on an animal
   k) Changes in anesthesia, analgesia, and/or sedation
   l) Changes(s) in methods of euthanasia to any method approved in the AVMA Guidelines for the Euthanasia of Animals Addition of reportable hazards
   m) Change in housing or use of animals in non-IACUC approved location
   n) Modification(s) impacting personnel safety

2) Minor changes: the Chairperson or designee, or primary/secondary reviewer may review and approve. Minor changes are, but are not limited to the following:
   a) Changes in non-key personnel other than PI, such as student, technician, or visiting faculty collaborator (justification must include experience, training and compliance with Occupational Health Program and with on-line training modules)
   b) Addition of another strain of same species (rodents)
   c) Change in sex or age of animals to be used,
   d) Small justified increase in animal numbers used less than or equal to 10% of non-USDA-regulated species (such as mice, rat, birds, etc.) or less than or equal to 5% of USDA-regulated species (such as dogs, cats, pigs, guinea pigs, ferrets, hamsters, rabbits, non-human primates etc.),
   e) Others, include, but not limited to room changes within the vivarium, OSPA#, etc.

C. Review and assurance of protocol - proposal congruence:
   Rationale:
   The NIH Grants Policy Statement defines contractual obligations between the funding agency and the institution accepting the award. The Policy Statement includes a requirement that the principal investigator (PI) adhere to the PHS Policy on the Humane Care and Use of Laboratory Animals,
including conducting animal activities according to an approved IACUC protocol. The Grants Policy Statement specifically states, “It is an institutional responsibility to ensure that the research described in the application is congruent with any corresponding protocols approved by the IACUC.” [Part II, A, 4.1.1.2]

1. **Congruence review requests:**
   The PI must submit an amendment to the protocol in order to request a congruence review. The following should be included in the amendment:
   
   o It should be indicated on the Modification Cover Sheet that the amendment is intended to assure congruence with existing grants and/or the new funding source. If there is a deadline for the congruence letter, the date should be indicated.
   
   o The associated OSPA number and the OSPA team handling the proposal should be indicated on the Modification Cover Sheet and the changes to the protocol (if any) being made to harmonize the protocol and grant should be clearly outlined.
   
   o The proposal should be added and/or activated on the Funding-Related Proposals page of the protocol.
   
   o A copy of Research Strategy and Vertebrate Animal sections of the grant(s) in question should be uploaded to the amendment workspace. Budget and salary information is not needed.

2. **What must be Congruent?**
   The VCU IACUC will ensure congruence by reviewing the following information in the grant and protocol:
   
   o General scope of work and overall aim of the study: disease area, target organs, and/or biological target being studied, etc.
   
   o Experimental procedures and manipulations proposed in the grant and protocol
   
   o Species
   
   o Number of animals justified for use in both the grant and protocol (numbers should be similar)
   
   o Anesthetics and analgesics used
   
   o Method of euthanasia

3. **Review Process:**
   The amendment is assigned to designated member review and congruence is determined by a designated reviewer(s) who compares the grant to the protocol. If the procedures in the grant remain significantly different from those in the protocol(s), the PI will be contacted to make additional changes to bring the protocol and grant into congruence.

   Once the reviewer(s) assure congruence between the grant and protocol, a memorandum of congruence will be prepared and provided to the PI to submit to OSP.
D. Frequency of Review of Approved Protocols:
Every protocol, regardless of funding source, is reviewed by the IACUC prior to the first and second
anniversaries of protocol expiration to determine the status of the protocol. The principal investigator of
the protocol is notified of IACUC approval for a one-year continuation of research unless the investigator
has failed to comply with IACUC administrative requirements. If the investigator has failed to comply
with IACUC administrative requirements, the protocol will be handled as described in section IV, WPP#
IV-4, A. Periodic Review.

Before the third anniversary of protocol approval, the investigator is notified that the protocol must be
submitted for a triennial, full committee review. . . In order to comply with PHS Policy, a triennial (three-
year) renewal must be reviewed and approved by the IACUC before its expiration date. The triennial
(three-year) period begins on the actual date of IACUC approval, and IACUC may not administratively
extend approval beyond three years. For example, the protocol reviewed by the full IACUC on April 12,
2013, expires on April 11, 2016. In light of this, the IACUC (ORSP office) would need to receive the
three-year renewal no later than the middle of February 2016 for March review to allow for an approved
protocol to be in force without interruption. If the renewal is not approved before the expiration date,
animal activities will not be allowed.

The ORSP has instituted a standard practice of sending the triennial renewal notice to each principal
investigator three months prior to the expiration date. Three notices will be sent to investigators and
protocol editors before the expiration date. The first notice (90 days reminder) will be sent 90 days
before the expiration date. The second reminder (60 days reminder) will be sent 60 days before the
expiration date. The third reminder (urgent notice) will be sent one day prior to the next renewal due date
indicated in the first and second notices. The last reminder notice will include information about the
holding protocol.

If the protocol expires with animals, any animals remaining on this protocol will revert to a holding
protocol after the expiration date with husbandry managed by the attending veterinarian or his designee.
The investigators will still be charged per diem, however, PHS funds may not be used to pay for per diem
when a protocol is expired. Thus, an alternative charge code should be provided to DAR if PHS funds are
used

E. Post-Approval Compliance Monitoring (PACM)
1. The PACM will be coordinated and largely performed by the Research Liaison Specialist (RLS),
a position accountable to ORSP. If for any reason the RLS is unavailable, the inspection may be
conducted by the Research Compliance Specialist. The RLS will report inspection findings and
follow-up directly to the IACUC. The RLS will perform post approval compliance monitoring
every 6 months on all protocols involving surgical manipulations in accordance with OLAW
regulatory requirements (PHS Policy.IV.B.2). Protocols involving the following will be
monitored ideally on an every 6 – 12 month basis (in order of decreasing priority): a) USDA
regulated species (which were not previously included in surgical manipulations inspections), b)
any animals in USDA Pain Category E, c) biohazard, d) food/fluid restriction, e) physical
restraint, f) behavior/manipulation, and g) breeding colonies. All other protocols not in the
categories above, such as collection, field, or teaching protocols, will be inspected at least once
every 3 years. Other protocols, such as those involving perceived public sensitivity or requested by the IACUC Chair or other IACUC members, may also be included for semi-annual inspection. Inspections will be scheduled at a mutually agreeable time with the investigator or senior research staff.

2. The PACM will be guided by a checklist devised by the RLS and IACUC and may incorporate additional items for RLS monitoring. The checklist is made available to investigators prior to inspections. In addition, the PACM will review deficiencies identified in previous inspections and the corresponding corrective action taken by the PI.

3. The principal investigator or senior research staff is required to be present to facilitate the inspection of laboratories, records, surgical areas and animal facilities by enabling immediate feedback to questions or concerns of the inspector(s).

4. All inspection areas will receive either “A - Acceptable”, “M – Minor”, “U- undetermined”, “D--Deficiency” or “N/A – not applicable”. Comments for M, U or D are required on the checklist. PI/senior research staff shall have findings explained at the time of the inspection visit. In some cases, further clarification will be required and some issues may be resolved by informal consultation with IACUC Chair, Attending Veterinarian or designees and/or ORSP. Uncertainties raised in the inspection may be resolved by (but not limited to) the following: a) Retraining of laboratory or DAR personnel, b) A change in laboratory or DAR procedures, or c) Close Veterinary Supervision (CVS, defined in WPP#: IV-8, H) in order to provide the necessary education of laboratory personnel and ensure animal welfare, or d) Retraining of facilities management personnel, a change in facilities management procedures, or the repair or upgrading of infrastructure as needed.

5. At the time of inspection (or post-inspection clarification), any undetermined (U) or deficiency (D) findings must also be conveyed to the ORSP, IACUC Chair, and Attending Veterinarian (by phone or email). The RLS will generate a memo to the PI indicating the findings at the PACM inspection within 7-14 calendar days (5-10 business days). The PI will have 28 calendar days (20 business days) to respond to the memo through the electronic system. If there are no issues found at the inspection, PIs do not need to respond through the electronic system.

6. The PI’s response is sent to the IACUC office. The IACUC Chair (or designee) reviews the response. If the PI's response is not acceptable, the IACUC Chair (or designee) will seek further revisions, and the PI will have 7 calendar days (5 business days) to respond through the electronic system. If an acceptable response is not forthcoming, the IACUC Chair (or designee) and Attending Veterinarian will take whatever steps are necessary to protect animal welfare. The RLS will also develop a plan for follow-up if indicated before the next 6 month inspection.

7. The RLS provides a summary of inspection findings to the IACUC for inclusion in the minutes of the next protocol review meeting. The PACM summary report is generated through Click Commerce and includes protocol #’s, Protocol Title, PI’s name, date of inspection, grade (acceptable, minor or significant) and deficiency. Comments, recommendations, serious continuing noncompliance and trends, if any, are also reported.

8. If the PI does not respond to inspection findings within 28 calendar days (20 business days), animal orders are blocked by the IACUC Coordinator. If no response is received within the next 14 calendar days (10 business days), the Attending Veterinarian is notified and the animals may be placed into a holding protocol and animal disposition is discussed with the Attending Veterinarian.
RESPONSIBILITY:
It is the responsibility of the Chairperson of the IACUC and the protocol reviewers/members to ensure that proper and appropriate review and monitoring procedures are followed for all protocols that come before the IACUC.

REFERENCE:
1. USDA-AWR: Title 9, Subchapter A, Parts 1-3
2. PHS Policy on the Humane Care and Use of Laboratory Animals
3. Guide for the Care and Use of Laboratory Animals, Eighth Edition
OBJECTIVE:
The purpose of this section is to describe the purpose and procedures for conducting Semi-Annual Program Evaluation, including:

Program Review component:
A. Semi-Annual Program Review

Facility Inspection component:
B. Semi-Annual DAR/Satellite Facility Inspection

DESCRIPTION:
The IACUC is authorized to conduct a Semi-Annual Program Evaluation of the Institutional Animal Care and Use Program.

The Semi-Annual Program Evaluation consists of two components:

Program Review component: “Semi-Annual Program Review” refers to the IACUC review of program components (e.g. Institutional Policies and Responsibilities, Veterinary Care Program, Training Program, OHS Program, Animal Facility Disaster Plan, etc.).

Facility Inspection component: “Semi-Annual Facility Inspection” refers to the physical inspection of all areas within the central or core animal facility and all study areas or satellite facilities.

Both components must be conducted at least semi-annually and the corresponding reports of these evaluations must be written and submitted to the Institutional Official (Vice President for Research and Innovation) at least semi-annually

A. Semi-Annual Program Review:
Key components of an animal care and use program that will be emphasized in the semiannual program reviews include:
1. Animal care and use program; IACUC; IACUC protocol review; IACUC membership and functions; IACUC records & reporting requirements; personnel security; investigating & reporting animal welfare concerns;
2. Disaster planning & emergency preparedness; veterinary care, including clinical care and management; animal procurement and transportation/preventive medicine; surgery; pain, distress, anesthesia and analgesia; euthanasia; drug storage and control;
3. IACUC training; Personnel qualifications and training;
4. Occupational health and safety of personnel.
The Chairperson of the IACUC, or designee, appoints the membership of and assigns the semi-annual program review to the following subcommittees: (1) the IACUC Function subcommittee reviews the animal care and use program; IACUC; IACUC protocol review; IACUC membership and functions; IACUC records & reporting requirements; personnel security; investigating & reporting animal welfare concerns; click commerce changes to IACUC protocol questions; (2) the IACUC Veterinary Care subcommittee reviews the VCU veterinary care animal program and disaster planning & emergency preparedness; (3) the IACUC Training subcommittee reviews IACUC training and personnel qualifications and training; (4) the IACUC Occupational Health and Safety subcommittee reviews the occupational health and safety program. Each subcommittee meets to conduct a program review at 6 month intervals by using the OLAW semiannual program review checklist. The Chair of each subcommittee prepares a written report and presents the report at the IACUC meeting. Changes to components since the last program review should be brought to the table for information purposes, and if necessary, discussion and deliberation, and finally documentation. Components which have not been modified should be reassessed for effectiveness. Any changes and substantive deliberations should be documented in the report to the Institutional Official along with identified deficiencies or departures (minor or significant), schedule and plan for corrective action, recommendations for program improvements and any minority views. Any areas in the program review are identified as minor or significant deficiencies, then the subcommittee should follow-up or come up with a plan and schedule for correction.

B. Semi-Annual DAR/Satellite Facility Inspection:
Under PHS policy and USDA regulations, the IACUC should inspect all institutional animal facilities at least once every six months, including:

1. Areas within the central or core animal facility including, but not limited to, buildings, rooms, corridors, enclosures, vehicles, holding areas, animal care support areas (e.g., anterooms, cage wash facilities, feed/bedding storage areas, implement storage areas, etc.), animal use support areas (e.g., procedure rooms, surgeon and patient preparation areas, surgery and recovery areas, euthanasia and necropsy areas, pharmacy, etc.) and personnel preparation areas (e.g., change facilities, locker areas, showers/rest rooms, etc.)
2. Satellite holding facilities – areas outside of a core facility or centrally designated area in which animals are housed out-of-vivarium for more than 24 hours (PHS Policy);
3. Animal study areas where USDA covered species are housed out-of-vivarium for more than 12 hours (AWR).

These inspections provide an ongoing mechanism for ensuring that VCU maintains compliance with the applicable animal care and use policies, guidelines, and laws. Every effort will be made to ensure that All IACUC members are expected to participate in the inspection process.

Pre-Inspection:
Prior to the facility inspection, all IACUC members will be provided with:

1. A copy of Semiannual DAR Facilities Inspection Checklist, including information about facility construction, physical environment for animals and animal care technicians, cage wash areas, surgical suites, out-of-vivarium areas (areas housing animals for more than 12 hours for USDA regulated species and for more than 24 hours for non-USDA regulated species);
2. A complete and accurate list of areas to be inspected;
3. A list of deficiencies and departures and the corresponding schedule for corrective action from the previous inspection. The inspection team will ascertain if corrections have been made and, if not, will report these as continuing deficiencies and departures.

**Inspection Procedures:**

1. The IACUC members will meet and obtain the above facility inspection checklist. The IACUC Chair will provide a brief introduction regarding how to use the facility inspection checklist.

2. The VCU Attending Veterinarian or his designee assigns a DAR (Division of Animal Resources) representative to accompany each inspection team. At least two IACUC voting members must be assigned to the inspection team when inspecting the areas for USDA-regulated animals or the USDA and non-USDA animal shared areas. The inspection team must have a working knowledge of the Guide and USDA regulations in order to fully evaluate the facilities that are being inspected.

3. The inspection teams should take inspection notes, in a legible form. (a) If appropriate, the condition of the facilities will be listed as “Acceptable”. (b) Deficiencies, where noted, will be graded as “Minor” or “Significant”. Significant deficiencies are those that are or may become a threat to animal health and well-being or to the safety and well-being of personnel who work in the facility.

4. After facilities inspections, one of the IACUC members from each inspection team presents their significant or undetermined findings to the IACUC committee. The IACUC committee votes to approve or oppose the deficiencies as reported. When deficiencies are identified as “Significant”, the Attending Veterinarian will need to take immediate action to follow-up and report back to the IACUC within 24 hours. When deficiencies are identified as “Minor”, the Attending Veterinarian or his designee will have to correct the deficiencies and respond within 30 days. Corrective action taken will be reported to the IACUC in writing at the next monthly administrative meeting.

5. Detailed inspection notes will be delivered to the ORSP. The ORSP staff will compile the inspection results into the Semiannual Reports listing minor and significant deficiencies and a timetable for the correction of all deficiencies. The report must be reviewed and approved by IACUC and signed by a majority of the quorum present. Minority views will be included in the report. The report will be submitted to the Institutional Official and the ORSP staff will maintain all original notes and reports in the IACUC files.

**RESPONSIBILITY:**

It is the responsibility of the IACUC Chairperson and the ORSP to ensure that the above procedures are completed in a timely and complete manner.

**REFERENCE:**

1. USDA-AWR: Title 9, Subchapter A, Parts 1-3
2. PHS Policy on the Humane Care and Use of Laboratory Animals
3. Guide for the Care and Use of Laboratory Animals, Eighth Edition
OBJECTIVE:
The purpose of this section is to describe the reporting requirements of the IACUC, including:

A. USDA Registration and Reporting Requirements
B. PHS/OLAW Registration and Reporting Requirements
C. PHS and USDA Reporting Requirements

DESCRIPTION:
A. USDA Registration & Reporting Requirements:
USDA Registration:
As stated in the USDA Animal Welfare Regulations, “each research facility…shall register with the Secretary” (9 CFR, Ch.1, Subpart C, §2.30). This registration form is filed with USDA’s Animal and Plant Health Inspection Service (APHIS), REAC Sector Supervisor and must be updated every 3 years by completing and filing a new registration form (9 CFR, Ch. I, §2.30).

VCU is registered under the Animal Welfare Act as a Class “R” Research Facility with the USDA-APHIS-Animal Care (AC) regional office in Raleigh, NC. VCU’s registration number is 52-R-0124.

USDA (APHIS-Animal Care) Annual Reports (APHIS form 7023):
As required by Section 13 of the Animal Welfare Act (AWA) and further explained in 9 CFR Part 2, §2.36, each reporting research facility shall submit an annual report to the Animal Care Regional Director. This annual report shall be signed and certified as correct by the legally responsible Institutional Official (IO). The annual report must document all species covered by the AWA used in research, tests, experiments, or teaching and those on hand at the end of the USDA fiscal year (October 1 to September 30). These reports must be submitted before December 1 of each year. The APHIS-Animal Care regional office sends the necessary forms for filing the annual report on or about September 15 of each year.

The report must show the number of animals with no pain or distress; the number with pain or distress relieved with anesthetic, analgesic, or tranquilizing drugs; the number with pain or distress not relieved; and the number of animals on hand as of September 30 which were not reported under another category and not assigned to any procedures. For those animals with pain or distress where the appropriate anesthetic, analgesic, or tranquilizing drugs was not used, there must be a detailed statement explaining the procedure producing the pain or distress and the reasons such drugs were not used.

The Annual Reports are also used to verify the VCU IACUC’s continuing compliance with the regulations and standards set forth in the Animal Welfare Act. Such items that must be verified and certified each year include proper membership of the IACUC and proper protocol approval and review standards and procedures.
The ORSP will compile the necessary information for the report and prepare the USDA forms at least 10 business days before the annual due date (December 1). The Institutional Official will be asked to sign the report following review by the Attending Veterinarian, IACUC Chair and Executive Director of ORSP. The final report will be submitted by ORSP. At this time, copies of each year’s report are kept on file in the ORSP (as feasible).

B. PHS/OLAW Registration & Reporting Requirements:
The Animal Welfare Assurance Statement:
In order to obtain funding from PHS for activities involving animals, VCU must provide written assurance that the institution will comply with the policies and procedures set forth by PHS. This assurance, called the Animal Welfare Assurance (Assurance), is a legally binding institutional commitment to the Office of Laboratory Animal Welfare (OLAW), a branch of PHS. The Assurance is VCU’s description of its own program for research animal subject protections, care, and use.

According to PHS Policy (IV.A.1., 2., and 3.), “no activity involving animals may be conducted or supported by the PHS until the institution conducting the activity has provided a written Assurance acceptable to the PHS, setting forth compliance with this Policy. Assurances shall be submitted to the Office of Laboratory Animal Welfare (OLAW), Office of the Director, National Institutes of Health.”

OLAW provides VCU with necessary instructions and an example of an acceptable Assurance. Using the Guide as a basis for developing and implementing an institutional program for activities involving animals, the Assurance must fully describe the components of an institution’s animal care and use program and facilities. The following comprise the basis of the IACUC Semiannual Program Reviews.

1. Institutional Program for Animal Care and Use:
   a) A list of every branch and major component of the institution, as well as a list of every branch and major component of any other institution, which is to be included under the Assurance;
   b) The lines of authority and responsibility for administering the program and ensuring compliance with this Policy;
   c) The qualifications, authority, and responsibility of the veterinarian(s) who will participate in the program and the percent of time each will contribute to the program;
   d) The membership list of the Institutional Animal Care and Use Committee(s) (IACUC) established in accordance with the requirements set forth in the Policy;
   e) The procedures which the IACUC will follow to fulfill the requirements set forth in this Policy;
   f) The health program for personnel who work in laboratory animal facilities or have frequent contact with animals;
   g) A synopsis of training or instruction in the humane practice of animal care and use, as well as training or instruction in research or testing methods that minimize the number of animals required to obtain valid results and minimize animal distress, offered to scientists, animal technicians, and other personnel involved in animal care, treatment, or use;
   h) The gross square footage of each animal facility (including satellite facilities), the species housed therein and the average daily inventory, by species, of animals in each facility; and
i) Any other pertinent information requested by OLAW.

2. Institutional Status: Each institution must assure that its program and facilities are in one of the following categories (VCU is currently a Category 1 Institution):

   Category 1: Accredited by the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC International). All of the institution's programs and facilities (including satellite facilities) for activities involving animals have been evaluated and accredited by AAALAC, or another accrediting body recognized by PHS. All of the institution's programs and facilities (including satellite facilities) for activities involving animals have also been evaluated by the IACUC and will be reevaluated by the IACUC at least once every six months, in accordance with IV.B.1. and 2. of this Policy, and reports prepared in accordance with IV.B.3. of this Policy.

   Category 2: Evaluated by the Institution. 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, in accordance with IV.B.1. and 2. of this Policy, and reports prepared in accordance with IV.B.3. of this Policy. The most recent semi-annual report of the IACUC evaluation shall be submitted to OLAW with the Assurance.

3. Institutional Animal Care and Use Committee (IACUC):
   a) The Institutional Official shall appoint an Institutional Animal Care and Use Committee (IACUC), qualified through the experience and expertise of its members to oversee the institution's animal program, facilities, and procedures.
   b) The Assurance must include the names, position titles, and credentials of the IACUC Chairperson and the members.

As noted above, VCU must apply for its Assurance four months before the expiration date (usually every five years). VCU’s Assurance identification number is A3281-01.

ORSP staff persons assigned to the IACUC, with the assistance of the IACUC Chairperson and members, are responsible for ensuring proper and timely preparation of the Assurance every five years. The Institutional Official will also play an important role in drafting and updating the Assurance. The Institutional Official signs and certifies the Assurance.

VCU’s Assurance statement is on file in the ORSP. Past years’ Assurances are also on file in the ORSP and are maintained indefinitely.

**Annual Reports to OLAW:**

According to the PHS Policy (IV. F. 1., 2., and 4.), at least once every 12 months, the IACUC, through the Institutional Official, shall report in writing to OLAW:

1. Any change in the institution’s program or facilities which would place the institution in a different category than specified in its Assurance (see IV.A.2. of this Policy);
2. Any change in the description of the institution's program for animal care and use as required by IV.A.1.a.- i. of this Policy;
3. Any changes in the IACUC membership and/or in Institutional Official;
4. Notice of the dates that the IACUC conducted its semiannual evaluations of the institution's program and facilities and submitted the evaluations to the Institutional Official; and
5. Include any minority views submitted by members of the IACUC regarding reports filed under PHS Policy IV.F., for this reporting cycle.

If, in at least once every 12 months, no changes in the areas listed above have occurred, the IACUC shall submit a report and letter, through the Institutional Official, to OLAW stating that there are no changes and informing OLAW of the dates of the required IACUC evaluations and submissions to the Institutional Official.

ORSP staff members assigned to the VCU IACUC compile the PHS Annual Reports. The VCU Institutional Official and IACUC Chairperson certify and sign them. OLAW strongly encourages institutions to use the calendar year (January 1 – December 31) as the reporting period. To standardize due dates, all annual reports are due to OLAW by the last day of the month immediately following the end of the institution’s reporting period. Copies of the PHS Annual Reports are kept on file in the ORSP indefinitely.

**Prompt Reporting to OLAW under the PHS Policy:**
According to the PHS Policy, IV.F.3, requires that:
"The IACUC, through the Institutional Official, shall promptly provide OLAW with a full explanation of the circumstances and actions taken with respect to:
1. any serious or continuing noncompliance with this Policy;
2. any serious deviation from the provisions of the Guide [for the Care and Use of Laboratory Animals]; or
3. any suspension of an activity by the IACUC."

**Guidance on Prompt Reporting:**
The examples below do not cover all instances but demonstrate the threshold at which OLAW expects to receive a report. VCU IACUC should use rational judgment in determining what situations meet the provisions of IV.F.3 and fall within the scope of the examples below and have an authorized representative from ORSP to consult with OLAW if in doubt.

Examples of reportable situations:
1. conditions that jeopardize the health or well-being of animals, including natural disasters, accidents, and mechanical failures, resulting in actual harm or death to animals;
2. conduct of animal-related activities without appropriate IACUC review and approval;
3. failure to adhere to IACUC-approved protocols;
4. implementation of any significant change to IACUC-approved protocols without prior IACUC approval as required by IV.B.7.;
5. conduct of animal-related activities beyond the expiration date established by the IACUC (note that a complete review under IV.C is required at least once every three years);
6. conduct of official IACUC business requiring a quorum (full Committee review of an activity in accord with IV.C.2 or suspension in accord with IV.C.6) in the absence of a quorum;
7. conduct of official IACUC business during a period of time that the Committee is improperly constituted;
8. failure to correct deficiencies identified during the semiannual evaluation in a timely manner;
9. chronic failure to provide space for animals in accordance with recommendations of the Guide unless the IACUC has approved a protocol-specific deviation from the Guide based on written scientific justification;
10. participation in animal-related activities by individuals who have not been determined by the IACUC to be appropriately qualified and trained as required by IV.C.1.f;
11. failure to monitor animals post-procedurally as necessary to ensure well-being (e.g., during recovery from anesthesia or during recuperation from invasive or debilitating procedures);
12. failure to maintain appropriate animal-related records (e.g., identification, medical, husbandry);
13. failure to ensure death of animals after euthanasia procedures (e.g., failed euthanasia with CO2);
14. failure of animal care and use personnel to carry out veterinary orders (e.g., treatments); or
15. IACUC suspension or other institutional intervention that results in the temporary or permanent interruption of an activity due to noncompliance with the Policy, Animal Welfare Act, the Guide, or the institution's Animal Welfare Assurance.

Examples of situations not normally required to be reported:
1. death of animals that have reached the end of their natural life spans;
2. death or failures of neonates to thrive when husbandry and veterinary medical oversight of dams and litters was appropriate;
3. animal death or illness from spontaneous disease when appropriate quarantine, preventive medical, surveillance, diagnostic, and therapeutic procedures were in place and followed;
4. animal death or injuries related to manipulations that fall within parameters described in the IACUC-approved protocol; or
5. infrequent incidents of drowning or near-drowning of rodents in cages when it is determined that the cause was water valves jammed with bedding (frequent problems of this nature, however, must be reported promptly along with corrective plans and schedules).

Time Frame for Reporting:
The PHS Policy, IV.F.3, requires a full explanation of circumstances and actions taken and the time required to fully investigate and devise corrective actions may be lengthy, therefore, an authorized VCU representative from ORSP will provide a preliminary report to OLAW as soon as possible and follow-up with a thorough report once action has been taken. Preliminary reports may be in the form of a fax, email, or phone call. Reports should be submitted as situations occur, and not collected and submitted in groups or with the annual report to OLAW.

Preliminary report should include the following information:
1. Name and contact information of person reporting
2. Name of institution
3. Assurance number
4. Funding component and if contacted (for situations related to PHS-supported activities)
5. Brief description of incident (e.g., species, category of personnel involved, dates, times, animal deaths)
6. Plan and schedule for correction and prevention (if known)
7. Timeframe for final report
**Final report:**
A final report must be submitted for reportable situations and include a detailed explanation of the circumstances and actions taken. The final report must be signed by the Institutional Official and must specify the following:

1. Name of institution;
2. Animal Welfare Assurance number (http://grants.nih.gov/grants/olaw/assurance/300index.htm);
3. Reporting requirement: Identify the reporting requirement of the PHS Policy IV.F.3. under which the incident qualifies (i.e., serious or continuing noncompliance with the PHS Policy, serious deviation from the provisions of the Guide, or suspension of an activity by the IACUC).
4. Preliminary report: Note when, by whom, and to whom a preliminary report was made, if applicable.
5. Explanation of incident: Explain in detail what happened, when and where, the species of animals(s) involved, and the category (but not the names) of the individuals involved.
6. Corrective actions: Describe the corrective and preventative actions taken to address the situation. Include all the short or long-term corrective plans along with the implementation schedule. Indicate whether the IACUC reviewed and accepted the corrective actions submitted by the responsible party and any ongoing actions taken by the IACUC (e.g., enhanced oversight).
7. Grant/contract number: Include the relevant grant or contract number (for situations related to PHS-supported activities).
8. Impact on PHS-supported activities: Describe any potential or actual effect on PHS-supported activities. This also applies to incidents that have occurred in a functional, programmatic, or physical area not supported by the PHS that could affect PHS-supported activities (see also NOT-OD-05-034).
9. Compliance with terms and conditions: If the incident involved PHS-supported activities and was not compliant with the terms and conditions of grant award, confirm that the situation was reported to the funding component and that all unauthorized costs initially paid from the grant have been removed and covered by other sources (see also NOT-OD-10-081). Or, certify that no unallowable costs were charged during the noncompliant period.

**C. PHS and USDA Reporting Requirements:**
Both USDA regulations and PHS Policy require that VCU evaluate its own animal care and use program and facilities at least once every six months. The semiannual program reviews and inspections are a means for the VCU IACUC to evaluate its own strengths and weaknesses – to identify the areas that are acceptable according to the regulations and those areas which may need improvement. These evaluations must be submitted as written reports to the Institutional Official, following review by the IACUC Chair, Attending Veterinarian and Director of ORSP.

**Public Health Service Policy on Semiannual Reviews, Inspections, and Reports:**
The PHS Policy states that, as an agent of the institution, the IACUC shall (with respect to PHS conducted or supported activities):

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;
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;

3. Prepare reports of the IACUC evaluations conducted as required by 1 and 2 above, and submit the reports to the Institutional Official. (NOTE: the reports shall be updated at least once every six months upon completion of the required semiannual evaluations and shall be maintained by the institution and made available to OLAW upon request. The reports must contain a description of the nature and extent of the institution’s adherence to the Guide and Policy and must identify specifically any departures from the provisions of the Guide and Policy, and must state the reasons for each departure. The reports must distinguish significant deficiencies from minor deficiencies. A significant deficiency is one which, consistent with 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. If some or all of the institution's facilities are accredited by AAALAC or another accrediting body recognized by PHS, the report should identify those facilities as such.);

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

5. Make recommendations to the Institutional Official regarding any aspect of the Institution’s animal program, facilities, or personnel training;

OLAW recommends that the report to the Institutional Official also include a narrative describing the process of program evaluation and facility inspection, and IACUC findings, positive and negative. While the IACUC may determine the best means of conducting an evaluation of the institution’s programs and facilities, the IACUC remains responsible for the evaluation and report. Final reports of the semiannual evaluations/inspections are considered full committee actions and should be reviewed and endorsed by a majority of the IACUC.

Semiannual program and facility review reports should be submitted to OLAW only if requested, or if the institution is submitting a new or renewal Animal Welfare Assurance and is not accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC International). VCU is currently AAALAC accredited.

**USDA Regulations on Semiannual Reviews, Inspections, and Reports:**

The USDA requirements for semiannual reviews, inspections, and reports are essentially the same as those for PHS, with three exceptions (9 CFR, §2.31(c)(1, 2, and 3):

1. USDA regulations include additional reporting requirements if the schedule and plan for correcting a deficiency is not followed. Failure to correct a significant deficiency in accordance with the specified schedule and plan must be reported in writing within fifteen business days by the IACUC, through the Institutional Official, to APHIS and any federal agency funding the activity.

2. USDA requires that reports be reviewed and signed by a majority of IACUC members. Any minority views must also be included in the report.

3. USDA does not require the identification of facilities accredited by AAALAC.
VCU also requires that minor facility deficiencies be brought to the attention of facilities managers through the Attending Veterinarian after the inspection. A memo from the IACUC is sent to the Attending Veterinarian, citing the minor deficiency(ies) and requesting that the deficiency/deficiencies be corrected within 30 days. The Attending Veterinarian will inform the IACUC once the deficiency has been corrected. Significant deficiencies will be brought to the attention of the Institutional Official and will be reported within 15 days to USDA and PHS/OLAW.

The semiannual reports are maintained by the VCU ORSP and are available to APHIS and other officials of federal funding agencies for inspection and copying.

**RESPONSIBILITY:**
It is the responsibility of the IACUC Chairperson and the ORSP to ensure that the above procedures are completed in a timely and complete manner.

**REFERENCE:**
1. USDA-AWR: Title 9, Subchapter A, Parts 1-3
2. PHS Policy on the Humane Care and Use of Laboratory Animals
5. Guide for the Care and Use of Laboratory Animals, Eighth Edition
OBJECTIVE:
The purpose of this section is to describe the record keeping policies and procedures of the VCU IACUC.

DESCRIPTION:
The IACUC maintains its records in the ORSP. The IACUC records maintained by the ORSP include (but are not limited to):

1. The VCU’s approved PHS-OLAW Animal Welfare Assurance statement;
2. The USDA-APHIS Registration;
3. Minutes of IACUC meetings, including records of attendance, activities, and actions of the Committee, and Committee deliberations;
4. Records of applications, protocols, and proposed significant changes in the care and use of animals and whether IACUC approval was given or withheld;
5. Completed or inactive protocols;
6. Records of continuing review of IACUC-approved protocols;
7. Records of semiannual IACUC inspections, reports, and recommendations (including minority views) as forwarded to the Institutional Official;
8. Copies of the annual reports sent to USDA-APHIS, OLAW and AAALAC;
9. Records of accrediting body determinations (AAALAC); and
10. Personnel training records;

The ORSP maintains all records for at least three years. Records that relate directly to proposed activities and proposed significant changes in ongoing activities reviewed and approved by the IACUC are maintained for the duration of the activity and for an additional three years beyond the completion of the activity. After those three years, limited information about such completed protocols is kept in a computer data base. Most other IACUC records, such as inspections reports, meeting minutes, committee membership lists, etc., are maintained in the ORSP files.

If an USDA-APHIS Administrator or other federal representative would notify the VCU in writing that specific records must be retained pending completion of an investigation or a proceeding under the Animal Welfare Act or other regulation, the VCU will hold those records until their disposition is authorized in writing by the federal agency administrator or representative.

responsibility:
ORSP Director and staff members assigned to the IACUC are responsible for maintaining the IACUC records.
REFERENCE:
None listed.
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| WPP #: IV-8 |

| Title 8: |
| Addressing Allegations of Mistreatment or Non-Compliance |

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**OBJECTIVE:**
The purpose of this section is to describe the policies and procedures for addressing allegations of mistreatment or non-compliance with the Animal Welfare Regulations, the PHS Policy, the Guide, VCU’s Assurance, or IACUC policy.

**DESCRIPTION:**
The VCU IACUC and ORSP will review and/or investigate any concern or complaint relating to animal care and use brought to the attention of the committee or ORSP. This includes claims made (1) by the public concerning any aspect of the animal care and use program and (2) by employees or students who report (a) alleged instances of animal abuse, (b) violation of approved protocols, (c) use of animals not covered by approved protocols, (d) violations of any animal-related regulation of standard (such as, the Animal Welfare Regulations, the PHS Policy, the Guide, the VCU Assurance, IACUC Policy), (e) complaints regarding the care received by animals housed in VCU facilities or the conditions of the facilities, and (f) other aspects of the animal care and use program. Observations during post-approval compliance monitoring or by veterinary staff and IACUC members can be investigated by the same process.

Making such complaints and reporting suspected violations of procedures, policies, or requirements will not be detrimental to an individual’s standing within VCU. The USDA Regulations provide specific protections, “No employee, Committee member, or laboratory personnel shall be discriminated against or be subject to any reprisal for reporting violations of any regulation or standards under the Animal Welfare Act Regulations”[9 CFR 1, Part 2, Subpart C, 2.32(c)(4)]. In addressing such concerns, due process respecting the rights of both the accused and the accuser will be carefully maintained at all times to assure that those individuals reporting alleged animal care complaints in good faith are protected from retaliation and that the reputations of those unfairly accused are not damaged or are restored.

1. “Mistreatment” is defined as physical or psychological, wrongful, or abusive treatment of an animal.
2. “Non-compliance” means that procedures or policies are not being followed, and this may stem from confusion or misunderstanding.

**Procedures to be followed for reporting allegations:**

**A.** Initial reporting may be made orally or in writing to the IACUC Chairperson, the Attending Veterinarian, the ORSP office, or any member of IACUC. Reports made anonymously will be treated in the same way as reports made with attribution. Each allegation should provide specific details. The party receiving an allegation will forward a copy of the allegation to the IACUC Chair (or vice-chair) and ORSP.
B. Initial Inquiry

1. The ORSP in conjunction with the IACUC Chairperson (or designee) and/or the Attending Veterinarian (or designee) will conduct an Initial Inquiry to determine whether a Formal Investigation is required. Those against whom the complaint is addressed will be notified in writing, and also by telephone, that such an Initial Inquiry is underway, and they will be informed of the specifics of the allegations made. If emergency action (e.g., euthanasia) is necessary in order to alleviate the suffering of animals, such action will be taken immediately by the Attending Veterinarian or designee to preserve animal welfare.

2. Those against whom the allegations are made and the PI of the protocol, if a protocol is involved, will be invited to address the allegations in writing and/or in person during the Initial Inquiry and actions may be taken at this point to resolve the situation that prompted the allegation to be made. The IACUC Chair or Attending Veterinarian in conjunction with ORSP will send an email to the PI regarding this Initial Inquiry and arrange a meeting. If an allegation is made against an individual in the Division of Animal Resources (DAR), the individual and the individual's supervisor will be invited to respond. If an allegation is made regarding facilities or conditions outside the control of the PI and DAR, such as problems regarding heat, humidity, electricity, water service, or other infrastructure concerns that are the responsibility of VCU facilities management staff, the supervisor responsible for the building and the individual with overall responsibility for facilities management will be invited to respond. The ORSP will send an email to all relevant individuals regarding this Initial Inquiry. The PIs whose animals may have been injured or put at risk will be kept apprised.

3. The Initial Inquiry will result in one of the following three findings:
   c) Rejection of the allegation as unfounded;
   d) Identification of a deficiency that can be resolved by 
      e) retraining of laboratory or DAR personnel, (2) a change in laboratory or DAR procedures, or 
      (3) close veterinary supervision (CVS, defined in paragraph 8) in order to provide the necessary education of laboratory personnel and ensure animal welfare; (4) a retraining of facilities management personnel, a change in facilities management procedures, or the repair or upgrading of infrastructure as needed, or
   f) Identification of a deficiency that requires a Formal Investigation because of the seriousness of the deviation or its continuing or repeated nature.

4. A written report of the results of the Initial Inquiry, including minority views and any written documentation provided, will be given to those against whom the allegations are made and the PI of the protocol (and to the Director of DAR or to responsible Senior Administrator in Facilities Management, if the allegations are made against DAR staff or facilities, respectively), and will be kept on file by ORSP for a period of 3 years. If a deficiency is identified [(2) or (3)], the results of the Initial Inquiry will be reported to the IACUC at its next meeting.

C. Formal Investigation

1. The IO will be notified of all Formal Investigations.
2. If the Initial Inquiry identifies deficiencies that require a Formal Investigation, the IACUC Chairperson (or designee), in consultation with the ORSP, will appoint a sub-committee of IACUC members, a veterinarian if animal welfare issues are involved, and any other competent persons needed. If a member of the Subcommittee becomes unable to serve, the IACUC Chairperson (or designee) will appoint a replacement for that member of the Subcommittee. The Subcommittee will conduct a thorough and fair investigation in an expeditious manner, typically within 30 days of referral of an allegation. The individual against whom an allegation is made and the PI of the protocol will have the right to present oral and written information to the Formal Investigation Subcommittee and have others present oral and written information to the Subcommittee. If the allegations are made against DAR staff or facilities, the Director of DAR or the responsible Senior Administrator in Facilities Management, respectively, will have the right to present oral and written information to the Formal Investigation Subcommittee and have others do so also on their behalf. The Subcommittee has the right to seek oral and written information from the complaining individual (if the complaint is made with attribution), VCU faculty, staff and students, and internal and external experts, as needed.

3. After conducting a Formal Investigation, the Subcommittee will make one of the following three findings by majority vote with all members in attendance:
   a) Rejection of the deficiencies identified in the Initial Inquiry as unfounded;
   b) Identification of a deficiency that can be resolved by (1) retraining of laboratory or DAR personnel, (2) a change in laboratory or DAR procedures, or (3) close veterinary supervision (CVS, defined in paragraph 8) in order to provide the necessary education of laboratory personnel and ensure animal welfare; (4) a retraining of facilities management personnel, a change in facilities management procedures, or the repair or upgrading of infrastructure as needed, or
   c) Identification of a serious deficiency that merits consideration of suspension of: (1) one or more animal activities, or (2) the use of one or more animal facilities by the full IACUC at a regularly scheduled or special meeting.

4. A written report of the results of the Formal Investigation including minority views and any written documentation provided will be given to the individual against whom the allegation is made and the PI of the protocol (and to the Director of DAR or the responsible Senior Administrator in Facilities Management, if the allegations are made against DAR staff or facilities, respectively) and be kept on file by ORSP for a period of 3 years.

D. Suspension of One or More Animal Activities or the Use of a Facility
   1. If the Formal Investigation Subcommittee recommends the IACUC’s consideration of suspension of one or more animal activities or the use of a facility, the Subcommittee report, minority views, and any written documentation obtained will be presented at a regularly scheduled or special meeting of the full IACUC.

   2. The individual(s) against whom an allegation is made and the PI of the protocol will have the right to respond, within a period of at least 10 working days, in writing to the report of the Formal Investigation. Individuals against whom allegations are made and/or the PI of the protocol have
the opportunity to make oral presentations and have oral presentations made on their behalf during the Informal Inquiry and Formal Investigation; additional oral presentations by these individuals will be made only at the request of and at the sole discretion of the IACUC.

3. If the initial allegation is made against a member of the DAR staff, the individual and the Director of DAR will have the same rights and responsibilities as described in 4.B. for the case of an individual and PI.

4. If the allegation is due to infrastructure defects not under the control of the PI or DAR, the Vice-President for Research and Innovation and Vice-President with responsibilities for facilities management, or their designees, will meet with the IACUC and provide the written corrective action plans, time tables and written assurances necessary for IACUC to decide whether animal research can continue in the building or facility in question.

5. The IACUC's decision whether or not to suspend one or more animal activities or use of a facility will be based upon (1) the written report, minority views and documentation presented by the Formal Investigation Subcommittee, (2) (a) the written responses of individuals against whom an allegation is made and the PI of the protocol or, (b) if paragraph 4.C. applies, the written responses of the individuals against whom an allegation is made and the Director of DAR, or (c) if paragraph 4.D. applies, the written corrective action plans, time tables, and written assurances endorsed by the Vice-President for Research and Innovation and Vice-President with responsibilities for facilities management, and (3) all applicable state and federal laws and regulations and VCU and IACUC policies. In addition, at its sole discretion, the IACUC may seek additional information in written or oral form and may seek internal or external expert advice before voting on a motion to suspend one or more animal activities.

6. Detailed procedures for suspension of animal activities by the IACUC and the reporting requirements after such action are described in WPP# IV-9 (Suspension of Animal Use Activities and Finding of a Significant Deficiency)

E. If allegations are against laboratory workers, those against whom an allegation is made and the PI of the protocol will be informed, in writing, of the final actions of the IACUC and of any response that is required from them. If the allegation is against a member of the DAR, the individual and the Director of DAR will be informed, in writing, of the final actions of the IACUC and of any response that is required from them. If the allegation is due to a facilities management problem or defects in infrastructure, the Vice-President for Research and Innovation and the Vice-President with overall responsibility for Facilities management will be informed, in writing, of the final actions of the IACUC and of any response that is required from them. In all cases, the PIs whose animals may have been injured or put at risk will be kept apprised.

F. If an Informal Inquiry, Formal Investigation, or IACUC determine that corrective action is required, the IACUC and ORSP will follow-up to make sure that the required action is taken in a timely fashion. Records of reports, actions taken and the reasons for those actions will be carefully documented and maintained for a minimum of 3 years by ORSP.
G. The Attending Veterinarian has the authority to restrict animal ordering and/or the use of animals in research when necessary to preserve animal welfare. If necessary, animals can be placed on the Holding Protocol. The Attending Veterinarian also has the authority to restrict the use of animal facilities deemed to be not in compliance with applicable laws and regulations.

H. Close Veterinary Supervision (CVS). CVS is intended as a prescription to educate and retrain laboratory personnel in proper procedures that ensure the humane care and treatment of animals, to assist investigators in optimizing experimental procedures to minimize discomfort and risk to animals, and to verify that proper procedures are being followed by laboratory personnel without the need for protocol suspensions. CVS may be imposed on one or more animal activities approved under an IACUC protocol by the Initial Inquiry, Formal Investigation Subcommittee, IACUC action, or the Attending Veterinarian. Under CVS, the Attending Veterinarian may limit access to animals by laboratory personnel to situations that are closely supervised by the Attending Veterinarian, DAR staff, or other appropriate personnel designated by the Attending Veterinarian.

I. Upon request of the ORSP, the complainant will receive a summary of the actions taken, but any confidential information concerning protocols will not be included.

RESPONSIBILITY:
It is the responsibility of each IACUC member, the Chairperson, Attending Veterinarian, staff of the ORSP to ensure that allegations of non-compliance are handled according to these standards.

REFERENCE:
1. USDA-AWR: Title 9, Subchapter A, Parts 1-3
2. PHS Policy on the Humane Care and Use of Laboratory Animals, IV.B.4.
3. Guide for the Care and Use of Laboratory Animals, Eighth Edition
OBJECTIVE:
To describe (1) the conditions under which the IACUC may suspend an activity involving animals that it previously approved or suspend use of an animal facility if it determines that the activity is not being conducted or the facility is not being maintained in accordance with applicable provisions of Animal Welfare Act, the Guide, the VCU Assurance or PHS Policy, (2) the basis for making a finding of a significant deficiency, and (3) the reporting requirements resulting from a decision to suspend an animal use activity or from making a finding of significant deficiency.

DESCRIPTION:
The IACUC is authorized to suspend an activity that it previously approved if it determines that the activity is not being conducted in accordance with the description of that activity provided by the principal investigator and approved by the Committee or with applicable provisions of the Animal Welfare Act's regulations, the Guide for the Care and Use of Laboratory Animals, the VCU’s Assurance, or the PHS Policy.

PHS Policy and AWRs require that in order to suspend an activity, the IACUC must review the matter at a convened meeting of a quorum of the IACUC and the suspension must be approved by a majority vote of the quorum present. Minority opinions are recorded in the minutes of the meeting. When animals are found to be suffering unremitting pain or discomfort, the Attending Veterinarian has the authority to restrict animal ordering and/or the use of animals in research when necessary to preserve animal welfare. In addition, the Attending Veterinarian, IACUC Chairperson, or their designees have the authority, acting for the University, to order an Administrative Postponement of activities previously approved by the IACUC, if necessary, to ensure animal welfare and or to verify that activities are consistent with regulations of the Animal Welfare Act, the Guide for the Care and Use of Laboratory Animal, VCU’s Assurance or PHS Policy. If necessary, animals can be placed on the DAR holding protocol.

Preceding an IACUC vote for suspension of some or all animal activity, a Formal Investigation of alleged non-compliance occurs in which the Principal Investigator, ORSP, Formal Investigation Subcommittee, IACUC Chairperson, and Attending Veterinarian have been active participants. (The Formal Investigation process is described in WPP #IV-8.)

Efforts may be made to correct the problem(s) with the protocol through the cooperation of the Principal Investigator, involved personnel, ORSP, the IACUC, the Attending Veterinarian, and/or the department chair and by providing Close Veterinary Supervision (see WPP #IV-8). If the problem(s) cannot be or are not corrected or addressed, or if for any other reason the IACUC and the Attending Veterinarian feel that such activity involving animals should be suspended, suspension will occur after review of the matter at a convened meeting with a quorum of IACUC members and a vote for suspension approved by the majority of those present. The investigator involved will be notified (both verbally and in writing, if
possible) of the IACUC’s intention to suspend such activity involving animals before that action is taken. When the IACUC suspends an activity involving animals, the Holding Protocol for the disposition of involved animals may be activated (see WPP # IV-10).

Upon suspension of an animal use activity, the IACUC will notify the Institutional Official. Written communication to the PI involving suspension of animal activity is copied to the department chair and/or Dean if indicated. The Institutional Official and designee in consultation with the IACUC shall review the reasons for the suspension, take appropriate corrective action, and as required by statute or regulation, report that action with a full explanation to OLAW, USDA-APHIS (regulated species only) and any federal agency or other funding agency that requires such reporting. On rare occasions, the ORSP, in consultation with DAR, IACUC Chairperson or designee and the sponsored program, may report to the sponsor or agency as deemed appropriate.

Suspended research activity(ies) may be reinstated if or when the IACUC is satisfied with the investigator’s efforts to correct the problem. Reinstatement requires an affirmative vote by IACUC at a regularly scheduled meeting, and IACUC may impose any conditions deemed appropriate (e.g., Close Veterinary Supervision). If all animal activities are suspended, appropriate provisions for care are made for active animals (See WPP#: IV-10: Holding Protocol) and the authority to order animals on the protocol also is suspended.

In situations where a DAR staff member is judged to be at fault, the Director of DAR will develop a written corrective action plan to ensure the retraining and supervision of the individual or reassign the individual to duties not involving direct animal contact.

In situations where animal facilities are either (1) not adequately maintained by the University or (2) when the conditions or infrastructure of a facility does not meet the requirements of applicable laws and regulations, the IACUC can make a finding that a significant deficiency exists and/or suspend use of the facilities for animal care.

IACUC can determine that a minor deficiency rises to the level of a "significant deficiency," if a deficiency is judged to be a serious threat to the health and welfare of animals, is continuing, or is repeated.

RESPONSIBILITY:
It is the responsibility of the IACUC and Attending Veterinarian to ensure that animals are treated and maintained humanely and that suspensions are handled according to the above standards and procedures. If there is just cause to suspend an activity involving animals, the IACUC and DAR are responsible for ensuring that neither the investigator nor research staff are permitted to continue such activity with animals. The attending veterinarian is responsible for overseeing the care and disposition of involved animals (see Title of WPP#: IV-10 Holding Protocol).

The ORSP is responsible for determining whether reporting of the suspension or findings of significant deficiency require reporting to OLAW, USDA, or any Federal agency funding that activity and sponsors. The IO is responsible for carrying out the reporting.
REFERENCE:
1. USDA-AWR: Title 9, Subchapter A, Parts 1-3
2. PHS Policy on the Humane Care and Use of Laboratory Animals
3. Guide for the Care and Use of Laboratory Animals, Eighth Edition
OBJECTIVE:
To describe the disposition of animals in a study (1) that has expired, (2) is subject to an administrative postponement (see WPP#IV-9 Suspension of Animal Use Activities for administrative postponement), (3) has been suspended by the Institutional Animal Care and Use Committee (IACUC), and also, (4) the importation of animals prior to protocol approval.

DESCRIPTION:
Circumstances may arise in the case of research protocols where the investigator is required to cease active involvement with animals in a protocol or to cease specific activities under a protocol. Such circumstances requiring automatic enactment of the holding protocol include:
1. Expiration of a protocol due to failure of the investigator to submit to the IACUC appropriate documents required for annual review or triennial review within adequate time to allow for IACUC review;
2. Expiration of a protocol due to failure of the investigator to provide requested modifications in a timely manner so that the protocol under review may not receive final approval before its expiration;
3. Administrative postponement of an active protocol or a specific activity under an active protocol by the Attending Veterinarian (AV), IACUC Chairperson, Institutional Official (IO) or acting IO, or their designees, if such action may be deemed in the best interest of the health and welfare of animals;
4. Suspension of an active protocol by the IACUC upon determining that the protocol is not being conducted in accordance with applicable provisions of the Animal Welfare Act (AWA), the Guide, VCU’s Assurance with Public Health Service (PHS) policy, or is not consistent with the health and welfare of animals;
5. Importation of animals by an investigator (or in emergencies) prior to protocol approval also can be covered by a holding protocol after consultation and approval by the AV. Director of the Division of Animal Resources (DAR) will notify IACUC of approved importation. While animals are covered by a holding protocol, no research activity using animals is allowed until the submitted IACUC protocol is approved, other than basic weaning of offspring under DAR supervision.

A. Conditions not requiring placement of animals to Holding Protocol
Upon administrative postponement of a specific activity, animals will remain under the active protocol, but the investigator and research staff will cease all activities that are subject to postponement or that are no longer approved under the revised protocol. The administrative postponement will be noted in the IACUC minutes and in correspondence with the investigator.
B. **Conditions requiring placement of animals to Holding Protocol**

Upon expiration or suspension of a protocol, the animals will be placed on the holding protocol, and all contact with animals by persons listed in the protocol will cease, except as specifically permitted in writing by the AV. The placement of animals on the holding protocol from an expired protocol will be noted in the IACUC minutes and in correspondence with the investigator. In addition, suspension of a protocol will be reported to the Office of Laboratory Animal Welfare (OLAW), and/or the United States Department of Agriculture (USDA), and the funding agency.

The investigator remains responsible for per diem charges and any special veterinary care charges that accrue when animals are placed on the holding protocol. However, no federal grant monies can be used to pay for per diem charges for animals under a holding protocol according to the "NIH Policy on Allowable Costs for Grant Activities Involving Animals when Terms and Conditions are not Upheld" issued by the National Institutes of Health (NIH). The investigator is required to provide an alternative source of funding (not federal grant) to DAR for per diem charges, or discuss the holding situation with the grant manager at the funding agency supporting the award regarding allowance of costs for the specific grant activities involving animals which are conducted when the terms and conditions are not upheld.

C. **Disposition of animals placed on the holding protocol**

At the time of enactment of the holding protocol, the attending veterinarian is notified of the circumstances and will take actions necessary for the temporary husbandry of the animals, including appropriate housing, feeding, and nonmedical care of the animals, or for their ethical and humane disposition consistent with the recommendations of the 2013 American Veterinary Medical Association (AVMA) Guidelines for the Euthanasia of Animals. For breeding colonies, the male adult may be removed from the cage to cease breeding per the AV’s decision if the PI is no longer at VCU or if the delay proves to be extended.

The following are possible options available to the AV, who will make a decision regarding the disposition of the animals based on professional judgment, knowledge of the protocol, species of animal, accumulated training of the animals, and the interventional needs of the animals.

**POSSIBLE SCENARIOS THAT COULD BE ENCOUNTERED** (not limited to these examples):

Option 1: A protocol has expired or has been suspended or subject to postponement but is **likely** to be re-approved within two months. The attending veterinarian may arrange maintenance husbandry for the animals until the protocol is approved.

Option 2: A protocol has expired or has been suspended or subject to postponement and is **unlikely** to be re-approved within two months. The AV will communicate with the investigator about disposition options.

Option 3: A protocol has expired or has been suspended or subject to postponement and the protocol requires complex interventions with the animals or may cause added suffering by the animals for no research purpose. In this scenario the AV will use professional judgment to determine the most humane disposition of the animals, which may include euthanasia.
D. PROCEDURES TO BE FOLLOWED BY THE RESPONSIBLE OFFICES
1. Expiration of protocols is determined by final approval dates and is not an IACUC action.
2. The Click Commerce notifies DAR and the investigator of the pending expiration (normally 10 days before expiration).
3. The DAR determines whether animals are present when the protocol expires. If the protocol expires with animals, holding protocol cage cards will be placed on cages to cease all animal research, testing or experimental activities except for basic animal weaning.

E. Procedures for expired protocol with active animals remaining
1. The investigator will be notified that the protocol has expired and the holding protocol has been enacted. The investigator is required to contact DAR to provide an alternative budget code to cover per diem charges if PHS/NSF funds are currently used for care of animals.
2. The AV or designee shall become familiar with the protocol and determine the status of the animals remaining. Discussion with the PI is indicated so that the AV or designee may best ascertain the status of research concerning what has been done to the animals to date and the condition of the animals. Example actions that can be taken are:
   a) The AV remains in contact with the IACUC Chairperson or designee to determine the likelihood of protocol re-approval. Depending on the likelihood and timeliness of approval of the expired protocol, the investigator may elect to hold the animals in the vivarium and communicate that to the AV or designee. The animals are then placed onto the Holding Protocol (AD10000424), where maintenance husbandry is directed by the AV. The PI will be responsible for all per diem expenses incurred until the protocol is re-approved.
   b) If the PI elects not to retain the animals, the AV determines their further disposition or humane euthanasia.
   c) Transfer of all or some of the animals can occur, if they can be utilized on another protocol.
3. Decisions on the use and disposition of animals may be made by the AV or designee consistent with the 3 R’s (Replacement, Reduction and Refinement).

The AV or designee will enter a public comment regarding his decision and actions taken in Click Commerce.

F. Procedures for administrative postponement or suspended protocols with active animals remaining
1. When the decision to administratively postpone or suspend a protocol is issued, the AV is asked to discuss disposition options with the PI. The IACUC Chairperson will be able to offer an indication of the possible length of suspension. If the PI wishes to retain the animals, the animals are placed onto the holding protocol and maintenance husbandry is directed by the AV or designee. The PI will be responsible for all per diem expenses incurred (except for administrative postponement by the IO or designee) until the administrative postponement or suspension is lifted and the protocol reinstated. If the PI wishes to not hold the animals, the AV determines their further disposition or humane euthanasia.
2. The AV or designee will enter a public comment regarding the decisions and actions taken in Click Commerce.
3. If corrective action is required, the IACUC and ORSP will follow-up to make sure that required action is taken in a timely fashion. Records of reports, actions taken and the reasons for those
actions will be carefully documented and maintained for a minimum of three years in the ORSP office.

RESPONSIBILITY:
The IACUC is responsible for ensuring that animals in research are treated humanely. The investigator is not permitted to continue animal use activities with an expired or suspended protocol. If suspension is required by the IACUC, ORSP or Administration, the attending veterinarian has the responsibility of overseeing the on-going care of the animals on a case-by-case basis. Responsibility for the disposition of animals is that of the Attending Veterinarian.

Although designating expiration of a protocol is not an IACUC action, the IACUC Chair and the ORSP are notified of expiration and authorize the Attending Veterinarian to initiate activities related to the humane disposition of active animals in expired research.

REFERENCE:
1. OLAW (communication with S. Potkay, Director of Compliance, OLAW)
2. NIH Policy on Allowable Costs for Grant Activities Involving Animals when Terms and Conditions are not Upheld, NOT-OD-07-044, released date: January 26, 2007, issued by National Institutes of Health (NIH)
4. USDA-AWR: Title 9, Subchapter A, Parts 1-3
INVESTIGATIONAL USE OF THESE ANIMALS
WHILE ON THIS HOLDING PROTOCOL IS PROHIBITED

These animals have been placed on an IACUC holding protocol. Questions concerning this action should be directed to the VCU Attending Veterinarian or IACUC Chairperson

Protocol number: IACUC WPP#: IV - 10

Date placed on hold:

DAR / IACUC Cage Card #:
OBJECTIVE:
The purpose of this section is to describe the responsibilities of the Institutional Official, “Acting” Institutional Official, IACUC Chairperson, IACUC Vice-Chairperson, IACUC Members, ORSP Staff, Attending Veterinarian, and Principal Investigators.

DESCRIPTION:
A. Institutional Official (IO):
The VCU Vice President for Research and Innovation has been appointed as the Institutional Official by the President of VCU. The IO has the authority to allocate organizational resources needed to maintain a smoothly functioning animal care and use program based on the recommendations and advice received from the IACUC, the Attending Veterinarian, and the ORSP (which provides the IACUC professional and administrative staff). The IO appoints all members, including voting and alternates, to the IACUC. The IO is responsible for ensuring that adequate resources are made available to support the IACUC.

B. Delegation of Responsibility for Operations by IO:
The IO has delegated responsibility for day to day operations to the Executive Director of ORSP. The delegated responsibilities include oversight of the operations of the IACUC and actively facilitating the Institutional Official’s daily responsibilities of coordinating with administration, IACUC, investigators and animal resources to ensure a clearly defined chain of authority and adequate resources.

C. IACUC Chairperson:
Selection and Appointment:
The IO (Vice President for Research and Innovation) appoints the IACUC Chairperson who has the responsibility to ensure compliance with all federal and state regulations.

Length of Appointment Term:
The Chairperson will serve the appointment term defined in the appointment letter, unless otherwise designated by the Institutional Official.

Duties:
The Chairperson is responsible for conducting the IACUC meetings and serving as primary signatory official for IACUC correspondence. The Chairperson of IACUC meets on a regular basis with the Executive Director of ORSP to discuss IACUC issues, advises the Executive Director of ORSP of the IACUC activities, and has direct access to the IO for all IACUC matters. The Chairperson advises the IO regarding the resources necessary to support IACUC.

D. IACUC Vice-Chairperson and Acting Chairperson:
Selection and Appointment:
The Vice President for Research and Innovation appoints the IACUC Vice-Chairperson.

Length of Appointment Term:
The Vice-Chairperson will serve a three-year appointment term, unless otherwise designated by the IO.

Duties:
In the absence or unavailability of the Chairperson and when the Chairperson has a conflict on matters under consideration by the IACUC, the Vice-Chairperson is responsible for conducting the IACUC meeting, serving as a signatory official for IACUC correspondence, and assuming all other responsibilities of the Chairperson.

If the Chairperson and Vice-Chairperson are absent or unavailable or in conflict on matters under consideration by the IACUC, the Executive Director of ORSP, Chairperson or Vice-Chairperson may designate an appropriate IACUC member to serve as Acting Chairperson with the duties and responsibilities of the Chairperson.

E. IACUC Members:
Selection and Appointment:
The Chairperson recommends candidates for appointment as IACUC members to the Executive Director of ORSP, and the Vice President for Research and Innovation (IO) appoints them.

Length of Appointment Term:
Members serve a designated appointment term, with the option to continue thereafter as appointed by the Institutional Official.

Duties:
Duties of IACUC members are specified in the individual WPP#II-2 (Authority of the IACUC) and include:

1. Review, at least once every six months, the research facility’s program
2. Inspect, at least once every six months, all of the animal facilities including animal study areas/satellite facilities
3. Prepare reports of IACUC evaluations and submit the reports to the Institutional Official (IO)
4. Review and investigate legitimate concerns involving the care and use of animals at the VCU research facility resulting from public complaints and from reports of noncompliance received from the University community
5. Make recommendations to the IO regarding any aspect of the research facility’s animal program, facilities, or personnel training
6. Review and approve, require modifications in, or withhold approval of those components of proposed activities related to the care and use of animals
7. Review and approve, require modifications in, or withhold approval of, proposed significant changes regarding the care and use of animals in ongoing activities
8. Suspend an activity involving animals when necessary, take corrective action, and forward findings to the IO to report to the funding agency and the USDA/OLAW.
F. ORSP (IACUC) Staff:
The ORSP (IACUC) staff report to the Executive Director of the ORSP and are responsible for providing administrative support to the IACUC members and the Vice President for Research and Innovation and also serve as the gatekeepers of information and communications for the Vice President for Research and Innovation, the IACUC Chairperson and members, the attending veterinarian, the animal resource program, the investigators, and the research sponsor. The staff responsibilities include:

1. screening protocols for completeness;
2. preparing agendas and distributing protocols and other materials to IACUC members;
3. sending out reminders of protocol expirations and approval letters;
4. maintaining records of protocols and minutes of the meetings, policies and procedures, program reviews and facility inspection reports;
5. coordinating and scheduling the IACUC’s meetings, facilities inspections and laboratory site visits;
6. preparation of minutes and other correspondence and reports, such as the PHS Assurance document, and annual PHS, USDA and AAALAC reports;
7. serving as an information resource for investigators and IACUC members regarding regulatory issues (only as appropriate) and the status of protocols.

G. Attending Veterinarian:
The Attending Veterinarian is responsible for monitoring animal health, providing adequate diagnostic support through clinical assessments, laboratory diagnosis and necropsy when required, and treating animals when illness or injury necessitates veterinary medical care. The Attending Veterinarian shall be a voting member of the IACUC. Using a written documented process, the Attending Veterinarian may delegate responsibility for care to another veterinarian or trained animal technical staff but must always be available to provide rapid diagnosis and treatment. The Attending Veterinarian shall establish and maintain programs of adequate veterinary care that include:

1. the availability of appropriate facilities, personnel, equipment, and services,
2. the use of appropriate methods to prevent, control, diagnose, and treat disease and injuries, and the availability of emergency, weekend, and holiday care,
3. daily observation of all animals to assess their health and well-being,
4. guidance to principal investigators and other personnel involved in the care and use of animals regarding handling, immobilization, the selection and utilization of suitable anesthetic and analgesic agents and methods of euthanasia, and
5. proper performance of surgical procedures and adequate preoperative, surgical, and post-operative care.

H. Principal Investigator:
1. Responsibilities for submission of materials and information to the IACUC: See “Section IV: IACUC Operations for Protocol Submission.” (WPP#IV-2)
2. Continuing Review (see WPP#IV-4): Protocols should be regularly updated and refined by investigators to comply with current regulatory and scientific standards. The Public Health
Service Policy (PHS Policy) and the U.S. Department of Agriculture Rules (USDA regulations) require that an institution’s IACUC perform both initial and continuing review of animal related activities. The PHS Policy (IV.C.5.) states “the IACUC shall conduct continuing review of activities covered by this policy at appropriate intervals as determined by the IACUC but not less than every three years (s).” The USDA regulations (9 CFR Ch. I, §2.31(d)(5)) use similar language, except that continuing review must be performed not less than annually.

3. Significant Changes to an IACUC-approved protocol: Investigators are required to seek approval from the IACUC for any proposed change (or changes) to a previously approved protocol. Changes in protocol must be reviewed and approved by the IACUC prior to implementation, except where an immediate change is necessary to eliminate a hazard to animals or personnel. The Attending Veterinarian should be contacted and the IACUC notified in writing within 72 hours of such immediate, emergency changes. Changes to a protocol could include, but are not limited to, an increase in the number of animals to be used, a change in the pain category for the protocol, or the introduction of new in vivo techniques or procedures. Investigators are also required to submit a Memo to describe the change to a previously approved protocol and a copy of the rewritten protocol. The Change in protocol is then forwarded to IACUC members for review and discussion. The committee votes on approval or disapproval of the requested change(s) to the protocol, following the same procedures outlined for new protocols.

4. Training of Personnel: The Animal Welfare Act was revised in 1985 to include training requirements for personnel working with animals. The USDA regulations state that “it shall be the responsibility of the research facility to ensure that all scientists, research technicians, animal technicians, and other personnel involved in animals 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 qualification of personnel reviewed, with sufficient frequency to fulfill the research facility’s responsibilities under this section and Sec. 2.31” (9 CFR Ch. I, §2.32). Additionally, the U.S. Government Principle for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training states: “investigators and other personnel shall be appropriately qualified and experienced for conducting procedures on living animals. Adequate arrangements shall be made for their in-service training, including the proper and humane care and use of laboratory animals” (printed in the PHS Policy, p. 5, VIII).

RESPONSIBILITY:
It is the responsibility of the ORSP Executive Director, IACUC Chair, Attending Veterinarian and the Institutional Official (Vice President for Research and Innovation) to ensure that all parties are aware of their responsibilities as outlined within this policy.

REFERENCE:
1. USDA-AWR: Title 9, Subchapter A, Parts 1-3
2. PHS Policy on the Humane Care and Use of Laboratory Animals
3. Guide for the Care and Use of Laboratory Animals, Eighth Edition