INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE POLICY
Review and Approval of IACUC Submissions
Approval Date: October 4, 2016

BACKGROUND
All vertebrate animal use for research, teaching, or testing at SUNY Downstate Medical Center must be reviewed and approved by the Institutional Animal Care and Use Committee (IACUC). The Principal Investigator (PI) is responsible for providing sufficient information to the IACUC about the purpose and plan to use laboratory animals so that the Committee may take a reasonable evaluation of the activities and assessment of the welfare of the animal subjects. During the review process, additional information or clarifications may be requested from the PI in an effort to facilitate the approval process. Simultaneous administrative review to evaluate current training for the species and procedures proposed as well as review and approval of any associated Institutional Biosafety Committee review are performed.

This policy offers direction on the following topics:
- Protocol and Amendment Pre-review
- Protocol Review Process
- Amendment Review Processes
- Annual Review Process

REGULATORY GUIDANCE
- Animal Welfare Act (AWA) and Regulations (AWR)
- Guide for Care and Use of Laboratory Animals (Guide)
- PHS Policy on Humane Care and Use of Laboratory Animals (PHS Policy)
- OLAW FAQ D9
- NOT-OD-14-126: Guidance on Significant Changes to Animal Activities

PROTOCOL and AMENDMENT PRE-REVIEW
For PIs using USDA-covered species involving procedures that have the potential for pain and/or distress (category D or E procedures), consultation with the Attending Veterinarian (AV) or their designee is required during the planning phase of the study. However, the AV and the Office of Animal Welfare (OAW) are always available for consultation with PIs to discuss any concerns during preparation of the protocol, design of the study and protocol review. This is particularly encouraged for new animal models and pilot studies to facilitate subsequent development of the protocol in regards to potentially applicable regulatory guidance and animal care and well-being.

Upon submission of protocols and amendments the Office of Animal Welfare (OAW) conducts a pre-review. All efforts are made to provide feedback from the veterinary pre-review and primary reviewer to the PI prior to distributing the submission to the remaining committee members. This allows changes to be made to the protocol prior to full committee review and facilitate a more efficient approval of the submission. Using this process:
- Comments and suggested edits are captured in the Word version of the document using the track changes feature and are sent to the PI.
- Revisions made to address the comments are requested using the ‘track changes’ feature.
- Comments that do not require revision to the document can be addressed within the comment by the PI.
- The PI is encouraged to email, call, or meet with OAW and the reviewer to clarify any comments or suggested edits if the comments or suggested language is unclear.
- Secondary reviews are performed for the following items:
  - Training requirements are assessed relative to the species being used and procedures performed. Any training that is needed is communicated to the PI and the personnel to complete the training. The IACUC approval of protocols and amendments cannot be processed until training requirements have been fulfilled.
  - Submissions are assessed to determine if Institutional Biosafety Committee (IBC) review is needed. If needed, the PI is advised to submit an IBC application or amendment to existing
application if appropriate based upon IBC feedback to the PI) to the IBC for review. The IBC and IACUC reviews can occur in parallel. The IACUC approval cannot be processed until the necessary IBC approvals have been obtained.

- If grant congruency is needed at the time of review for a new award or change in scope to an existing award, it can be performed in conjunction with the IACUC review. The grant congruency review process occurs independent of the IACUC review and does not impact approval of the protocol. Any modifications that are needed to make the protocol congruent with the grant can be made during the course of the IACUC review of the protocol or by amendment after the protocol has been approved.

**PROTOCOL REVIEW PROCESS**

**FULL COMMITTEE REVIEW (FCR)**

Any member of the IACUC may request FCR of any protocol at any time. All initial and three-year renewal protocols are reviewed by FCR. FCR takes place at a convened meeting with at least a quorum of the members present. No member may participate in the review of a protocol in which the member has a conflict of interest (e.g. personally involved in the project) except to provide information requested by the IACUC. Members with a conflict of interest do not contribute to quorum and depart the meeting during the vote.

The PI has the opportunity to attend the IACUC meeting during review of their protocol to provide members with clarifications and better understand any additional clarifications that may be needed prior to approval of their protocol. Investigators are notified in writing of the outcome of the review. For FCR, the outcomes include:

- **Approval**: requires a majority vote by the members.
- **Modifications Required to Secure Approval** –
  - Deferred to Designated Member Review (DMR): requires a unanimous vote of the members; if the vote is not unanimous, the submission is returned to FCR. When protocols are deferred to DMR subsequent to FCR, the IACUC Chair designates the IACUC member(s) to work with the PI to address and review the response to the concerns. Once the DMR(s) agree that the concerns have been addressed and any outstanding training completed or associated IBC approvals obtained, the protocol is approved. If the DMRs are unable to resolve the concerns, the submission is returned to FCR.
  - Returned to FCR: requires the request of at least one member.
- **Approval withheld - disapproval**: requires a majority vote by the members.
AMENDMENT REVIEW PROCESS
Amendments are changes to existing and active protocols. Amendment reviews must be conducted as per the SUNY DMC Assurance and the USDA Animal Welfare Act and Regulations, and must be consistent with PHS policy and OLAW expectations (NOT-OD-14-126).

DESGINATED MEMBER REVIEW
Amendments (submitted as a protocol amendment form or as a revised version of the approved protocol in track changes format) that are processed by DMR include:
– changing from non-survival to survival surgery;
– changes resulting in greater pain, distress, or degree of invasiveness, such as:
  • Addition of survival surgical procedure.
  • Addition of a painful procedure.
  • Change in protocol that would require an animal to undergo more than one survival surgery.
  • Change in protocol that would require animals to be fed, housed or cared for in a way that is not standard for that species, or does not meet that species' minimum requirements.
  • Increase in the degree of invasiveness of a procedure or discomfort to an animal.
  • Change in protocol that would eliminate or restrict an animal's access to veterinary care.
  • Change to withhold analgesics.
  • Change in protocol where death becomes the experimental end point.
– changes in housing and or use of animals in a location that is not part of the animal program overseen by the IACUC;
– changes in purpose, specific aim or study objectives;
– change in species;
  • Some changes in species require a separate animal protocol – i.e., changing from mouse to rat, or changing from pigs to sheep.
  • Some changes in species can be accomplished by amendment – i.e., addition of another species of rat (addition of Rattus norvegicus to a protocol that is approved for the use of Rattus rattus), or addition of another species of macaque (addition of Macaca radiata or Macaca fascicularis to a protocol that is approved for the use of Macaca mulatta).
– an increase in number of USDA-regulated animals needed;
– a greater than 30% increase in the number of non-USDA regulated animals needed;
– changes in Principal Investigator (PI); and
– changes that impact personnel safety.

All members receive the submission by email, indicating that they have 72 hours to request clarifications or call for FCR. The IACUC Chair assigns specific DMR(s) to review the submission. Any clarifications requested by the DMRs are communicated to the PI. For DMR, the outcomes include:
– Approval: if no member calls for FCR within the 72 hour time frame detailed in the email, any outstanding training requirements completed or IBC approvals obtained for the amended activities, and the DMR(s) agree that any concerns have been addressed, the amendment is approved.
– Modifications Required to Secure Approval –
  • The DMR(s) to work with the PI to address and review the response to any concerns. If the DMRs are unable to resolve the concerns, the submission is added to the next full committee agenda for FCR.
  • Call to FCR: requires the request of at least one DMR.
Administrative Amendments with Veterinary Consultation

In support of the use of performance standards and professional judgment and to reduce regulatory burden, IACUC-reviewed and -approved policies (e.g., guidance documents, standard operating procedures, drug formularies) for the conduct of animal activities may be used for the administrative handling of amendments. Specific protocol changes may be handled administratively in consultation with an IACUC authorized veterinarian. The veterinarian serves as a subject matter expert to verify that compliance with IACUC policy is appropriate for the animals affected by the proposed changes. The veterinarian may refer any request to the IACUC for review for any reason and must refer any request that does not meet the parameters of IACUC policies. These changes include:

- Anesthesia, analgesia, sedations or experimental substances.
  - *Anesthesia, analgesia, sedations* – Reference material for anesthesia, analgesia, or sedation dosages may include textbooks (such as Harkness and Wagner’s Biology and Medicine of Rabbits and Rodents; Flecknell’s Laboratory Animal Anesthesia; Plumb’s Veterinary Drug Handbook; Hawk and Leary’s Formulary for Laboratory Animals; Lumb and Jones Veterinary Anesthesia and Analgesia; Quesenberry and Carpenter’s Ferrets, Rabbits and Rodents Clinical Medicine and Surgery; Carpenter’s Exotic Animal Formulary; Fish, Brown, Danneman and Karas Anesthesia and Analgesia of Laboratory Animals); journal publications (peer reviewed from PubMed and CAB database), personal communications with a veterinary anesthesiologist; or IACUC Formularies.

- *Experimental substances* – Addition of or change in dosage of an experimental drug in the same class as one previously approved.

- Euthanasia to any method approved in the AVMA Guidelines for the Euthanasia of Animals.

- Change of sex in the animal to be used.

- Addition of another strain or breed of the same species.

- Duration, frequency, or type (e.g., blood collection site or volumes, route of administration, volumes, and dosages), or number of procedures contingent upon them not exceeding IACUC guidelines. This cannot be used to add new procedures, but instead to make specific modifications to approved procedures. These approvals are communicated to the IACUC.

Administrative Amendments

Specific protocol changes may be handled administratively without additional consultation or notification. Examples include:

- Increase in numbers <30% of non-USDA regulated species.

- Addition or removal of personnel (other than the PI) after verifying training requirements are complete.

- Change in procedure locations that are part of the animal program overseen by the IACUC.

- Correction of grammar or typographical errors.

- Contact information.
ANNUAL REVIEW PROCESS
Investigators are reminded prior to annual review date to renew, amend or close the protocol. The annual review includes providing a brief summary of the progress made over the past year towards the research goals, documenting any unanticipated adverse events or animal deaths prior to experimental endpoints, request to continue currently approved scientific reasons for single housing of social species, and requests to continue currently approved scientific justifications for not providing environmental enrichment. Members are notified each month of annual reviews that have been performed by the AV, AV designee, or OAW veterinarian since the last full committee meeting and have the opportunity to call for FCR.