Protocol or Amendment Submission and Review

I. Applications or Amendments to Applications for Live Animal Use in Research, Teaching, Exhibition or Training at Georgia Southern University will be submitted in writing or electronically to the IACUC office through ORSSP, P.O. Box 8005, Veazey Hall or IACUC@georgiasouthern.edu using the most current form available.

   a. Current applications are available on the IACUC website.

II. Applications will be reviewed for completeness by the ORSSP IACUC Administrator prior to distribution to the IACUC committee.

   a. At this point the Primary Investigator (PI) may be asked for additional information to complete the Application.

III. Application titles and tracking numbers are distributed to the full IACUC committee via e-mail for review.

   a. A copy of the entire protocol for review will be posted on Web CT under protocol number. Alternately, a copy of the protocol may be provided by email to any member upon request.

   b. All members of the IACUC have access to ALL Applications submitted for IACUC review.

IV. IACUC members have 3 working days after distribution of an Application to request a committee review to be conducted at the next convened IACUC meeting, or to approve the use of a Designated Reviewer (DR).

   a. Committee members may respond via email.

      i. Although not required, committee members are encouraged to list any concerns they may have regarding the proposed animal work listed in the Application or Amendment request.

      b. Committee members may only request a full committee review or approve the use of DR. An Application may not be disapproved outside of a convened committee meeting.

      c. A lack of a response from a committee member within the 3 working days is considered to be a tacit approval of the DR process by that committee member.

      d. Request for a full committee review by any one member of the IACUC will automatically require review by a convened quorum of the committee.

V. Designated review procedure

   a. On the 4th working day, following distribution of the Application, the IACUC chairperson will be notified of the status of the Application.

   b. And, if no committee member has requested full committee review, the IACUC Chair will assign 2 designated reviewers.

      i. Appointments will be based upon specialty and workload.

      ii. Volunteer reviewers will be given priority.

      iii. All protocols will also be sent to the Attending Veterinarian and Community Member.
c. Any voting member(s) of the IACUC may serve as Designated Reviewer(s) provided there is no conflict of interest associated with the Application presented for review.

d. Actions available to the Designated Reviewer(s) in relation to the Application being reviewed are:
   i. Approve the Applications as written
      1. A DR is considered to represent the entire IACUC. Approvals granted by the DR are considered equal to those granted by a committee vote.
   ii. Request additional information from the submitting PI to clarify any questions or concerns, and then approve the Application.
      1. Changes or clarifications requested by any DR will be considered to represent the entire IACUC.
      2. If information received from a PI is inadequate, the Application may still be referred for review by a convened quorum of the committee.
   iii. Refer to the Application for review by a convened quorum of the committee
      1. If referred to a committee meeting, it is at the discretion of the IACUC chairperson to either convene a meeting or to wait until the next regularly scheduled IACUC meeting.

e. Reviewer Resources
   i. Comments concerning a protocol up for review will be accepted from any member of the IACUC for protocols submitted for designated review and forwarded to the review team. The DR team may accept or reject the comments.
   ii. DR team members will review the protocol, confer to reach consensus and approve the protocol, request clarification or modifications from the PI through the IACUC office or refer the protocol to the full committee for action. Any comment sent to the PI from a DR through the IACUC office will be relayed as a comment from the entire IACUC.
   iii. All DR comments and requests for information will be forwarded from the IACUC email account to the PI without identification of the individual reviewer.
   iv. Review resource material will be maintained with IACUC training materials and made available to reviewers in hard copy or electronic format.

f. A Designated Reviewer may not disapprove an Application.
   (Unacceptable applications must be referred to full committee.)

g. Designated Reviewers are encouraged to confer with one another and/or seek expert advice (from within or outside of the IACUC) when reviewing Applications with procedures or information unfamiliar to the reviewer.

h. The DR has 5 working days to complete the initial application review process.
i. If the DR is unable to conduct an Application review in a timely manner, the IACUC Chair will assign the Application to another member of the IACUC to serve as a DR.

ii. The time restriction noted here assumes the PI is available to reply to questions or concerns raised by the DR.

iii. The DR should forward their decision regarding the Application to the IACUC office as soon as the review process is complete.

iv. The IACUC Administrator will forward reviewer comments to the PI, receive the reply and will provide the DR access to the revisions by email or on Web CT for evaluation.

v. Final approval will be sent to the PI via email (and/or letter) by the IACUC office.

i. The DR is asked to summarize, forward or cc copies of correspondence (e.g. e-mails, notes on phone conversations, etc.) conducted during Application review that illustrates review questions answered by experts other than the PI to the IACUC office for inclusion in the review file. All comments or correspondence with the PI should be made through the IACUC office.

VI. Upon request of any IACUC member during the initial review period, or upon recommendation of the Designated Reviewer(s), an Application will be reviewed and voted upon in a convened meeting of a quorum of the IACUC.

a. Actions available to the IACUC during an Application review during a convened meeting in relation to the Applications are:

   i. Approve the Application as written.
   
   ii. Approve the Application providing the PI is willing to make specific changes to the protocol as requested by the IACUC (i.e. Approval with Modification).

   iii. Disapprove the protocol.

b. All actions taken by the Committee in relation to Applications will be approved by a majority vote of a convened quorum of the committee.

c. Any dissenting votes (i.e. Minority Opinions) will be appropriately noted in the meeting minutes.

d. The PI has 30 working days to reply to questions or concerns raised by the IACUC or the DR.

   i. If no reply has been received within 15 days, the PI will be notified by the IACUC office and reminded of concerns.

   ii. If no reply is received in 30 working days, the committee members will vote to disapprove the protocol due to lack of response.

VII. There are no specific laws, regulations, or guidelines dictating which Applications may be reviewed by a Designated Reviewer or those which must reviewed by the full committee; however, Committee review allows for a wider range of input. Therefore, Committee members may consider the following criteria to identify protocols that could potentially benefit from full Committee review. Committee members are not obligated to send any specific protocol or protocol type to full committee.
a. Use of species covered under the Animal Welfare Act (AWA).

b. Studies of Federally protected animals (i.e. endangered species).

c. Use of non-human primates.
   i. GSU does not currently house or own any non-human primates.

d. Applications involving painful procedures (i.e. Category D and E).
   Specific examples include:
   i. Survival surgery
   ii. Death as an endpoint studies
   iii. Food deprivation studies

e. Applications containing new and/or complicated procedures

f. Applications submitted by PIs who have previously had problems with the compliance.

VIII. A quorum of GSU IACUC members present at a convened meeting may decide by unanimous vote to use Designated Review subsequent to Full Committee Review when modification is needed to secure approval.
   a. Any member of the IACUC may, at any time, request to see the revised protocol and/or request full committee review of modifications.

IX. The GSU IACUC has granted the IACUC Administrator the authority to conduct the Administrative Review process to speed the approval of commonly submitted changed or additions to Protocols. This authority has been granted for a few specifically designated areas which include:
   a. Addition of new personnel to Protocols upon completion of appropriate training.
   b. Option to request review from one IACUC member for approval of strictly observational protocols.
   c. Option to request review from one IACUC member for approval of Protocols from reciprocal IACUC.
      i. E.g., A researcher at Georgia Southern University might collaborate with a researcher (e.g., to obtain animal tissue) at another institution who houses the animals under his or her own IACUC approval.

X. The IACUC does not conduct after-the-fact reviews.
   a. Animal Use conducted in the absence of an approved IACUC protocol is in violation the GSU Animal Use Policy and may require disciplinary action by either the IACUC or by Georgia Southern University.
      i. Any actions taken by the IACUC in regard to inappropriate use of animals will be conducted in accordance with IACUC SOP# 3 IACUC Response to Animal Care and Use Concerns and IACUC SOP# 2 Sanctions of Animal Users for Issues of Non-Compliance and University policy.