1. **Purpose:** The intent of this policy is to provide guidance and procedures governing protocol and programmatic review of projects involving work with live animals with collaborating institutions and agencies.

2. **Policy:**
   2.1. If all or part of work with live animals is being done at Georgia Southern University (GSU), or at field locations by a GSU person (faculty, staff or student), a complete IACUC protocol must be submitted and approved by the GSU IACUC before work with animals can start.
   2.2. If work with live animals is being done externally by collaborators through a sub-award or a sub-contract, and GSU is the awardee institution, the terms and conditions of the grant flow through to the sub-awardee. GSU is held accountable for ensuring that the work being conducted on the project meets all applicable regulations and guidelines. Therefore such projects are subject to review and approval by the GSU IACUC. The extent of the review will depend upon the accreditation and the Assurance status of the institution/agency. Minimum documentation required by GSU will be the animal care and use methodology approved by the collaborating institution, collaborating institution approval letter and a memo of understanding signed by the Signatory Official for both institutions.
   2.3. If work with live animals is being done wholly at a collaborating site by GSU person (faculty, staff or student), and GSU is the awardee institution, the terms and conditions of the grant flow through to the sub-awardee. (GSU is still considered the awardee for self-funded or internally funded work.)
      2.3.1. If the collaborating location is PHS assured, the GSU researcher may:
         2.3.1.1. apply to the GSU IACUC for approval through the GSU application process and make full application to the collaborating site IACUC or
         2.3.1.2. request a reciprocal approval from the GSU IACUC by providing a copy of the collaborating institutions approval letter, approved animal care and use protocol and documentation of IACUC training/health clearance. Reciprocal request should include the collaborating site’s AWA number and expiration date and full contact information for the collaborating site’s IACUC. Upon GSU approval and at the GSU IACUC’s discretion, a memo of understanding (MOU) will be executed between the two assured facilities to define institutional roles. No animal work may be done prior to receipt of the fully executed MOU.
         2.3.1.3. If the subawardee institution has a current Assurance with OLAW, the GSU IACUC will decide on a case-by-case basis whether it will perform a full review of the protocol or will choose to rely on the other institution’s IACUC to oversee the animal care and use on the protocol.
      2.3.2. If the collaborating location does not maintain PHS assurance, the GSU researcher must make full application to the GSU IACUC. Prior to approval, the collaborating location must acquire a AWA or a negotiated memo of understanding must be established with GSU to provide coverage under the GSU assurance. The decision to accept a collaborating site under the GSU assurance shall be at the sole discretion of the GSU IACUC and Institutional Official.
         2.3.2.1. If the subawardee institution does not have a current Assurance with OLAW, the GSU IACUC will make a decision as to whether or not work at such an institution can be allowed and if so, define the terms and conditions under which the work can be performed.

3. **Procedure for Reciprocal:**

Attachment:  Primary performance site IACUC approval letter,
      Copy of approved IACUC methodology for primary performance site
3.1. The GSU PI on the project submits an IACUC protocol to the GSU IACUC with the following information:

3.1.1. Compliance Cover page

3.1.2. A copy of the protocol approved by the participating institution with the research proposed in the grant/proposal (if applicable).

3.1.3. An approval letter from the participating institution’s IACUC with the PHS Animal Welfare Assurance (AWA) status and AAALAC Accreditation status or information and the dates of approval. The approval letter must recognize the GSU PI as a collaborator and the role played by the GSU PI in the overall project.

3.1.4. The protocol is reviewed by the Research Compliance Officer and the Chair of the IACUC or designee.

3.1.5. If accepted, IACUC contacts the PI and the participating institution to initiate an authorization agreement (see Appendix). If rejected, the PI will be notified of conditions of approval.

3.1.6. Once the Authorization agreement is signed by all parties, the protocol is administratively approved and the agreement is part of the record of the protocol and, if externally funded, the grant file.

3.1.7. The protocol is reported to the IACUC at an IACUC meeting. Any reports from the institution related to the protocol are shared with the IACUC.

3.1.8. All such agreements and their status are reported to the Institutional Officer as part of the IACUC semi-annual report.

3.1.9. The PI is responsible for submitting annual reviews and three-year renewals and reporting any modification to the participating agencies approval or any adverse events to the GSU IACUC as for any other protocol.

3.2. If additional conditions are attached to the MOU it is the PI’s responsibility to assure compliance and notify the GSU IACUC Administrator in the event of any deviation from the approved protocol or agreement.

4. Authority

Guide for the Care and Use of Laboratory Animals, 8th ed., Collaborations, Pg 15

"Inter-institutional collaboration has the potential to create ambiguities regarding responsibility for animal care and use. In cases of collaboration between institutions that involves animal use (beyond merely transporting animals), institutions should have a formal written understanding (e.g., contract, memorandum of understanding or inter-institutional agreement) between the institutions. The written agreement should address the responsibility for offsite animal care and use, animal ownership and IACUC review and oversight (AAALAC 2003). In addition, IACUCs from both participating institutions may choose to review protocols for the work being conducted. ” (National Research Council, 2010)

NOT-OD-01-017; NO REQUIREMENT FOR DUPLICATE REVIEW

"There are many circumstances that involve partnerships between collaborating institutions or relationships between institutional animal care programs. OLAW and APHIS agree that review of a research project or evaluation of a program or facility by more than one recognized IACUC is not a federal requirement.

It is imperative that institutions define their respective responsibilities. PHS Policy requires that all awardees and performance sites hold an approved Animal Welfare Assurance. OLAW negotiates Interinstitutional Agreement Assurances of Compliance when an awardee institution without an animal care and use program or IACUC will rely on the program of an Assured institution. Assured institutions also have the option to
amend their Assurance to cover nonassured performance sites, which effectively subjugates the performance site to the Assured institution and makes the Assured institution responsible for the performance site.

If both institutions have full PHS Assurances, they may exercise discretion in determining which IACUC reviews research protocols and under which institutional program the research will be performed. It is recommended that if an IACUC defers protocol review to another IACUC, then documentation of the review should be maintained by both committees. Similarly, an IACUC would want to know about any significant questions or issues raised during a semiannual program inspection by another IACUC of a facility housing a research activity for which that IACUC bears some responsibility or exposure.” (National Institutes of Health, 2001/2010)

Bibliography


National Institutes of Health, NIH. (2001, Mod. 2010). Office of extramural research guidance regarding administrative IACUC issues and efforts to reduce regulatory burden. NOT-OD-01-017, 2.
Institutional Animal Care and Use Committee (IACUC) Performance Site Authorization Agreement

Primary Performance Site Institution or Organization Providing IACUC Review

IACUC Animal Welfare Assurance (AWA): __________________________

Name of Institution Relying on the Designated Primary Performance Site IACUC

Georgia Southern University        AWA #: A3902-01

The Officials signing below agree that Georgia Southern University may rely on the primary institution/organizations designated IACUC for review and continued oversight of the animal care, housing and use for the research described below: (check one)

(____) This agreement is limited to the following specific protocol(s):

Name of Research Project: ____________________________________ Agency Number: __________________
Name of Principal Investigator: _____________________________
Name(s) of GSU Co-investigators and personnel: ______________
Sponsor or Funding Agency: ____________________________ Award Number, if any: __________________
GSU Grant Number, if any: ______________________________

(____) This agreement covers (describe covered functions):

- The review performed by the primary institution/organizations designated IACUC will meet the animal subjects protection requirements of the Animal Welfare Act, the Guide (Guide for the Care and Use of Laboratory Animals) and GSU OLAW-approved AWA.
- The IACUC at the primary institution/organization will follow written procedures for reporting its findings and actions to appropriate officials at GSU including minutes of meetings that address any process relating to actions required in continuing review of the project.
- The performance site will provide the primary institution with notification of IACUC approvals, approved amendments, annual continuing review determinations, reports of unexpected events or incidents or significant issues related to animal welfare of the animals associated with GSU projects or personnel.
- The primary institution remains responsible for ensuring compliance with the IACUC’s determinations and with the terms of its OLAW-approved AWA.
- This document must be kept on file by both parties and provided to OLAW upon request.
- Other findings and actions of the designated IACUC that affect the animal work proposed in the protocol will be reported to GSU IACUC.

Effective Date: ________________ Expiration Date: ____________________

GSU IACUC Chair Approval:

Dr. William Irby, Associate Professor of Biology; Chair, GSU IACUC

Date: ______________

Primary Performance Site Signature Authority:

_____________________________ Date: ______________

Print Full Name: ___________________________ Institutional Title: ___________________________

GSU Signature Authority:

_____________________________ Date: ______________

Dr. Charles E. Patterson, Vice President for Research and Dean of Graduate Studies

Attachment: Primary performance site IACUC approval letter,
Copy of approved IACUC methodology for primary performance site