

# **Winston-Salem State University**

## **The Office of Sponsored Programs and Research**

### **Institutional Animal Care and Use Committee**

#### **(IACUC)**

## **A Guide to the IACUC Process**

We hope that this FAQ will orient you to basic policies and procedures for IRB review and approval. It is one of a number of resources available to researchers from the Winston-Salem State University IACUC. Although we serve a regulatory function, we take a collegial approach to consultation with researchers and their staff. Feel free to call on us as you navigate the process. Please contact the IACUC or the Compliance Officer at (336) 750-2982. We are happy to respond to your questions.

A more in-depth **Winston-Salem State University Assurance of Compliance with Public Health Service Policy on Humane Care and Use of Laboratory Animals** is available as a separate WORD document.

### **What is the IACUC?**

The Institutional Animal Care and Use Committee established to oversee and evaluate the institution's animal programs, procedures, and facilities to ensure that they are consistent with the recommendations in The Guide for the Use of Laboratory Animals, and in compliance with applicable federal, state, and local laws and regulations, such as the federal Animal Welfare Regulations (AWRS, CFR 1985), and the Public Health Service Policy on Human Care and Use of Laboratory Animals (PHS Policy, 1996).

### **What are the IACUC Responsibilities?**

- To review the Institution's Animal Program every six months
- To inspect animal facilities
- To evaluate programs and animal-activity areas
- Review, approve and require modifications or withhold approval of proposed research activities, testing or education involving animal subjects.

- To suspend activities involving animal subjects

## Who is on the IACUC?

The IACUC membership must consist of at least 5 members and includes:

- one veterinarian with training or experience in laboratory animal science and medicine, who has direct or delegated authority and responsibility for activities involving animals at the institution;
- one practicing scientist experienced in research with animals;
- one member whose primary concerns are in a nonscientific area (e.g., ethicist, lawyer, member of the clergy); and
  - one member who is not affiliated with the institution other than as a member of the IACUC.

## What is animal research?

"An animal care and use program ... comprises all activities conducted by and at an institution that have a direct impact on the well-being of animals, including animal and veterinary care, policies and procedures, personnel and program management and oversight, occupational health and safety, IACUC functions, and animal facility design and management." (Guide, [p. 11](#))

## What kinds of IACUC review are there?

- There are two levels of IRB Review (full board review, continuing review), determined by the nature of the protocol and the level of pain associated with the protocol.
- **The determination of level of review applicable to a particular study is made by the IACUC**
- Regardless of the kind of review, all applications use the same submission form.

## How do I apply?

- Submit a *Winston-Salem State University Animal Use Protocol Form*.
- Instructions accompany the application.

## What is the required ethics education?

- Animal Subject Protection Education is required of all faculty, staff and students who are engaged in the planning, conduct or analysis of research at Winston-Salem State University that involves animal subjects.
- [www.citiprogram.org](http://www.citiprogram.org)

## Where do I send the application?

The principal investigator (PI) develops a protocol, consulting with the Compliance Officer as needed. The PI should then forward a completed electronic version to the IACUC Chair and the Compliance Officer. The principal investigator submits a hard copy of the IACUC protocol to the appropriate department and college or school for approval and signatures. Next, the PI sends the hard copy of the completed IACUC protocol with signatures to the Compliance Officer in the Office of Sponsored Programs and Research. The Compliance Officer will then forward the IACUC protocol to the IACUC Committee for review.

## What happens after submission?

The IACUC oversees the specific use of animals by formally reviewing animal use protocols and granting approval prior to the work commencing. The 2 valid methods of protocol review are either full committee review (FCR) or designated member review (DMR). ([PHS Policy IV.C.2.](#))

FCR may only be conducted at a convened meeting with a quorum (simple majority) of members present. A majority vote of the quorum present is needed to approve, require modifications in (to secure approval), or withhold approval of a protocol. When substantive modifications are required in a protocol to secure approval, the resubmitted protocol must be reviewed using either FCR or DMR.

DMR may occur only after all IACUC members have been provided with a list of the protocols to be reviewed and have an opportunity to call for FCR. If FCR is not requested, at least one member of the IACUC qualified to conduct the review is designated by the Chair. DMR may result in approval, require modifications in (to secure approval), or request FCR. DMR may not result in disapproval.

OLAW formally recognized an alternative practice for protocol review subsequent to FCR in [NOT-OD-09-035](#) (*Guidance to IACUCs Regarding the Use of DMR for Animal Study Proposal Review Subsequent to FCR*). USDA concurs with this alternative practice.

IACUC approval of proposed animal activities or significant changes to previously approved animal activities is granted after FCR or DMR. Additionally, institutions may establish and IACUCs may approve policies (e.g., guidance documents, standard operating procedures, drug formularies) for the conduct of animal activities. These policies must be reviewed by the IACUC at appropriate intervals of no less than once every 3 years to ensure they are appropriate and accurate.

## Approval of research

- Research may proceed on receipt of written documentation of IRB approval.

## **All projects are subject to renewal, usually annually.**

### **Postapproval Monitoring**

Monitoring of animal care and use is required by the PHS Policy. The *Guide* (p. 33) describes methods for continuing review to include “continuing protocol review; laboratory inspections (conducted either during regular facilities inspections or separately); veterinary or IACUC observation of selected procedures; observation of animals by animal care, veterinary, and IACUC staff and members; and external regulatory inspections and assessments.”

Continuing protocol review may consist of an annual update. “Some institutions use the annual review as an opportunity for the investigator to submit proposed amendments for future procedures, to provide a description of any adverse or unanticipated events, and to provide updates on work progress.” (*Guide*, p. 34) The PHS Policy determines the maximum interval between IACUC review and approval as 3 years, i.e., a complete *de novo* review is required at least every 3 years. The review must encompass all of the criteria in the Policy at [IV.C.1.a.-g.](#) Animal work may not be administratively extended beyond the 3-year expiration date.

### **Suspension of Animal Activities**

The IACUC is empowered to suspend a project if it finds noncompliance with the PHS Policy, *Guide*, Assurance, or violations of the Animal Welfare Regulations. Suspension may occur only after review of the matter at a convened meeting of a quorum of the IACUC, and with the suspension vote of a majority of the quorum present. Further, the IACUC must consult with the IO regarding the reasons for the suspension. The IO is required to take appropriate corrective action and report the action and the circumstances surrounding the suspension to OLAW. Because an IACUC action to suspend a project is a serious matter, the action must be reported to OLAW promptly. Additional information can be found on the [Reporting Noncompliance](#) webpage.

## **What if I want to modify the study?**

- Once the project is submitted to the IACUC, you may not make changes to the study until the IACUC has completed the approval process for your original submission.
- Once your study is approved, you may submit modifications.
  - All protocol changes must be approved by the IACUC prior to implementation.
  - The review of the amendment request may be expedited or may require full board review.

## **Where do I send the application?**

- Please send a hard copy of the IACUC protocol packet to the Compliance Officer in the Office of Sponsored Programs and Research

## Where do I get more information?

- WSSU Office of Sponsored Programs web site is a good source of additional information, providing links to many ethics, research, and regulatory sites. .
- The **Winston-Salem State University Institutional Animal Care and Use Manual for Research Involving Animal Subjects** (Investigator's Manual), a WORD document is available.
- Office of Laboratory Animal Welfare website
  - <http://grants.nih.gov/grants/olaw/olaw.htm>
- We are happy to respond to your questions. Feel free to call or email us. Please contact the IACUC or the Compliance Officer at (336) 750-2982.