

Procedure for IACUC submissions and review.

Submissions to the IACUC from Principal Investigators include: New Protocols, Renewal Protocols, Amendments to protocols, or Annual Reports.

New protocols are submitted to the IACUC via the Office of Research Compliance on the IACUC protocol form (found at: <http://www.uncg.edu/rsh/orc/iacucform2.dot>). New protocols are first evaluated by the departmental IACUC reviewer and the IACUC veterinarian. Upon incorporation of the veterinarian's comments and approval by the department reviewer, the original copy (signed by PI and department reviewer) is forwarded to the UNCG Office of Research Compliance. New protocols may receive an initial evaluation by the full committee or be assigned to a designated reviewer. This decision is determined by the IACUC chair.

Amendments to currently approved protocols are submitted directly to the UNCG Office of Research Compliance (original copy signed by the PI). Nonsignificant changes to protocols (Table 1) are generally reviewed by the Compliance Officer, IACUC Chair, and IACUC Veterinarian and the IACUC Chair may make an administrative decision on the amendment. Such decisions will be reported to the full committee at the next convened meeting. Significant changes (Table 1) will be handled using the IACUC procedure outlined below. Highly significant changes (Table 1) to protocols can not be handled via an amendment and require submission of a new protocol.

Renewals. Federal regulations do not recognize renewals of approved protocols beyond the initial expiration date. Thus, an investigator who wishes to continue work on a protocol beyond its expiration must submit a new protocol.

Annual Reports. Annual reports are solicited by the UNCG Office of Research Compliance. Upon completion of the report, the signed original is returned directly to the Office of Research Compliance. Generally, annual reports are reviewed by the IACUC Chair and, in consultation with the Compliance Officer, may be approved and placed in the protocol file with a copy of the approval forwarded to the PI. Such actions will be reported to the full committee at the next convened meeting.

IACUC Procedure:

1. Once submissions are received, the UNCG Office of Research Compliance will forward copies to the IACUC Chair and Veterinarian for preliminary review. In consultation, the IACUC Chair, Veterinarian and Compliance Officer will determine if the submission requires significant revision or can be considered further. Once approved for further consideration and based on the type of submission (i.e., amendment involving non-significant change, amendment involving significant change, or new protocol), when appropriate the Chair will consult with the Veterinarian and Compliance Officer to either administratively approve the submission, recommend the submission for a designated member review, or recommend a full committee review. All administratively approved submissions will be reported to the full IACUC, and may be re-evaluated.

2. Protocols and amendments for designated review or full committee review will be distributed to all IACUC members by the UNCG Compliance Officer.
3. **Designated Member Review:** If no IACUC member objects within one week of receiving a submission recommended for a designated review, then the submission will be reviewed and a decision made by the designated reviewer appointed by the IACUC Chair. If any IACUC member feels that a submission recommended for designated review should be discussed by the whole IACUC, then the member must notify the IACUC chair or the UNCG Compliance Officer, and the protocol will receive full review.
4. **Full Review:** Full review of a protocol will be taken up at the next regularly scheduled meeting of the IACUC at which reviews are discussed. The action of the IACUC will be to “approve,” “disapprove,” or “request modifications in order to secure approval” of protocols or protocol amendments. The IACUC Chair will communicate the results of the review in writing to the submitting PI, and a copy will be sent to the UNCG Compliance Officer.

Table 1. Examples of non-significant, minor, and significant protocol changes.

Non-Significant (PI can institute these changes without approval, no amendment required)

If protocol requires terminal surgery/euthanasia:

Harvesting of additional tissues

Taking of additional measures

Longer duration (provided anesthesia is adequate)

Additional surgical manipulations during terminal procedures (provided that anesthesia is adequate)

Increase in number of animals by less than 5%

Significant (Amendment required)

Change or addition of funding agency

Change in personnel (other than PI)

Change in emergency contact person

Increase in number of animals by 5 – 25%

If protocol requires terminal surgery/euthanasia:

Alteration in anesthesia

Alteration in method of euthanasia

If protocol terminates in survival of animals:

Addition of minor surgery to an experiment that already involves anesthesia

Alteration of surgical approach

Alteration in choice of analgesics, anesthetics

Alteration in schedule

Additional sampling or minor surgeries provided that the additional procedures do not involve more distress than procedures already approved.

Highly Significant (Requires submission of new protocol)

Change in number of animals >25%

Change in experiment or project goal

Major change in species (e.g. mouse to lizard [change of order])

Change in procedure (non-surgical)

Change in surgical procedure