

## IACUC PROCEDURE STATEMENT

**Policy/Procedure:** Frequency of Protocol Review

**Policy/Procedure ID:** 15-1-001

**Effective:** January 26, 2015

### A. Background

In an effort to reduce regulatory burden, the Bowling Green State University (BGSU) Institutional Animal Care and Use Committee (IACUC) has chosen to apply the protocol review frequency required by the Animal Welfare Act only to approved projects that describe the use of USDA covered species. All other protocols (e.g., rats of the genus *Rattus*, mice of the genus *Mus*, etc.) will be held only to the PHS Policy requirements for protocol review frequency.

The USDA Animal Welfare Act Regulations require that, once approval for a protocol has been granted, the IACUC must review the protocol on an annual basis and the Principal Investigator reconsider alternatives at least once every three years (9 CFR 2.31). In order to approve a protocol “not less than annually”, it is possible for the second renewal of a protocol to expire before the three year time period. To compensate for this, the IACUC allows for the Principal Investigator to complete a third renewal that is valid for the time period that equals the gap between the end of the second annual renewal and the end of the three year time period. A de novo review is required no less than once every three years.

PHS Policy states that the maximum interval between IACUC review and approval is three years. A complete de novo review is required at least once every three years. The review must encompass all of the criteria in the Policy at IV.C.1.a.-g. To comply with these requirements the IACUC has chosen to require an informal progress report due approximately one year and two years after initial approval and a de novo review no less than once every three years.

### B. Procedures

#### Projects subject to the Animal Welfare Act Regulations:

1. The Principal Investigator (PI) receives 60, 30, 15, and 7 day upcoming expiration notices. The date listed in the notice is the expiration date of the project, rather than the due date for IACUC review.

2. The PI completes the “Annual renewal/Progress report” form and electronically submits it to the IACUC for review.
3. If approved before the protocol expiration date:
  - a. When the first or second annual renewal is approved, a new protocol expiration date, which is one year from the new approval date, is assigned.
  - b. When the final renewal is approved, a new protocol expiration date, which is three years from the initial expiration date, is assigned.
4. If not approved before the expiration date:
  - a. All research activity stops and animals are transferred to the University Animal Facilities holding protocol.
  - b. The PI can resubmit a revised “Annual renewal/Progress report” form for review in a timely manner.
  - c. When the first or second annual renewal is approved, a new protocol expiration date, which is one year from the new approval date, is assigned.
  - d. When the final renewal is approved, a new protocol expiration date, which is three years from the initial expiration date, is assigned.
5. The PI is notified electronically of all IACUC actions.

Projects subject only to PHS Policy:

1. The Principal Investigator (PI) receives 60, 30, 15, and 7 day upcoming expiration notices. The progress report must be submitted by the due date. If a progress report is not submitted by the due date, the IACUC will consider this notice of the PI’s intent to close the project.
2. The PI completes the “Annual renewal/Progress report” form and electronically submits it to the IACUC for review.
3. If there are no major concerns, such as animal welfare concerns, with the progress report:
  - a. The IACUC formally acknowledges the report.
  - b. There is no change in the originally set three year expiration date.
4. If there are major concerns, such as animal welfare concerns, with the progress report:
  - a. The IACUC asks that the PI address the concerns by a specific date.
  - b. There is no change in the originally set three year expiration date.
  - c. If major concerns go unaddressed the IACUC can suspend the project.
5. The PI is notified electronically of all IACUC actions.