

IACUC POLICY AND PROCEDURE STATEMENT

Policy/Procedure: Methods of Review

Policy/Procedure ID: 14-10-001

Effective: 10/15/14

Revised: 7/18/18

A. Background

Bowling Green State University (BGSU) has an Animal Welfare Assurance on file with the Office of Laboratory Animal Welfare. The Assurance states that the IACUC may use Full Committee Review (FCR), Designated Member Review (DMR) subsequent to FCR or DMR to review activities related to the care and use of live vertebrate animals used in research, research training, experimentation, biological testing, and related activities conducted at BGSU or at another institution as a consequence of the subgrant or subcontracting of a PHS-conducted or supported activity by BGSU.

The Assurance states that the IACUC always uses FCR when presented with proposed animal work that will involve invasive procedures, which include but are not limited to invading a body cavity, biopsy, amputation, or procedures that cause more than momentary pain and distress.

B. Procedures

1. Full Committee Review of new submissions:
 - FCR may only be conducted at a convened meeting with at least a quorum of the voting members present.
 - Prior to each convened meeting, the material under review is distributed electronically to all members.
 - At the convened meeting, the members discuss each protocol in depth after which a motion is made and a vote taken. A majority vote of the members present at the convened meeting is required to approve, require modifications in (to secure approval), or withhold approval.
2. Designated Member Review subsequent to Full Committee Review:
 - If no member at the convened meeting expresses a desire to have the subsequently modified protocol reviewed by FCR, DMR may be employed by unanimous decision.

If this occurs, then the IACUC Chair selects at least one member qualified to conduct the review to serve as the Designated Reviewer (DR).

- The DR(s) is/are responsible for reviewing the revised material submitted by the investigator and has/have the authority to approve, require additional modifications in (to secure approval), or refer back for FCR. DMR may not result in withholding approval.
- If more than one DR is selected, then each DR is provided with and reviews the same material as the other DR(s).
- The DRs must be unanimous in their decision to approve or require modifications in (to secure approval). If they are unable to unanimously agree on the outcome, then the protocol must be returned for FCR.
- The decisions resulting from DMR are final and are recorded in the IACUC meeting agendas/minutes.
- The approval date is the date that the designated member(s) approved the study.

3. Designated Member Review of new submissions:

- All voting IACUC members are emailed the material to be reviewed before DMR is implemented.
- If no voting member requests FCR of the material, then DMR may be employed. Members have three business days to respond to a request for DMR.
- If no member calls for FCR within the three business day period, the IACUC Chair selects at least one member qualified to conduct the review to serve as the Designated Reviewer (DR).
- The DR(s) is/are responsible for reviewing the material and has/have the authority to approve, require additional modifications in (to secure approval), or refer back for FCR. DMR may not result in withholding approval.
- If more than one DR is selected, then each DR is provided with and reviews the same material as the other DR(s).
- The DRs must be unanimous in their decision to approve or require modifications in (to secure approval). If they are unable to unanimously agree on the outcome, then the protocol must be reviewed using FCR at a convened meeting with at least a quorum of voting members present.
- The decisions resulting from DMR are final and are recorded in the IACUC meeting agendas/minutes.
- The approval date is the date that the designated member(s) approved the study.

This written policy is reviewed at least once a year and whenever new members are appointed to the committee.