

IACUC POLICIES, PROCEDURES, and GUIDELINES

Coordination of Review of Research Projects Requiring IACUC and IBC Review

OBJECTIVE

To describe procedures for coordination between the Institutional Animal Care and Use Committee (IACUC)/Office of Research Integrity (ORI) and the Institutional Biosafety Committee (IBC) on projects involving the review of recombinant DNA and biohazardous research conducted at or sponsored by the institution for compliance with the NIH Guidelines as specified in Section III, Experiments Covered by the NIH and other appropriate guidelines and approving those research projects that are found to conform to the guidelines.

GENERAL DESCRIPTION

Both the IBC and the IACUC are committed to ensuring the protection of the research staff, the animal husbandry staff, veterinarians and others involved in research or who may have contact with or exposure to biohazardous agents. They have enacted a number of coordination activities in significant areas including: joint committee membership; protocol review; training for IBC/IACUC personnel; complaints and alleged noncompliance; quality assurance/improvement findings; and joint policy/procedures.

RESPONSIBILITY

Execution of SOP: Institutional Biosafety Committee (IBC) Members, Biological Safety Officer (BSO) or designee, Biological Safety Department staff, IACUC Members, ORI Staff, DLAR Veterinary Staff, and Principal Investigator (PI)/Study Personnel.

PROCEDURES

Joint Committee Membership

1. The Director of the University of Kentucky Environmental Health and Safety Division (EHS) serves as an alternate voting member of the IACUC. The EHS Director serves as the primary liaison for ensuring coordination between the IBC and the IACUC with respect to IACUC protocol review.
2. The ORI Director serves as an ex officio non-voting member of the IACUC and is an ex officio member of the Committee on Safety and Environmental Health, of which the IBC is a subcommittee.
3. Two members of the IACUC serve on the IBC. One member is a veterinarian; the other is a member with scientific and animal expertise.

Protocol Review

1. Research which falls under the purview of the IBC is initially processed as follows:
 - a. The EHS Director, in the normal course of IACUC protocol review, identifies research that falls under the purview of the IBC. IACUC application material is provided to IBC staff for processing follow-up by EHS Director
 - b. Additional EHS staff have access to and review IACUC protocol application material for all environmental health and safety issues. Those pertaining to the IBC are forwarded to the IBC staff for processing follow-up by EHS staff.
 - c. If ORI staff receives an IACUC application, which in their judgment may require IBC approval, ORI staff contact the BSO, IBC staff, or EH&S staff for assistance in determining whether IBC review is required.
 - d. The PI recognizes that his/her research requires IBC review and submits a separate application to the IBC.
2. The EHS Director or staff notifies ORI through the online IACUC protocol review process that IBC approval will be required for the project.
3. If the EHS Director or staff determines that the protocol does not need prior IBC approval, the IACUC protocol application proceeds with standard IACUC protocol review.
4. If the EHS Director or staff determines that the protocol requires prior IBC approval, the protocol proceeds through the IACUC review process but approval is withheld until IBC has completed its review and has approved the project.
5. The EHS Director in the role of IACUC member and/or an EH&S designate attend IACUC meetings to provide input during the protocol review of IBC issues, concerns or actions.
6. The PI is referred by Biosafety staff for IBC registration for either a modification to an existing IBC registration or a new full IBC registration. Attachment V (for vertebrate) of the IBC registration documents are completed if animals are used with potential biohazards.
7. The IBC meeting is generally held the week before the IACUC meeting.

8. After all conditions for IBC approval have been met, an electronic copy of the IBC approval letter and approved IBC registration documents (containing Attachment V) are sent to the Principal Investigator and copied to the ORI staff, EHS staff, and committee members who serve on both the IACUC and IBC. The Attachment V will be attached to the IACUC electronic protocol records by ORI staff for use by the IACUC reviewers.
9. One week before the IACUC meeting, ORI staff will send the IACUC agenda containing the Principal Investigator's names to the Biological Safety Department as notification of the research to be reviewed at the upcoming IACUC meeting.
10. Any problems or issues with the above procedures should be reported to the EHS Director from EHS personnel and to the ORI Associate Director (Secretary for the IACUC) from ORI personnel. The EHS Director and ORI Associate Director will resolve problems to ensure effective communication.

Approved May 12, 2010 by Institutional Biosafety Committee

[Signature on file in the Office of Research Integrity]

Douglas Harrison, PhD, co-chair of IBC

[Signature on file in the Office of Research Integrity]

Thomas Chambers, PhD, co-chair of IBC

[Signature on file in the Office of Research Integrity]

Marcia Finucane, MS, Biological Safety Officer

Approved May 19, 2010 by the Institutional Animal Care and Use Committee

[Signature on file in the Office of Research Integrity]

Sidney W. Whiteheart, PhD, chair of the IACUC

Approved and Adopted by the
Institutional Animal Care and Use Committee
May 19, 2010