IACUC policy for review of protocols with biohazardous materials

The intent of this policy is to define the requirements and process for the review and approval of protocols that propose the use of biohazardous materials with animals.

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1. Policy
   a. All animal protocols involving the use of biohazardous materials (regulated animal and plant pathogens, biological toxins, and recombinant DNA molecules), are subject to additional review by the Institutional Biosafety Committee (IBC).
   b. The IBC must approve the Memorandum of Understanding and Agreement (MUA) describing the use of a Biohazardous agent in a lab setting, before it can be approved for use with animals on an IACUC protocol. Therefore IACUC approval of an animal protocol involving the use of Biohazardous agents is contingent upon IBC approval of the MUA describing the use of the agent.
   c. The AUHSP (Animal User Health and Safety Program) Working Group is responsible for performing occupational health and safety reviews of IACUC protocols submitted in eSirius and MUAs or amendments submitted to the IBC, and making recommendations to the IACUC and IBC on requirements related to both compliance committees.

2. Procedures
   a. Submitting an IACUC protocol with biohazardous or recombinant DNA materials:
      • When the research proposed in the IACUC protocol by the PI, involves the use of biohazardous and recombinant DNA materials, the PI must ensure that there is an active, approved MUA on file with the IBC describing the use of the material in a lab or setting. More information about the IBC, including meeting schedules and review timelines, is at [www.ibc.cornell.edu](http://www.ibc.cornell.edu).
      • If the PI does not have an MUA with the IBC, one must be initiated in order for the protocol to be considered by the IACUC.
      • If there is an active, approved MUA on record, however the particular biohazardous agent or recombinant DNA material is not included on the MUA, the PI must submit an amendment to the MUA describing the use of the agent in the lab setting.
   b. Pre-review of protocols and MUAs: The IBC and IACUC administrators perform a pre-review of the protocol and MUA documents to determine concurrence between the two. Any inconsistencies or gaps are flagged to be for the AUHSP working group. The AUHSP
performs a review of the safety and health aspects of the protocol makes recommendations to the IACUC regarding:

- Requirements for a new MUA or an amendment to an existing MUA
- Changes to those portions of the protocol that relate to occupational health and safety issues, to improve clarity, provide more information or correct inaccuracies
- The need for SOPs describing the use of the biohazardous agent in the research
- Requirements for additional PPE, engineering controls, precautions in handling and disposal of infected materials and implementing other precautions or procedures designed to ensure safe conduct of research by the researchers and facility staff.

c. IACUC review:

- At its monthly meeting, the IACUC reviews the recommendations made by the AUHSP and the responses by the PI and determines if the conditions for approval of the protocol have been met. The protocol can be approved once the conditions for approval have been met by the PI.
- If a new MUA or an amendment to an MUA is recommended by the AUHSP, the protocol cannot be approved until the IBC approval has been completed.

3. Regulatory guidelines

- Excerpt from the Guide, “Institutions should have written policies governing experimentation with hazardous biologic, chemical, and physical agents. An oversight process (such as use of a safety committee) should be developed to involve persons who are knowledgeable in the evaluation of hazards and safety issues. Because the use of animals in such studies requires special considerations, the procedures and facilities to be used should undergo review for specific safety concerns. Formal safety programs should be established to assess the hazards, determine the safeguards needed for their control, ensure that the staff has the necessary training and skills, and ensure that the facilities are adequate for the safe conduct of the research. Technical support should be provided to monitor and ensure compliance with institutional safety policies.”
- BMBL 5th edition (http://www.cdc.gov/od/ohs/biosfty/bmbl5/bmbl5toc.htm) states, “the use of experimentally infected animals housed in indoor research facilities (e.g., vivaria), .... the maintenance of laboratory animals that may naturally harbor zoonotic infectious agents. In both instances, the institutional management must provide facilities, staff, and established practices that reasonably ensure appropriate levels of environmental quality, safety, security and care for laboratory animal.” The BMBL provides additional information on Animal BioSafety Levels and the need for review of projects involving biohazards, by an Institutional BioSafety Committee.
- More information on CDC guidelines and the BMBL as well as the Cornell IBC, is available at www.ibc.cornell.edu.

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