Institutional Biosafety Committee (IBC) response to amendments to Institutional Review Board protocols involving recombinant DNA (approved February 17, 2010)

**Background:** All human trials involving recombinant DNA (rDNA) require both IBC and IRB approval before initiation. The primary role of the IRB is to protect the human subjects. The primary roles of the IBC are to assess risks posed by the rDNA to other humans or the environment, and to define appropriate containment conditions based on those risks. The Biological Safety Officer (BSO) works with the Principal Investigator (PI), Infection Control, Investigational Pharmacy, and others to develop an Investigational Product Handling Protocol (IPHP) to implement the containment conditions prescribed by the IBC.

This document describes the IBC response to amendments to IRB protocols involving rDNA.

1. The PI will communicate to the BSO every amendment to every IRB protocol involving rDNA at the time the amendment is submitted to the IRB. The BSO will review the IRB amendment to determine whether it involves new rDNA material and whether the amendment has a negative impact on the containment conditions prescribed by the IBC to assure personnel safety or environmental containment. If the BSO determines that the IRB amendment has no new rDNA and no negative impact on containment conditions, then no further IBC review will be required. The BSO will communicate this determination to the PI.

2. If the IRB amendment involves new recombinant DNA material, the PI will be required to submit an IBC protocol amendment, and IBC approval will be required before the modification is carried out. This would be an unusual circumstance for a human trial.

3. If the IRB amendment has a negative impact on the containment conditions prescribed by the IBC, the BSO will work with the PI to modify the IPHP to address this impact. The BSO may involve Infection Control, Investigational Pharmacy, specific IBC members, or other experts in this process. If the BSO determines that the modified IPHP provides containment conditions equivalent to prescribed by the IBC, then the BSO will approve the modified IPHP and will convey this approval to the PI. If the BSO cannot make this determination, then the BSO will submit the IRB amendment and IPHP to the IBC for review. In this circumstance, IBC approval will be required before the IRB amendment can be carried out.

4. The BSO may consult with Infection Control, Investigational Pharmacy, specific IBC members, or other experts to make the determinations described in this document. When there is uncertainty about any determination, the BSO has discretion to refer the IRB amendment to the IBC for review. In this circumstance, IBC approval will be required before the IRB amendment can be carried out.