DukeHealth

Institutional Biosafety Committee

Institutional Biosafety Committee (IBC) review of amendments to Institutional Review Board (IRB) protocols involving nucleic acid materials

Background: All human trials involving the administration of nucleic acid materials 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 nucleic acid material to non-study participants or the environment, and to define appropriate containment conditions based on those risks. The Biological Safety Officer (BSO) works with the Principal Investigator (PI), the study team, Infection Control, Investigational Pharmacy, and others to develop an Investigational Product Handling Protocol (IPHP) to implement the containment conditions prescribed by the IBC.

Amendments to IRB protocols involving nucleic acid materials. Most amendments to these IRB protocols have no effect on the risks posed by the nucleic acid material, so do not require IBC review. **This document outlines the types of IRB amendments that do require IBC review, and the process for initiation of this review.** If the study team has uncertainty about the need for IBC review, they may consult with the BSO at biosafety@duke.edu.

Study Team Procedures:

1. The study team will route, via iRIS, any amendments to an IRB protocol to the IBC when the changes to the protocol involve changes to one or more of the following:
    a. Composition of the nucleic acid material(s)
    b. Route of administration of the nucleic acid material(s)
    c. Dose of the nucleic acid material(s)
    d. Major changes in procedures that would influence containment of nucleic acid material(s) affecting non-study participants and/or the environment
2. Additionally, the study team will submit an IBC amendment when there is a change in the Principal Investigator.

The following are examples of nucleic acid materials covered under the NIH Guidelines:

Category of nucleic acid material	Examples
Any mRNA	Pfizer or Moderna COVID-19 vaccines
Any viral vector	AAV vector, adenoviral vector (e.g., J&J or Astrazeneca COVID-19 vaccine)
Any genetically-modified cells	CAR-T cells (e.g., Kymriah, or other autologous cells)
Any genetically-modified organisms (virus, bacterium, or other agents)	Oncolytic viruses (Imlygic, others), certain live attenuated vaccines, challenge viruses or challenge bacteria
Any plasmid DNA	DNA vaccines

Approved by IBC on February 17, 2010. Last revised in May, 2024.