

IBC Policy

Defining the Responsibilities of an IBC Research Investigator

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I. NIH Guidelines:

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)* specifies the practices and handling of recombinant or synthetic nucleic acid molecules used in research experiments.

Institutional Biosafety Committee (IBC) review of research proposals includes the assessment of the training and expertise of personnel involved in recombinant or synthetic nucleic acid research (*Section IV-B-2-b*) as well as notifying the Principal Investigator of the results of the review. In accordance with the *NIH Guidelines Section IV-B-7*, the Principal Investigator is responsible for full compliance with the *NIH Guidelines* in the conduct of said research, responsible for ensuring that the reporting requirements are fulfilled, and will be held accountable for any reporting lapses.

It must be noted, that throughout *Section IV-B-7*, the term ***Principal Investigator*** is used, which conveys that a single investigator is responsible for compliance with the *NIH Guidelines* in the laboratory including the responsibility for all research staff handling or using materials involving recombinant or synthetic nucleic acid molecules.

In addition, the University Policy on the Rights, Roles and Responsibilities of Sponsored Research Investigators, (<http://www.cfo.pitt.edu/policies/policy/11/11-01-02.html>), makes clear that investigators retain the responsibility for the oversight of all research conducted for projects where they are the named Principal Investigator. Where one investigator is producing a recombinant agent, and another investigator is using that agent in separate research, both investigators may need their own IBC protocol.

II. IBC oversight is required for the following situations:

1. If an investigator plans to obtain a vector or an agent that contains recombinant or synthetic nucleic acid molecules from a “core” facility, collaborator(s), or a commercial vendor, then the “use or handling” of that vector or agent requires IBC approval for the investigator who takes possession and is handling or using the materials in a research project.

2. If an investigator obtains or plans to obtain independent funding for research involving a vector or agent produced or obtained under another investigator or collaborator’s IBC protocol, then the investigator obtaining the

funding must have an IBC protocol under their name. If a funded investigator is a junior member of a research team, for example a Post-doctoral researcher, a signed IBC Mentor Agreement must be provided with the application submission, and the supervisory investigator must agree to assume all responsibilities under the *NIH Guidelines*. Reference Section III, Mentored Research below.

3. The only instance in which an individual is not required to have their own IBC protocol, is if the named investigator on the IBC protocol has a supervisory role over all the named individuals in a laboratory, and therefore assumes the responsibilities under the *NIH Guidelines*.

This situation is further defined by the following requirements:

- a) All personnel involved must be listed on the IBC protocol, including those who are identified as working for any collaborator-investigator(s) with other associated protocols, such as ARO.
- b) Co-Investigators or Collaborator-Investigators must understand that the Principal Investigator named on the IBC protocol has jurisdiction over all aspects of the study, including procedures conducted in the collaborating laboratory facilities.
- c) Any exposures, spills, or loss of containment of recombinant or synthetic nucleic acid containing materials or agents must be reported to the Principal Investigator named on the IBC protocol.
- d) The Principal Investigator named on the IBC protocol will be responsible for filing all Incident Reports related to the project, regardless of the person(s) involved. Co-Investigators or Collaborator-Investigators must aid the Principal Investigator named on the IBC protocol in filing an Incident Report, should an exposure occur to one of their direct reports.

III. Mentored Research:

1. The IBC has maintained the perspective that the researcher who identifies as the Principal Investigator on the IBC protocol has agreed to the responsibilities outlined in the *NIH Guidelines*.
2. The IBC has approved a form of Mentor Agreements, in which laboratory personnel such as a graduate student or post-doctoral researcher may present as the named Principal Investigator on an IBC protocol, but the Mentor agrees to the responsibilities outlined in the *NIH Guidelines*

3. In accordance with the current processes, the IBC continues to identify the named Principal Investigator on the research submission as the individual who takes the responsibilities outlined in the *NIH Guidelines*
4. If there is a valid Mentor Agreement form attached to the research submission, then the Mentor is recognized by the IBC as having the responsibilities outlined in the *NIH Guidelines*