Reason for Policy

To establish criteria permitting individuals within Indiana University and Indiana University-affiliated researchers to submit Institutional Biosafety Committee (IBC) protocols and thereby assume all responsibilities for the conduct of that research.

Scope

All personnel conducting research involving recombinant DNA (rDNA) or synthetic nucleic acid molecules, biohazardous materials, or research/teaching activities that present a biological safety risk should have access to, read, and adhere to this policy. This includes researchers on all Indiana University campuses and Indiana University-affiliated researchers at the Roudebush VA Medical Center.

Procedures

1. Responsibilities and requirements for Principal investigators (PI) on protocols:
a. The PI is responsible for registering their recombinant DNA (rDNA) or biohazardous work with the IBC.
b. The PI assures that all individuals involved in the registered research have all required training prior to participating in any research.
c. The PI will maintain complete, up to date and accessible records that are required by institutional and IBC policy and regulations.
d. It is the responsibility of the PI to ensure all research compliance with all applicable state and federal laws governing research involving rDNA or synthetic nucleic acid molecules and/or biohazardous materials.

2. Titles that may serve as PI on an IBC protocol:
   a. Professors with an official faculty position,
   b. Lecturers,
   c. Emeritus Professors,
   d. Various Clinical Professors
   e. Various Scholars/Scientists
   f. Additional titles if given PI status by the Office of the Vice Provost for Research for the purpose of obtaining external grant support.

3. Student Directed Research:
   a. The IBC recognizes that a primary mission of a Research 1 University is the training and education of researchers in the pre- and post-doctoral graduate positions. These individuals may design and execute research programs that require the use of rDNA or synthetic nucleic acid molecules and/or biohazardous materials. The research can be supported by fellowships and grants which target graduate student and post-doctoral fellows. The IBC further recognizes that individuals in the graduate and post-doctoral positions are competent to independently design, perform, and take some of the responsibilities in a proposed research project. However, the IBC does not believe that members of the graduate and post-doctoral community can assume full responsibility for a given research project. Furthermore, the IBC does not feel that it is appropriate for graduate and post-doctoral fellows to accept all consequences and sanctions resulting from the non-compliant use of rDNA or synthetic nucleic acid molecules and/or biohazardous materials. As such, members of the graduate and post-doctoral fellow communities must seek support of one of the above listed members of the Indiana University faculty to submit a protocol. In this situation, the faculty member will be assigned as the PI while the graduate student or post-doctoral fellow will be considered a co-investigator. All communication regarding the IBC protocol in question will include the PI and, in the case where a graduate student or post-doctoral fellow is listed as the alternate contact, the co-investigator with the aforementioned contact status. It is recommended that the PI should be the student’s thesis/dissertation advisor or direct supervisor. If the PI on a given IBC protocol is no longer affiliated with Indiana University, the co-investigator must identify another PI to take over said research in order to continue active research.
   i. All titles below can assume the co-investigator role:
      1. Graduate Students,
      2. Post-Doctoral Fellow,
      3. Visiting Scientist, or
      4. Research Associate

Sanctions
Violations of Indiana University policies, including the failure to register all abovementioned work with the IBC, will be dealt with in accordance with applicable university policies and procedures. This may include disciplinary actions up to and including termination from the University.

History

This policy was created in 2009 and updated in November 2017.