

University of Michigan Institutional Biosafety Committee Charge

A list of acronyms and explanation of terms is provided at the end of this document.

The Regental Policy on Recombinant DNA Research states:

The University of Michigan shall adhere to all applicable federal and state laws regarding the approval, conduct, and safety monitoring of recombinant DNA research. The vice president for research shall report to the Regents upon request or when it is deemed appropriate by the vice president. The vice president will report to the Regents on any initiation of research requiring containment above Biosafety Level 3 (BL3) (July 1992).

In accordance with the *NIH Guidelines for Research Involving Recombinant DNA Molecules*, the University of Michigan has established an Institutional Biosafety Committee (IBC). The IBC has jurisdiction over the University's Ann Arbor, Dearborn and Flint campuses, and may give approval to non-faculty members (e.g., non-UM entities performing work on campus) on a case-by-case basis.

The vice president for research is the executive officer who has authority over this compliance area including appointment authority. The IBC is provided with administrative support from the Office of the Vice President for Research (OVPR).

Composition of Committee

The IBC is comprised of "no fewer than five members so selected that they collectively have experience and expertise in recombinant DNA technology and the capability to assess the safety of recombinant DNA research and to identify any potential risk to public health or the environment" (Section IV-B-2-a-(1), *NIH Guidelines*). Members of the committee fulfill the areas of expertise specified by Section IV-B-2-a of the *NIH Guidelines* and are appointed by the vice president for research for renewable three-year terms.

Scope of Committee's Responsibility: Recombinant DNA and Select Agents Recombinant DNA

With regard to work with recombinant DNA, the IBC is responsible for functions as described in *NIH Guidelines* Section IV-B-2-b. These responsibilities include approval of recombinant DNA work through review of registration information submitted by the principal investigator. The review includes independent assessment of the biosafety containment level proposed for the work, and through coordination with the Biological Safety Officer, assessment of facilities, procedures, practices, and training and expertise of personnel involved in recombinant DNA research.

For human gene transfer experiments, the IBC performs reviews, grants approval, and provides oversight in accordance with *NIH Guidelines* Section IV-B-2-b-(1), Section I-E, Section III-C and Appendix M.

Select Agents

Approval to transfer or work with select agents at UM is granted through a process that involves review by the appropriate academic decision-makers, the IBC, OSEH, the Department of Public Safety (DPS), and Information Technology Central Services. Each of

these entities reviews an aspect of the investigator's plan to transfer or work with select agents. The role of the IBC in this process is review and approval of the plan for biological containment and safety in the use of select agents, regardless of whether there is recombinant DNA use in such work.

The OSEH Director and the Biological Safety Officer share institutional responsibilities to register, as appropriate, with the Centers for Disease Control (CDC) any select agents or other specifically designated agents, and to handle the transfer of such agents into and out of the University.

At the time of any request to transfer a select agent or to commence work with such an agent on campus, including agents which are designated as "select" after the work has commenced, the Biological Safety Officer will ensure application, registration and approval from the IBC and other designated institutional entities for such research.

The Biosafety Officer will provide the IBC with an annual report on select agents being used or stored at UM. Any such report will be held confidential to the extent required by state and federal statutes and regulations.

Acronyms and Explanations

NIH OBA or National Institutes of Health Office of Biotechnology Activities:

The office within NIH that monitors scientific progress in basic and clinical research involving recombinant DNA and human gene transfer and which develops and implements policies and procedures for the safe conduct of such research.

NIH RAC or Recombinant DNA Advisory Committee:

A technical committee within NIH OBA which acts in an advisory role to the NIH director, and whose goal is to consider the current state of knowledge and technology regarding recombinant DNA, including review of human gene transfer trials and an assessment of the ability of DNA recombinants to survive in nature and the potential for transfer of genetic material to other organisms. This committee is managed by and provided with analytical support from NIH OBA.

NIH Guidelines for Recombinant DNA Activities:

Document promulgated by NIH OBA specifying practices for constructing and handling: (i) recombinant deoxyribonucleic acid (DNA) molecules, and (ii) organisms and viruses containing recombinant DNA molecules. The *NIH Guidelines* are applicable to research at institutions receiving any support from NIH.

UM OVPR or University of Michigan Office of the Vice President for Research:

The vice president for research is the executive officer with authority over this compliance area including appointment authority. The office of the vice president for research provides administrative support to the IBC.

UM OSEH or University of Michigan Occupational Safety and Environmental Health:

The office to which the University's Biological Safety Officer (BSO) reports.

CDC or Centers for Disease Control and Prevention:

The federal agency requiring registration before any transfer or use of select agents can occur. The OSEH Director and the Biological Safety Officer are the UM institutional officials with the responsibility for registering Select Agents.

Recombinant DNA:

“In the context of the *NIH Guidelines*, recombinant DNA molecules are defined as either: (i) molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or (ii) molecules that result from the replication of those described in (i) above. Synthetic DNA segments which are likely to yield a potentially harmful polynucleotide or polypeptide (e.g., a toxin or a pharmacologically active agent) are considered as equivalent to their natural DNA counterpart. If the synthetic DNA segment is not expressed *in vivo* as a biologically active polynucleotide or polypeptide product, it is exempt from the *NIH Guidelines*. Genomic DNA of plants and bacteria that have acquired a transposable element, even if the latter was donated from a recombinant vector no longer present, are not subject to the *NIH Guidelines* unless the transposon itself contains recombinant DNA.” (From Section I-B of the *NIH Guidelines*)

Select agent:

Biologics and toxins listed by HHS or USDA. See the Appendix to the IBC Charge which lists the following: HHS non-overlap select agents and toxins; high consequence livestock pathogens and toxins/select agents (overlap agents); USDA high consequence livestock pathogens and toxins (non-overlap agents and toxins); and listed plant pathogens. Reference for list: 42 CFR 73, interim final rule; www.cdc.gov/od/sap.

Other Documents Pertaining to IBC Responsibilities and Functions:

- Appendix to IBC Charge: select agents list (reference: 42 CFR 73, interim final rule; www.cdc.gov/od/sap)
- NIH Guidelines for Research Involving Recombinant DNA Molecules
- UM Regental Policy on Recombinant DNA Research (July 1992)
- UM IBC Guidance Document on Registration of rDNA Work and Oversight of Select Agents
- UM IBC Standard Operating Procedures
- UM IBC Staff Manual
- UM OSEH – Guideline – “Infectious Biological Agents and Recombinant DNA”
 - http://www.umich.edu/~oseh/Infectious_Biological_Agts.pdf
- UM OSEH – Guideline – “Patriot Act”
 - <http://www.umich.edu/~oseh/patriot.pdf>