




Biosafety and the *NIH Guidelines*

This section will explore:

- Why the *NIH Guidelines* are important
- The definition of recombinant or synthetic nucleic acid research
- Content of the *NIH Guidelines*
- ✓ **What is an IBC and its function?**
- ✓ **How to submit a research proposal to the IBC for review**



Review: What is an Institutional Biosafety Committee (IBC)?

IBCs were established under the ***NIH Guidelines*** specifically for the review of research involving recombinant or synthetic nucleic acid molecules:

- Responsible for oversight at the *local* level
 - Transparency in research requires Open meetings
 - IBC Minutes are available to public upon request
- Minimum membership of an IBC is five (5), which includes appropriate collective expertise and at least two (2) non-affiliated members
- A Biological Safety Officer (BSO) member is required for IBCs that review large scale (greater than 10 Liters) or BSL-3 research



IBC Responsibilities

What are IBC required to review?

- All research involving recombinant or synthetic nucleic acid molecules for conformity with the *NIH Guidelines*
- Potential risk to environment and public health
 - Containment level and practices according to the *NIH Guidelines*
 - Adequacy of facilities, applicable SOPs, and investigator and laboratory staff training
 - Institutional and Investigator compliance (e.g. Adverse events, incident reporting, etc.)



How to register with the IBC

The University of Pittsburgh has an on-line IBC review system: **MyIBC**

- New, modifications, and continuing approvals of IBC research proposals are processed through the on-line IBC review system, **MyIBC**
- The **Biosafety - NIH Guidelines** training module is required in order to use the **MyIBC** web-portal
- Your HS Connect Username will be identified in the **MyIBC** on-line system 24-hours after successful completion of this module
- For additional information or a quick access link to the **MyIBC** system, visit the University of Pittsburgh IBC website at: www.ibc.pitt.edu

Resources

- IBC Office: staff are available for individual consultation or guidance for research proposals to be submitted for IBC review
 - ibo@pitt.edu or call: 412-383-1768
 - Website: www.ibc.pitt.edu
- Department of Environmental Health and Safety (EH&S): staff are available for consultation or advice on laboratory safety, including equipment or procedures
 - biosafe@ehs.pitt.edu or call: 412-624-9505

References

- The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (NIH Guidelines); April 2016
https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.html
- Educational Materials from NIH Office of Biotechnology Activities;
<https://osp.od.nih.gov/biotechnology/nih-guidelines-faqs/>
- Biosafety in Microbiological and Biomedical Laboratories, 5th Edition, HHS Publication No. (CDC) 21-1112, also available
<https://www.cdc.gov/biosafety/publications/bmbl5/bmbl.pdf>

References/links updated on September 29, 2016



End of Chapter 5