

What do the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines) mean to me?

A guide for Vanderbilt Graduate Students, Postdoctoral Fellows, and Laboratory Workers

The NIH Guidelines specifies practices for the construction and use of recombinant or synthetic nucleic acid molecules* and any organisms or viruses that contain recombinant or synthetic nucleic acid molecules. As an institution that accepts NIH funding, Vanderbilt has agreed to follow the practices described in the NIH Guidelines and so have the researchers that work here including your PI. Part of the NIH Guidelines detail the kind of training and information that lab workers should receive before they begin new experiments in the lab. This guide will serve as a summary of what is required under the NIH Guidelines as it affects a laboratory worker that uses recombinant or synthetic nucleic acid molecules.

- Laboratory activities that use recombinant or synthetic nucleic acid molecules must be registered with and approved by the Institutional Biosafety Committee (IBC). The IBC is charged with reviewing all proposed research that uses recombinant or synthetic nucleic acid molecules and live microorganisms. Be aware that the use of some biological agents and procedures requires approval by the IBC before the experiments can begin. Check with your PI when developing new experiments to make sure those new activities are covered by your PI's existing IBC approval.
- Prior to working with any new biological agent, you should be educated about any risks that the agent presents and what precautions you should take when working with the agent. This training should also include how to respond to a spill of the material, what steps to take if you are exposed to the material, and reporting requirements if there is a spill or exposure incident. If you are working with an infectious microorganism, you may be offered a vaccination against the agent or placed in a medical surveillance program.
- You must follow standard microbiological techniques, which are summarized on the back of this sheet, and any additional bio containment practices as applicable. Training in these techniques by your PI, or PI's designate, must occur before your begin working in the lab and training should be refreshed when new materials and techniques are added.
- All laboratory waste containing recombinant or synthetic nucleic acid molecules must be disposed of as biohazardous waste.

Related Documents and Useful Links

These related documents are available on the OCRS website (vumc.org/safety):

- [Using Sharps Safely in Laboratory Research Applications](#)
- [IBC Best Practices for Research Laboratories: Responding to Personnel Exposures and Spills Involving Biological Materials](#)
- [Biohazardous Waste Segregation, Collection and Disposal Guide](#)
- [High-Risk Biological Agents: Safeguarding Against Accidental Exposure](#)

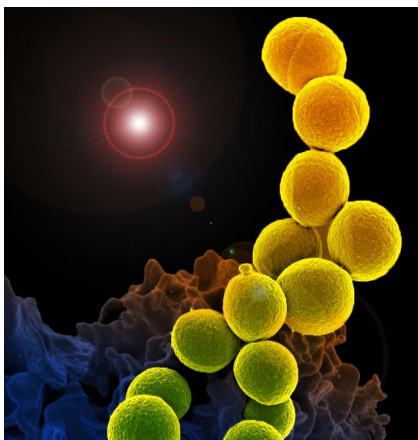
These websites provide information on training resources, applicable standards, and agent-specific information:

OCRS Training: [Lab-related hazards training grid](#)

NIH Guidelines: [Page with latest guidelines and interpretations](#)

CDC Lab/Animal Biosafety (BMBL): [Link to latest full document](#)

Pathogen-specific information: [Health Canada Pathogen Safety Data Sheets](#)



*What materials are considered recombinant or synthetic nucleic acid molecules?

Under the NIH Guidelines, recombinant and synthetic nucleic acid molecules are defined as molecules that are (1) constructed outside living cells by joining natural nucleic acid segments that can replicate in a living cell, i.e. recombinant nucleic acids (2) nucleic acid molecules that are chemically synthesized and can base pair with naturally occurring nucleic acid molecules i.e. synthetic nucleic acids or (3) molecules that result from the replication of those described in (1) above. Common examples include: bacterial expression plasmids, mammalian expression plasmids, viral vectors and the inserted genes they carry, transgenic animals and genetically modified cells.

“Standard Microbiological Practices”

Standard microbiological practices (SMPs) are generally defined as the basic minimum “hygiene” practices that apply to all labs that manipulate microbiological agents or any biological material/samples that may contain these agents. SMPs serve to minimize the spread of contamination generated through lab processes and to protect both personnel and the environment. Below is a summary of these practices. Please contact OCRS Biosafety at 615-322-2057 for further guidance as needed.



1. Wear fluid-resistant gloves when handling biological materials. Lab coats are recommended to reduce the possibility of contaminating your street clothes which could contribute to infection risk. Safety glasses are recommended as a minimum means of eye protection. It is not uncommon for liquids and debris to become “airborne” in lab settings, especially where large quantities of sample materials are present and/or vacuum systems or pressurized air or water may be used. Splash goggles must be worn for procedures that are likely to create splashes or sprays, unless the wearing of such equipment will create a more significant safety hazard.
2. Do not mouth pipette; use mechanical pipetting devices if you must pipette.
3. Perform procedures carefully. Minimize the creation of splashes and aerosols whenever possible.
4. Consider restricting access to the lab while work with biological agents is underway. More than anything, this will help to control distractions that may contribute to accidents or breaks in lab procedures.
5. Wash your hands after handling biological materials, after removing gloves, and before leaving the laboratory.
6. Do not eat, drink, smoke, handle contact lenses, or apply cosmetics in the lab. Additionally, do not store food for human use in the lab areas. These actions are intended to minimize the potential for contact exposure and accidental ingestion of pathogenic contaminants that may be present in the agents manipulated in the lab.
7. Clean and disinfect work surfaces daily when they are in use for manipulation of biologically-viable materials including those containing recombinant or synthetic nucleic acid molecules, and regardless of the infectious disease risk associated with the materials.
8. Wastes from biological cultures needs to be managed as biohazardous waste. This requires that wastes be collected in a leak-proof container that is labeled with the biohazard symbol and has a lid. (The lid needs to be closed when the container is not actively in use.) The container needs to be lined with a biohazard bag. More information on biohazardous waste disposal can be found in the OCRS Biosafety document entitled “Biohazardous Waste Segregation, Collection and Disposal”, or contact OCRS Biosafety at 2-2057 for specific guidance.
9. Sharps, such as needles, razor blades and broken glass, must be handled and disposed of according to Vanderbilt’s “Using Sharps Safely in Laboratory Research Applications” document. In brief, sharps must be disposed of in hard-walled containers designed for the purpose. Use of sharps should be eliminated where possible and the use of safer needle devices is advised when feasible. Procedures with sharps should be carried out in a manner that minimizes any potential for the non-dominant hand to be in contact with the sharp edge.
10. Keep the lab clean and free of excess clutter. Spills of biological material should not be left on the bench or lab floor but attended to as quickly as possible to minimize exposure and cross-contamination risk. Periodic general cleaning of the common lab surfaces (i.e., keyboards, phones, etc.) can also minimize the spread of contamination.
11. Report spills and exposure incidents to your supervisor or the Vanderbilt Biosafety Officer as soon as possible. Follow all incident response practices as outlined in “IBC Best Practices for Research Laboratories: Responding to Personnel Exposures and Spills Involving Biological Materials”.