

NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (*NIH Guidelines*): What You Should Know

A Guide for Graduate Students, Postdoctoral Fellows, and Laboratory Staff

The *NIH Guidelines* specifies practices for the construction and use of recombinant DNA molecules* and any organisms or viruses that contain recombinant DNA. As an institution that receives NIH funding, Vanderbilt University has agreed to follow the practices described in the *NIH Guidelines* and so have the Vanderbilt researchers including Principal Investigators (PIs). Part of the *NIH Guidelines* detail the kind of training and information that lab members 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 member 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 Vanderbilt University 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 (including those that are synthetically-derived) and specific 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. If they are not, a biomaterials registration amendment and IBC approval will be necessary.
- 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. Visit the Biosafety Program section of the [VU EHS training webpage](#) for more information and use the [biosafety training orientation checklist](#) to document your training. 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 page 2, and any additional bio containment practices as applicable. Training in these techniques by your PI, or PI's designate, must occur before you begin working in the lab and training should be refreshed when new materials and techniques are added.
- All laboratory waste containing recombinant DNA must be disposed of as biohazardous waste. Transgenic animals and their tissues (regardless of species) must not be discarded in the trash or disposed of via the sewer.

Related Documents and Useful Links

These related documents are available on the VU EHS Biosafety webpage

(<https://www.vanderbilt.edu/ehs/biological-safety/>):

- Institutional Registration & Review of Recombinant or Synthetic Nucleic Acid Molecule Use
- 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

Applicable standards and agent-specific information:

- [NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, 2019](#)
- [CDC/NIH Biosafety in Microbiological and Biomedical Laboratories, 6th edition](#)
- [WHO Laboratory Biosafety Manual, 4th edition](#)



***Under the *NIH Guidelines*, recombinant and synthetic nucleic acid molecules (RDNA) are defined as:**

1. molecules that are (a) constructed by joining nucleic acid molecules, and (b) that can replicate in a living cell, i.e., recombinant nucleic acids;
2. nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but 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 or 2 above.

Examples: bacterial or mammalian expression plasmids, viral vectors, and insert genes they carry, synthetically-derived agents, 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 VU EHS Biosafety at (615) 343-8918 or VUBiosafety@vanderbilt.edu 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 consumption in the lab areas. Restrain long hair so that it cannot contact hands, lab reagents or equipment. 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 VU EHS Biosafety document entitled “Biohazardous Waste Segregation, Collection and Disposal”, or contact VU EHS Biosafety at (615) 343-8918 or VUBiosafety@vanderbilt.edu for specific guidance.
9. Biohazardous sharps (such as biologically contaminated needles, blades, Pasteur pipettes and slides) 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”.