

How to Assemble & Use a Biosafety Manual

Research teams working with biological materials should ensure that they have assembled a biosafety manual (or have a section dedicated to biosafety in their lab's general safety manual). **Not only does this help satisfy requirements of NIH & CDC standards for biological material use, but a biosafety manual can also help standardize onboarding training for new researchers and periodic in-lab safety practice reviews.**

As a tool to support training and emergency preparedness, the biosafety manual needs to be readily available and accessible to lab members in either hard copy or electronic format. Regardless of the format selected, **the manual needs to be integrated into routine lab support activities and discussions to serve its intended purpose.** The following summarizes 4 categories of items that should be included in a biosafety manual.

Core Institutional Biosafety Procedural Documents

These electronically linked institutional Biosafety Program documents include cornerstone standards of practice that all researchers using biological materials in research should follow.

1. [Biological Risk Assessment Resource](#)
2. [NIH RDNA Guidelines + Standard Microbiological Practices summary](#)
3. [Sharps Safety in the Lab](#)
4. [Biohazardous Waste Guide](#)
5. [Ready-to-use BBP Disinfectant Guide](#)
6. [Transporting Biomaterials on Campus Guide](#)
7. [Biomaterials Spill & Exposure Response Guide \(Vanderbilt IBC Policy\)](#)

Lab Activity/Equipment-Related Guides

Depending on the location of the lab and the scope of research activities, the following (or equivalent) should be included as applicable.

1. **Biohazardous waste preparation/disposal guide** that applies to the lab's physical location
 - a. Guidance for VU labs in [VUMC buildings](#)
 - b. Guidance for VU labs in [VU buildings](#)
2. **Equipment guides** as applicable
 - a. [Biosafety cabinet \(BSC\) operational guidance](#)
 - b. [Autoclave safety checklist](#)
 - c. Operational safety guides from manuals for centrifuges, cryostats, liquid handlers or any other lab device in use that has an inherent sharps hazard or can generate aerosols or sprays during routine operation or failure scenarios.

Biomaterial-specific Policies & Procedures

Depending on the category of biomaterials used and the scope of research activities, the following (or equivalent) should be included as applicable.

1. **Human-derived materials including unfixed cells and tissues**
 - a. [Human-derived materials/bloodborne pathogens in research \(Vanderbilt IBC policy\)](#)
 - b. [Bloodborne Pathogen Profile and Exposure Control Basics](#)
 - c. Human-derived materials safety procedures prepared for animal protocols
2. **Recombinant or synthetic nucleic acid molecules**
 - a. In vitro safety procedures prepared in consultation with institutional Biosafety Program representative as appropriate (i.e., elevated risk agent, large-scale, prototype equipment)
 - b. RDNA vector safety procedures prepared for animal protocols
3. **Acutely hazardous toxins of biological origin**

- a. [Biological toxins & venoms in research \(Vanderbilt IBC policy\)](#)
- b. Lab research-specific/toxin-specific safety plans (all components) as outlined in IBC policy

4. Macaque-derived materials

- a. [Macaque-derived materials in research \(Vanderbilt IBC policy\)](#)
- b. Activity profile and safety procedures prepared in consultation with institutional Biosafety Program representative
- c. Exposure response procedures provided by institutional Biosafety Program representative

5. Infectious agents (including human, animal or plant pathogens)

- a. Policies that should be included if reasonably anticipated to apply based on lab's mission:
 - i. [BSL-2 with enhanced practices \(Vanderbilt IBC policy\)](#)
 - ii. [Safeguarding against exposure to high-risk agents \(Vanderbilt IBC policy\)](#)
 - iii. [Temporary trainee researchers and infectious agent activities \(Vanderbilt IBC policy\)](#)
- b. Material transfer permits (i.e., USDA/APHIS, CDC) which outline specific containment practices for permitted materials/specimens
- c. Agent-specific hazard profiles (including routes of exposure, sign/symptoms of infection, etc.) that a researcher should understand before working with agents. In addition to agent-specific research articles, sources may include:
 - i. [Pathogen safety data sheets \(Health Canada\)](#)
 - ii. [Bad Bug Book \(FDA\)](#)
 - iii. [Veterinary Manual \(Merck\)](#)
- d. In vitro safety and response procedures prepared in consultation with institutional Biosafety Program representative as appropriate (i.e., core collaborations, large-scale, prototype equipment)
- e. BSL-2/ABSL-2 safety and response procedures prepared for in vivo activities

Institutional Biosafety Registration & Training Records

This recordkeeping section of the manual should include the following:

1. **IBC registration communications** – this should include all IBC-approved documents including amendments for the current registration cycle
2. **Roster and training records** – include a copy of [completed site-specific training checklists](#) along with a biosafety training completion history for all lab members who work with biomaterials NOTE: Any trainings that were completed in Oracle Learn will be recorded in the learner's transcript in that system. If a person completed a "Live" training through OCRS, then that person should have received an email record of their completion of that course from OCRS Biosafety or the trainer directly.
3. **Biosafety activity audit reports and corrective action records** – audits may be performed by institutional Biosafety Program representatives to support external agency requirements, IBC surveillance activities or as a follow-up to an exposure incident. Lab teams are encouraged to perform self-audits as well. These records can provide insight for self-audits and preparing lab-specific safety refresher sessions. (Remember: lab-specific trainings should also be documented with a roster and an outline of content reviewed.)
4. **Biosafety cabinet (BSC) certification reports** - BSCs need to be certified annually and under other circumstances, and the certification vendor should provide a report to lab management.

For further assistance regarding assembling and using a biosafety manual, please contact [Robin Trundy](#), Institutional Biosafety Officer (615-343-8918) or send an email to the [Biosafety Team](#).

Related References:

- [NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules \(2019\)](#), Appendix G
- [WHO Laboratory Biosafety Manual, 4th ed. \(2020\)](#), Section 7
- [CDC/NIH Biosafety in Microbiological & Biomedical Laboratories, 6th ed. \(2020\)](#), Section IV