



Safe Operating Procedure

(Revised 9/23)

PREPARING A LABORATORY BIOSAFETY MANUAL

Scope

This SOP applies to all work at UNL that is subject to the UNL Biosafety Guidelines. The content of this SOP is based on requirements established by the following standards:

- *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)*, National Institutes of Health
- *Biosafety in Microbiological and Biomedical Laboratories (BMBL)*, Centers for Disease Control and National Institutes of Health
- *Bloodborne Pathogens Standard, 29 CFR 1910.1030*, Occupational Safety and Health Administration

These standards require a Principal Investigator to develop and implement a biosafety manual. The primary purpose of the biosafety manual is to provide an appropriate training and reference tool relative to biosafety for laboratory staff, as discussed in the EHS SOP, ***Biosafety Training***.

The biosafety manual is not a replacement or substitute for a general laboratory safety manual, which covers other occupational hazards in the laboratory. The ***EHS Virtual Manual*** can be used to easily generate a general laboratory safety manual, as well as the foundation of a biosafety manual (which is then augmented with lab-specific information as detailed below).

Content

An adequate biosafety manual will contain general biosafety information, as well as information specific to the biological agents and procedures used in the lab. The Virtual Manual (VM) can be used to create the core of the laboratory biosafety manual. The following lab-specific items should be added to this core manual, as applicable:

Lab-Specific Biosafety Manual Components:

Additional details about each section of the manual can be found in the fillable PDF form “**Biosafety Manual Table of Contents Form**” found on the EHS website at <http://ehs.unl.edu/forms>.

- ☐ Risk Assessment and Research Description (*A PDF or paper copy of the current IBC protocol and other research committee documents and approvals*)

- ☐ Agent Hazard Summary (*This describes the hazards associated with handling and use of a biological agent, e.g., transmission, symptoms, containment, etc.*)
- ☐ Medical qualification and/or surveillance requirements (*As applicable, copies of immunization records or declination statements for each employee*)
- ☐ Laboratory access restrictions and entry/exit procedures
- ☐ General laboratory precautions and procedures
- ☐ Standard and special microbiological practices
- ☐ Procedures for proper use, limitations, care, and maintenance of personal protective equipment specific to the lab and/or operations.
- ☐ Laboratory-Specific Practices and Techniques for high-risk operations
 - *Special emphasis on procedures and/or equipment that increases risk of occupational exposure (e.g., use of sharps or aerosol production)*
 - *This can include EHS SOPs specific to lab operations (e.g., Biosafety Cabinets, Lentiviral Vectors, etc.)*
- ☐ Disinfection/Decontamination/Waste Disposal Considerations
 - *EHS SOPs provide general guidance for disinfection and decontamination, but lab-specific procedures should be developed that apply to the agents used in your lab. Describe the decontamination/sterilization agents, procedures, and frequency for the following:*
 - *Laboratory work surfaces including benchtops, sinks, doorknobs, telephones, faucet handles, and any other areas likely to become contaminated.*
 - *Laboratory waste.*
 - *Laboratory equipment.*
 - *Spill residues/waste products.*
- ☐ Emergency procedures
- ☐ Bloodborne pathogens program documents
 - *Declination statements for HBV vaccination and lab-specific training records*
- ☐ Permits for possession, transfer, or use of restricted agents from CDC or USDA/APHIS
- ☐ Training records (EHS and lab-specific)
 - *Annual biosafety refresher training documentation*

Accessibility

As we live in a digital age and hardcopies of documents are becoming less commonplace, it is not required to keep hardcopies of the lab-specific components of the biosafety manual available in the laboratory or nearby offices, but it is recommended for quick access. However, if you choose to keep only electronic copies of these documents in addition to the VM, they must be readily accessible to all laboratory staff. For electronic versions to be acceptable, all personnel must know how and where to access the documents and VM.

Regardless of how you decide to store your biosafety manual, you **must** complete the “**Biosafety Manual Table of Contents Form.**” This form can be downloaded as a fillable PDF form found on the EHS website at <http://ehs.unl.edu/forms>. A copy of the form must be

uploaded to your IBC protocol in NuRamp or emailed to the IBC administrator for attachment to your protocol at ibc@unl.edu.

Having this information available does **not** mean that direct training of lab personnel can be overlooked. All lab personnel must be trained about the hazards present and emergency spill and response procedures. Consult the EHS SOP, ***Spill and Exposure Response for Biohazardous Materials***, for guidance.

Uploading to NuRamp

To upload the Biosafety Manual Table of Contents Form to NuRamp follow these steps:

1. Log in to NuRamp
2. Navigate to your Protocol Summary Page (see Figure 1).

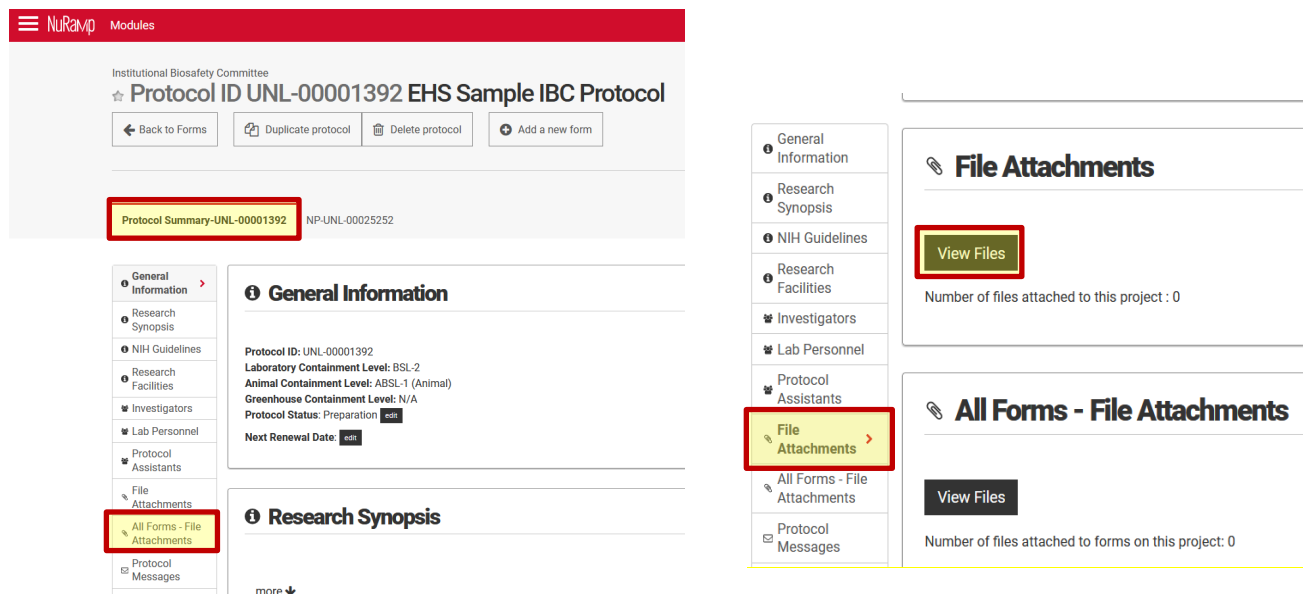


Figure 1

3. Click on “View Files” under the **File Attachments** section.
4. Click on “Browse” at the top of the file upload window (See Figure 2) and select the saved copy of the PDF form from your computer. Once you click “Open” or “OK” in the file selection window, the file will be uploaded.



Files

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Figure 2