

Instructions- BSL1 and BSL2 Laboratory Manual Templates

Version 1.0

Office of Animal Care and Institutional Biosafety (OACIB)
Institutional Biosafety Committee (IBC)

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I. Introduction

To ensure compliance with the NIH Guidelines for Research Involving Recombinant DNA Molecules (*NIH Guidelines*) and the CDC-NIH 5th Edition of the Biosafety in Microbiological and Biomedical Laboratories (BMBL), all laboratories conducting work at Biosafety Level 1 or 2 (BSL1 or BSL2) must complete a laboratory specific biosafety manual. The manual must describe the specific practices and procedures used in the laboratory for use and handling of BSL1 or BSL2 agents.

The Institutional Biosafety Committee (IBC) has developed a template manual to help investigators with this requirement. The manuals cover all major issues related to BSL1 and BSL2 research and should be used as a starting point for development of laboratory/project specific biosafety manuals.

II. Instructions

A. General Instructions

1. All manuals must be typed.
2. To use template, do the following:
 - a. Right-click on the template you want to download.
 - b. Depending on your browser, select **Save Target As** or **Save Link As**.
 - c. Save the file somewhere on your computer where you will remember where to find it (e.g., C:\My Documents\BSL2 manual.doc).
 - d. Open the file from your computer.
3. The templates are protected as a form. It can be used as is; but typing is only allowed in form fields (**blue highlighted areas**). To manipulate information that is not part of a form field, click on tools and click on unprotect document. Investigators should use caution when changing information provided in the template to ensure that the manual still contains the appropriate information required for BSL1 or BSL2 work and is in compliance with the CDC-NIH 5th Edition of the BMBL, the UIC Biosafety Manual, and the *NIH Guidelines*. Deletion of pertinent information will result in revisions to the manual being required. **NOTE: DO NOT REPROTECT DOCUMENT OR YOU WILL LOSE ALL INFORMATION ENTERED IN FORM FIELDS.**
4. For each template, if the item or section is not applicable to the research in the laboratory, it must be marked **not applicable (N/A)** or **removed from the manual**.

B. Instructions for BSL1 Manual Template

1. Standard Microbiological Practices

- a. Item 2, list the personnel [*e.g. Laboratory Supervisor, PI and Department Head.*] who are emergency contacts and whose name and contact information will be listed

on Laboratory ID Data Card. *The ID Data cards can be obtained from the Environmental Health & Safety Office. An example is shown at the end of these instructions.*

- b. Item 6e, if additional personnel protective equipment (PPE) is used beyond the minimum requirements listed in items 6a-d, it should be listed here.
- c. Item 7d, if non-disposable sharps are used, the specific method of decontamination must be identified. If these will not be used, indicate N/A. See Appendix C of the UIC Biosafety Manual for additional guidance- <http://www.uic.edu/depts/envh/HSS/Documents/BSM2004.pdf>. It should be noted that 70% ethanol is generally not considered to be an effective liquid disinfectant for most applications.
- d. Item 7f, if additional precautions are used when handling sharps, they should be identified in this section.
- e. Item 9, the specific method of decontamination of work surfaces needs to be identified. (e.g., 10% bleach (fresh dilution) followed by 70% ethanol)
- f. Item 11, the specific method used to decontaminate liquid waste must be identified. (e.g., 10% bleach (final concentration) for 15 minutes prior to disposal of liquid).
- g. Item 12, the specific method used to decontaminate solid waste must be identified. (e.g., autoclave for 30 minutes).

2. Safe Use of Autoclaves

- a. For all autoclaves used in the research, the location of the autoclave and the Principal Investigator (PI) or Department responsible for the autoclave must be identified.
- b. Item 4a, for autoclaves owned by an individual PI, the service provider and frequency of preventative maintenance must be listed. If autoclave is department owned/maintained, then mark N/A.
- c. Item 4b, for autoclaves owned by an individual PI, the method used to validate the autoclave and frequency of validation must be listed. If autoclave is department owned/maintained, then mark N/A.

3. Principal Investigator and Personnel Certifications

- a. The PI must sign and date the manual upon submission. The PI must review the manual on an annual basis and sign and date the certification for annual review.
- b. All personnel working in the laboratory on the projects covered by this manual must sign the certification upon submission and annual review.

C. Instructions for BSL2 Manual Template

1. Section 1.0 Responsibilities

- a. Item 1.1.9, any additional responsibilities of the PI as it relates to biosafety issues on projects covered under this manual should be listed here or mark N/A.
- b. Item 1.2.6, any additional responsibilities of the research personnel as it relates to biosafety issues on projects covered under this manual should be listed here or mark N/A.

2. Section 2.0 Agents and Projects Covered by Manual

- a. All items that are applicable should be marked and the agents or materials covered must be identified.
- b. If an item does not apply, mark N/A.

3. Section 3.0 Medical Surveillance Plans

- a. Item 3.2, verification of bloodborne pathogen training by all members of the laboratory conducting work covered by this manual must be maintained with the manual. Verification includes a certificate of attendance at a bloodborne pathogen training seminar or a certificate for completion of online bloodborne pathogen training. Training must be completed on an annual basis per OSHA requirements; therefore, verification must be updated annually.
- b. Based on a risk analysis of the specific agent being used and the manipulations with the agent, a detailed medical surveillance plan may need to be developed in coordination with the IBC and UHS. Note that if vaccinations, medical tests, baseline blood collection, are required by the plan, then no personnel may be added to an IBC protocol and begin work until the IBC office receives a signed clearance for work document from UHS.

4. Section 4.0 Practices and Procedures

- a. 4.1 General Signage, Item 4.1.2.d, list the personnel [*e.g. Laboratory Supervisor, PI and Department Head*] who are emergency contacts and whose name and contact information will be listed on Laboratory ID Data Card. *The ID Data cards can be obtained from the Environmental Health & Safety Office. An example is shown at the end of these instructions.*
- b. 4.2 Entry and Exit Procedures
 - i. This section contains the recommended information that should be posted at entry and exit doors to the laboratory. It can be customized for your laboratory; however, remember that the practices and procedures must follow the BMBL, 5th Edition and the UIC Biosafety Manual. To customize see item A3 on editing template.
 - ii. Item 4.2.1, list PI.
 - iii. Item 4.2.2, indicate whether or not entrance into the medical surveillance program for this project is required for entry into the laboratory
 - iv. Item 4.2.3, indicate whether or not vaccination is required for entry into the laboratory and against what agent.
 - v. Item 4.2.6.b.v., if an N95 respirator is required, all personnel must have a medical clearance from UHS and be fit tested to wear an N95. Documentation of both clearance and fit testing must be maintained and available for inspection.
- c. 4.3 Procedures for Working in Biosafety Cabinet
 - i. List the biosafety cabinets that will be used (make and model) and the date of last certification. **Biological Safety Cabinets (BSC) must be certified annually.** BSCs are certified by an outside contractor. Companies with

approved certifiers are posted on the EHSO web site:
<http://www.uic.edu/depts/envh/HSS/BioSafetyAppCert.html>.

- ii. Biological safety cabinet training is available online. Any UIC staff member can register to take the training by going to: <http://www.uic.edu/depts/envh/> and selecting "Training."
 - iii. Item 4.3.1, indicate whether cabinet is operated continuously or as needed. If operated as needed, indicate the minimum time the cabinet blower is on prior to beginning work and after completion of work. NOTE: BSCs are designed for 24 hours per day operation and some investigators find that continuous operation helps to control the laboratory's level of dust and other airborne particulates. Although energy conservation may suggest BSC operation only when needed, especially if the cabinet is not used routinely, room air balance is an overriding consideration. Air discharged through ducted BSCs must be considered in the overall air balance of the laboratory. If blower is turned off, be sure to allow sufficient time to purge airborne contaminants from the work area when the cabinet is turned back on (Centers for Disease Control and the Public Health Agency of Canada recommend a minimum of 5 minutes before and 5 minutes after work, taking into account sufficient time for settling of aerosols).
 - iv. Item 4.3.12, indicate the specific liquid disinfectant used in aspirator suction flasks and the final concentration. If this is not done, indicate N/A. See diagram in section 5.9 of UIC Biosafety manual for appropriate use.
 - v. Item 4.3.16, indicate whether or not an open flame is used in the BSC. If used, describe use and if not, indicate N/A. NOTE: Any use of open flames in a biosafety cabinet must be approved by EHSO. Open flames (e.g., Bunsen burners) are rarely necessary in the near microbe-free environment of a biological safety cabinet. An open flame creates turbulence that disrupts the pattern of HEPA-filtered air supplied to the work surface. When deemed absolutely necessary, touch-plate microburners equipped with a pilot light to provide a flame on demand may be used. Internal cabinet air disturbance and heat buildup will be minimized. The burner must be turned off when work is completed. Microincinerators (electric) are also a possible alternative for use in the BSC. If either of these will be used, obtain permission from EHSO, indicate so in this section and describe procedure for use.
 - vi. Item 4.3.17, indicate whether or not a ultraviolet (UV) light will be used in the BSC. If used, describe use and if not, indicate N/A. NOTE: Use of UV light in the BSC is discouraged. UV bulbs in the BSC must be cleaned and monitored regularly, as dust and debris inhibit effectiveness as well as gradual degradation of the UV bulb over time. Therefore, chemical surface disinfection must be the primary means of decontaminating the BSC. However, if UV light will be used, indicate so in this section, describe frequency at which lights are dusted, and describe procedures for use and frequency at which bulbs are replaced.
 - vii. Item 4.3.18, indicate the specific disinfectant and concentration that is used to clean BSC after use.
- d. 4.4. Handling Sharps
- i. Item 4.4.1.d., if non-disposable sharps are used, the specific method of decontamination must be identified. If these will not be used, indicate N/A.. See Appendix C of the UIC Biosafety Manual for additional guidance-
<http://www.uic.edu/depts/envh/HSS/Documents/BSM2004.pdf>. It should be

- noted that 70% ethanol is generally not considered to be an effective liquid disinfectant for most applications
- ii. Item 4.4.1.f., if additional precautions are used when handling sharps, they should be identified in this section.
 - iii. Item 4.4.2.a, list the contact personnel/department and extension for sharps disposal of full sharps containers.
- e. 4.5 Liquid Waste Decontamination and Disposal
- i. Item 4.5.1, List the specific method used in laboratory. If a liquid disinfectant is used, list specific agent, final concentration of agent used, and contact time. See Appendix C of the UIC Biosafety Manual for additional guidance- <http://www.uic.edu/depts/envh/HSS/Documents/BSM2004.pdf>. It should be noted that 70% ethanol is generally not considered to be an effective liquid disinfectant for most applications.
- f. 4.6 Solid Waste Decontamination and Disposal
- i. Item 4.6.1, list the specific method used in the laboratory. See Sections 5.13-5.18 and Appendix C of the UIC Biosafety Manual for additional guidance- <http://www.uic.edu/depts/envh/HSS/Documents/BSM2004.pdf>.
- g. 4.7 Decontamination of Work Surface
- i. Item 4.7.1, list the specific method used in the laboratory. See Appendix C of the UIC Biosafety Manual for additional guidance- <http://www.uic.edu/depts/envh/HSS/Documents/BSM2004.pdf>
- h. 4.8 Spill Clean-up
- i. Item 4.8.1, attach spill procedures from UIC Biosafety Manual to this manual.
- i. 4.9 Transport of BSL2 Agents
- i. Identify the locations potentially infectious materials will be transported to and from. This does not apply to infected animals or indicate N/A.
 - ii. Describe the containment during transport.
 - iii. Transport of infected animals must follow the UIC IBC/ACC Guidelines for Transport of Infected Animals and must be approved by both the IBC and ACC on a case-by-case basis, which must include a justification as to why this must be done. This should be discussed with veterinary staff and the ACC/IBC office prior to submission.
- j. 4.10 Shipping and Receiving
- i. For receiving only, the UIC IBC Guidelines on receiving potentially infectious material must be following. See attached Guidelines. [Attach a copy of the Guidelines].
 - ii. For shipping, additional training is required, documentation of training is required, and depending on the nature of what is being shipped, permits may be required. Shipping of any potentially infectious material must be described in the IBC protocol.
- k. 4.11 Laboratory Specific Procedures
- i. Describe **any** laboratory specific procedures required when handling biohazardous material. Examples of procedures needed include, but are not limited to, centrifugation, sonication, shakers, etc.

- i. 4.13 Procedures for Handling Animals
 - i. If biohazardous material or rDNA (BSL2 level) will be used in rodent animals then this section is applicable. If biohazardous material or rDNA (BSL2 level) will be used in non-rodent species, then this section must be revised to reflect procedures for the species in use.
 - ii. Once an animal is infected with replication competent biohazardous material or rDNA it will be maintained in biohazardous housing for the duration of the study. Animals infected with replication deficient rDNA viral vectors will remain in biohazardous housing for 7 days following infection.
 - iii. ACC and IBC protocols must be match and all personnel wishing to gain access to the animal biohazard rooms must be listed on both protocols.
 - iv. If animals will not be used, then this section should be removed. See section A3 for editing.
- m. 4.14 The Safe use of Autoclaves
 - i. For all autoclaves all autoclaves used in the research, the location of the autoclave and the Principal Investigator (PI) or Department responsible for the autoclave must be identified.
 - ii. Item 4a, for autoclaves owned by an individual PI, the service provider and frequency of preventative maintenance must be listed. If autoclave is department owned/maintained, then indicate N/A.
 - iii. Item 4b, for autoclaves owned by an individual PI, the method used to valid the autoclave and frequency of validation must be listed. If autoclave is department owned/maintained, then mark N/A.

5. Section 5.0 Certifications

- a. The PI must sign and date the manual upon submission. The PI must review the manual on an annual basis and sign and date the certification for annual review.
- b. All personnel working in the laboratory on the projects covered by this manual must sign the certification upon submission and annual review.