Instructions for Completing and Submitting a MOUA

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Background

Laboratories conducting work involving biological agents must submit a MOUA that will be reviewed by Institutional Biosafety Committee (IBC). Biological agents include microorganisms; recombinant and synthetic nucleic acid molecules; biological toxins; human blood, body fluids, tissues, and cells; nonhuman animal tissue and cells; plant tissues and cells; and insect tissues and cell cultures. A separate MOUA is not required for each grant proposal or project; in fact, investigators are encouraged to write MOUAs broadly enough to cover multiple projects that involve similar work and risk. For many laboratories, a single MOUA will be sufficient; however, some laboratories will require multiple MOUAs.

An MOUA amendment form must be submitted to the IBC for approval when a new agent is introduced to the laboratory or when the risk changes significantly (for example, initiation of large scale work). If the IBC determines that the changes are significant submittal of a new MOUA will be requested. For ongoing projects, a new MOUA must be resubmitted every three years.

Additional information on the UNR Biosafety Program, including policies and work practices, and approval of projects, can be found in the UNR Biosafety Manual . Questions about the MOUA process should be directed to Ben Owens at 327-5196 or bowens@unr.edu, or Kristin Eliasen at 327-5192 or keliasen@unr.edu.

Completing the MOUA

General

Use the most recent version of the MOUA form which is available on the EH&S forms and applications webpage, under the "biological safety" section. There are three different MOUA to select from depending on the type of lab you work being conducted:

1) Research and Service laboratories
2) Teaching laboratories
3) private business associates' laboratories.

Select the appropriate MOUA link below.

MOUA – for Research and Service Labs

MOUA – for Teaching Labs only

MOUA – for private business only

Download the appropriate MOUA form by clicking the link above and complete the MOUA in its entirety; do not leave sections blank. If a section is not applicable to your situation indicate this by stating that it is "not applicable" but include an explanation of your reasoning whenever possible. Try to anticipate situations where it will not be obvious to the IBC members why the section is not applicable.

Section 1: Project Summary

Provide a description of the overall purpose and goals of the work to be conducted.

Section 2: Biological Agents and Recombinant DNA or Synthetic Nucleic Acid Molecules To Be Used

Assigning a Biosafety Level

Recommended biosafety levels for many agents are contained in the CDC/NIH Publications, "Biosafety in Microbiological and Biomedical Laboratories" and "*Research Involving Recombinant or Synthetic Nucleic Acid Molecules*" For agents not specifically listed in these documents, the PI should make a determination of the appropriate biosafety level based on knowledge of the agent and the definitions of the various biosafety levels (see above documents for description of biosafety levels). In some instances it is appropriate to combine the facility requirements of a lower biosafety level with the work practices of a higher biosafety level (for example, a BSL2 facility with BSL3 procedures).

Select Agents and Dual Use Research of Concern (DURC)

Possession or use of any agents or toxins listed as select agents or toxins is highly regulated and requires registration with the CDC and specific approval of personnel. All select agents must be identified on the MOUA.

Life science research involving any of the agents or toxins listed below must complete a DURC evaluation form in accordance with the UNR policy on DURC.

Agents and Toxins

a) Avian influenza virus (highly pathogenic)
b) *Bacillus anthracis*
c) Botulinum neurotoxin (any quantity)
d) *Burkholderia mallei*
e) *Burkholderia pseudomallei*
f) Ebola virus
g) Foot-and-mouth disease virus
h) *Francisella tularensis*
i) Marburg virus
j) Reconstructed 1918 influenza virus
k) Rinderpest virus
l) Toxin-producing strains of *Clostridium botulinum*
m) Variola major virus
n) Variola minor virus
o) *Yersinia pestis*

Bloodborne Pathogens

Work involving human blood, body fluids, unfixed tissue, or cells; or animal cell lines suspected of containing recognized bloodborne pathogens, requires adherence to a minimum of BSL-2 procedures and practices, and personnel working with these materials must be included in the UNR Bloodborne Pathogens Program. Cell lines demonstrated to be free of recognized bloodborne pathogens may be exempted from the regulatory Bloodborne Pathogens requirements. Evidence supporting an exemption claim should be included with the MOUA. The IBC makes the final determination as to whether a specific cell line can be exempted from the OSHA Bloodborne Pathogens requirements.

Storage
Floor maps are available for freezer rooms located in Howard Medical Sciences room 140 and Fleischmann Agriculture room 229. If biological materials are stored in a freezer located in one of these rooms, indicate the building, room, and freezer number on the MOUA. Additionally, print a copy of the relevant floor map, label the appropriate freezer, and attach the map to the completed MOUA form.

Special Permits
Any permits required for any biological agents or materials involved in the work covered by the MOUA must be listed. For each required permit, information regarding the agency or group issuing the permit, the scope of the permit, and the expiration date must be indicated. A copy of each required permit must be submitted with the MOUA.

Section 3: Experimental Procedures
Provide enough detail of the experimental procedures and manipulations to allow the IBC members to objectively judge the biosafety issues associated with the work and the biosafety equipment and procedures that are required. The IBC is particularly interested in procedures that have potential for generation of infectious aerosols, or which pose a risk of personnel exposure by other routes. Step-by-step details of experimental protocols are generally not required.

Section 4: Biological Hazards
Describe the hazards associated with the biological agents to be used. Consider the risks to humans, animals, plants, and the environment. Provide enough detail so that IBC members can assess the adequacy of the assigned biosafety level, training of laboratory personnel, and associated control and preventative measures.

Section 5: Exposure Control Procedures
Check applicable boxes to indicate the personal protective equipment, engineering controls, facility controls, and administrative controls that will be used. Provide text to describe additional controls as necessary. Consideration should be given to potential unknown agents; for example, primary tissue or even established cell lines may contain unidentified infectious agents.

Indicate any approved protocols issued by the UNR Institutional Animal Care and Use Committee that involve any biological agent or materials covered by the MOUA.

Section 6: Security
Describe security procedures in place to prevent unauthorized access to biological agents, and their release to the environment. Also describe accountability procedures used to track agents and detect missing quantities of agents. Agents listed as select agents or toxins or other high-risk agents require a high level of security and strict accountability. For example, if a claim was made that a high-risk agent was obtained from UNR by unauthorized means, could you confirm or deny that the agent was obtain from your laboratory?

Section 7: Decontamination and Disposal

Check applicable boxes to indicate the chemical disinfectants and biohazardous waste decontamination methods that will be used.

For decontaminating surfaces or equipment, a chemical disinfectant that is known to effectively kill the biological agent in use must be specified. Indicate the category of the active ingredient of the chemical disinfectant that will be used by marking the appropriate check box.

For decontamination of biohazardous waste, treatment with a bleach (sodium hypochlorite) solution that has a final concentration of 0.5% (5,000 ppm) or greater sodium hypochlorite, with a minimum of 30 minutes contact time, is the only chemical approved method.

Biological toxins, and in particular Select Toxins, must be inactivated prior to disposal. Many toxins are susceptible to inactivation by pH (acid or base) and/or heat. Dilution and disposal to the sanitary sewer is not an acceptable disposal practice. Provide the details of the procedure to be used to inactivate toxins.

Section 8: Emergency Procedures

If you have read the response procedures for spills and other releases, and personnel contamination and exposure contained in the UNR Biosafety Manual and feel that they adequately describe your laboratory's incident procedures, you can mark the appropriate check box to indicate that. If additional or alternative incident response procedures will be used, describe the *response* procedures for personnel exposure, and laboratory and environmental releases (spills and airborne). Describe how your laboratory would respond to an actual exposure or release event. Do not list standard laboratory preventative measures such as wearing lab coats, banning mouth pipetting, working in a biological safety cabinet, etc.

Section 9: Monitoring Procedures

Describe any immunizations, medical monitoring, or personnel sampling (airborne, skin contamination, etc.) that will be employed. Personnel handling animals or animal tissue or fluids are required to be enrolled in the animal handler's occupational health program. Personnel who work with Select Agents (and generally other BSL-3 agents) must participate in the BSL-3 laboratory users occupational health program. Persons who are exposed to human body fluids, cells, or unfixed tissue must be enrolled in the UNR Bloodborne Pathogens Program and must be offered the hepatitis B vaccination at no cost to them. Additionally, describe any laboratory or environmental monitoring procedures that will be used.

Section 10: Facility Operational Procedures

Describe administrative procedures relating to facility access control, traffic control (such as controlled, designated work areas), personnel limitations (such as maximum number, limited custodial service, and exclusion of known immunosuppressed individuals), or other relevant procedures.

Section 11: Lab Map

Include a floor map of the laboratory that shows the rooms where biological agents will be used. Be sure to clearly label the floor plan with the requested information, including any special room ventilation features such as negative air pressure, one-pass ventilation, and HEPA filtration of exhaust air. Text description can be provided as needed to effectively convey the information.

Signatures

The PI and Department Chair must sign the completed MOUA at the designated locations on page 1. For the research & service labs and teaching labs approval can be supplied as an email is from the department chair. Send the approval email to Kristin Eliasen at keliasen@unr.edu or alternatively to Ben Owens at bowens@unr.edu.

Submitting the MOUA

Send the completed MOUA in Word format to Kristin Eliasen at keliasen@unr.edu, or alternatively to Ben Owens at bowens@unr.edu. Copies will be disseminated to the IBC members for review revisions to the MOUA may be requested to address IBC comments and concerns. An MOUA must be approved by a majority of the committee members and once approved, an approval notification will be provided to the Office of Sponsored Projects Administration and the PI.