SUBJECT: GUIDELINES FOR HANDLING BIOLOGICAL HAZARDS

1. PURPOSE:

All projects conducted by Research Service personnel that involve infectious agents or potentially infectious materials require prior approval from the Subcommittee on Research Safety (SRS) and the Research & Development Committee (RDC). Projects that involve recombinant and synthetic nucleic acids are reviewed by the Institutional Biosafety Committee (IBC). On a case-by case basis, the SRS may request guidance from the facility Infection Control Committee (ICC) before some projects with virulent microorganisms are given final approval. The MVAHCS has adapted Standard Precautions consistent with recommendations from the Centers for Disease Prevention and Control (CDC) and the Occupational Safety and Health Administration (OSHA) for all Health Care Workers (HCW) whose functions could bring them in contact with blood and body substances.

2. BASIC LABORATORY BIOSAFETY PRECAUTIONS:

- a) Biosafety Levels: Principal Investigators (PIs) shall determine the appropriate Biosafety Level (BSL) for their research, as defined in CDC-NIH Manual, 6th Edition, Biosafety in Microbiological and Biomedical Laboratories (1). Investigators may need to consult the "Agent Summary Statement" Section VIII of the CDC-NIH Manual, to determine the appropriate BSL (1-4) for specific infectious agents they propose to use. Biosafety levels are also defined in the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (2). BSL levels determined by PI are reviewed and confirmed by SRS, prior to protocol approval.
- b) Standard Laboratory Practices:
 - i) All laboratories using infectious microorganisms or laboratory animals shall follow, at a minimum, Biosafety Level 1 requirements (1). These include:
 - 1) Access to the laboratory is limited to necessary personnel as determined by the principal investigator (PI).
 - 2) Eating, drinking, smoking/electronic cigarette, chewing tobacco, and applying cosmetics is not permitted in the laboratory. Employee food shall be stored in facilities outside the laboratory, i.e., break rooms.
 - 3) A biohazard sign with denoted BSL shall be posted at the entrance to any laboratory that is using potentially infectious agents/materials or animal/human tissues
 - 4) Appropriate Personal Protective Equipment (PPE), including lab coats, gowns, or uniforms, shall be worn when working with any potentially hazardous material including work with infectious agents, body fluids/tissues, and laboratory animals. Before leaving the laboratory for nonlaboratory areas, laboratory coats along with other PPE shall be removed and left in the laboratory.
 - 5) Employees shall wash their hands before leaving the laboratory and after handling hazardous materials and/or animals.
 - 6) All procedures shall be performed carefully to minimize the creation of splashes or aerosols.
 - 7) Work surfaces shall be wiped with an appropriate hospital approved disinfectant (HAD) at the end of each day of experimentation and after a spill.
 - 8) Mouth pipetting is prohibited.
 - 9) An insect and rodent control program shall be in effect. Windows shall always remain closed to limit the possibility of insects or other organisms gaining entry to the work area.

- 10) Non-infectious trash (e.g., not containing biological materials or cultured microorganisms) shall be disposed of as routine trash in heavy duty clear plastic bags. If the non-infectious material is a liquid, it may be poured down the sink, provided the material is also non-hazardous and after a "Waste Evaluation Form for Sewered Waste" has been completed. Radioactive and solvent wastes are covered by the *Hazardous Waste Materials Plan* (9).
- 11) Spills and accidents which result in exposure to infectious materials or animal bites/scratches shall be reported immediately to the employee's supervisor and, if appropriate, to Occupational Health. All employee incidents are to be entered in the ECOM Portal (ECOMP) by the employee within 5 business days for evaluation by Occupational Health. This includes both VA and non-VA staff conducting research on the MVAHCS campus. Reports of employee injuries must also be made to supervisor.
- ii) **Waste** consisting of human/animal tissues, containing cultured live microorganisms, or which comes in direct contact with the above is considered potentially infectious and should be disposed of as indicated below:
 - Solid biohazard waste: Place in biohazard (red or orange) bags or containers. Biohazard bags/containers must be taken to designated biohazard-labeled barrels in the autoclave rooms in Bldg. 49 or in 4Q-127 of Bldg. 70 for subsequent disposal. All biohazard waste disposed in these common service barrels must be contained in biohazard bags/containers, i.e., unbagged solid waste cannot simply be tossed into the lined biohazard barrel. Further, biohazard bags must not go into regular trash. [See also d) below.]
 - 2) Liquids in which potentially infectious microorganisms have been cultured:
 - a. Place in a closed container and dispose of materials using biohazard bags/containers as described in a) above, OR
 - b. Chemically decontaminate (i.e., bleach) and then sewer decontaminated liquid with appropriate Waste Evaluation Form. The container must be disposed of as solid biohazard waste [see a) above] or decontaminated for future use.
 - 3) <u>Biological liquids without cultured organisms</u> including blood and other liquid body substances:
 - a. Place in a closed container and dispose of in biohazard bags/containers as described in a) above, OR
 - b. Directly sewer liquid with appropriate Waste Evaluation Form. The container must be disposed of as solid biohazard waste [see a) above] or decontaminated for future use
 - 4) <u>Satellite biohazard waste collection</u>: Biohazard waste collected in satellite containers in the lab must be leak-proof, lined with a red biohazard bag, covered, and labeled "biohazard waste". The cover shall remain in place except during active use. The preferred method of transporting biohazard materials from the lab to the large biohazard barrels in 4Q-127 [see a) above] is the use of a closed leak-proof container lined with a red biohazard bag. For light-weight biohazardous materials without sharp edges or protrusions that could puncture through plastic, the practice of double bagging (red biohazard bags) for transport from the lab to the collection site remains an acceptable alternative.
 - 5) Dual waste (combination of hazardous chemical and biohazard waste):
 - a. Apply labels for both hazardous waste and biohazardous waste, and
 - b. Place in 3N-101 or contact IHO (Ext. 31-2647) for further assistance, if needed.

- iii) **Needles, glass, and sharps** must be disposed of in a red plastic biohazard/sharps containers supplied by the hospital. Needles shall not be bent, broken, or recapped prior to disposal. Full sharps containers are disposed of, and new containers are acquired as follows:
 - a) In Bldg. 70, a full, closed/sealed sharps container is placed in the biohazard barrel in 4Q-127. Replacement containers are available in room 3N-101.
 - b) In Bldg. 49, a full, closed/sealed sharps container is placed in the hallway for pickup by EMS personnel. Replacement containers are available in rooms 3, 11, and 119.
 - c) Sharps contaminated with radioactive material must be disposed of as radioactive waste.
 - d) Disposal of sharps contaminated with chemotherapeutics or carcinogens are addressed in the facility's policy IC-09 *Needle and Syringe Storage and Disposal* (4). This also addresses the general guidelines for safe handling, storage, and disposal of sharps.
- iv) **Equipment must be surface cleaned** by wiping with hospital approved disinfectant (HAD) prior to being sent to Biomedical Instrumentation or to the manufacturer for repair. If internal mechanisms are known to be contaminated with blood or body fluids, a biohazard label shall be attached to the equipment with all relevant biohazard information.

BSL-2 standard and special practices, containment equipment, and facilities apply to all activities involving human bodily fluids (including blood drawn for research purposes) and tissues. These materials shall be treated as potentially infectious, and therefore handled as per MVAHCS Policy IC-011 *Infections Precautions Policy* (6).

BSL-2 laboratories shall follow these additional precautions:

- The PI shall limit access to the laboratory and is responsible for excluding persons at high risk for the infectious agent(s) being used and/or reassigning job responsibilities to avoid exposure to the infectious agent(s) for personnel at high risk.
- 2) The PI is responsible for establishing written policies and procedures for the laboratory. Personnel will be advised of special hazards and are required to read and follow instructions on practices and procedures. Personnel will receive periodic updates or additional training as necessary for procedural or policy changes.
- 3) A hazard warning sign incorporating the universal biohazard symbol and a BSL-2 label shall be posted adjacent to the access doors to all laboratories using BSL-2 agents. In addition, a second posting including identification of the infectious organism or biohazardous material, appropriate PPE, laboratory entrance and exit procedures, and the names and phone numbers of persons to contact in the event of an enquiry or emergency is required whenever BSL-2 agents are present in the laboratory. These are to be reviewed/updated annually, including a current date.
- 4) Gloves and a lab coat shall be worn when skin contact with potentially infectious materials is possible. PPE such as masks, safety goggles, or face shields should be worn in situations where splashing or possible aerosolization of any bodily fluids is anticipated.
- 5) Hand washing post-procedure is mandatory when handling <u>any</u> potentially infectious materials.
- 6) Cultures, tissues, body fluid specimens, or potentially infectious wastes shall be placed in a container with a cover, or a sealed biohazard bag that prevents leakage during collection, handling, processing (including centrifugation), storage, transport, or shipping.
- 7) Any spill of potentially infectious substances shall be cleaned up promptly by personnel wearing appropriate PPE using a HAD.
- 8) Spills and accidents which result in exposure to infectious materials shall be reported immediately to the employee's supervisor and, if appropriate, Occupational Health. Medical

evaluation, surveillance and treatment shall be provided under direction of Occupational Health. All employee incidents are to be entered into ECOMP.

- 9) When appropriate and considering the agent(s) handled, baseline serum samples for laboratory and other "at risk" personnel shall be collected and stored in a location determined by the PI. Additional serum samples may be collected periodically, depending on the agents handled.
- 10) Laboratory personnel shall be offered appropriate immunization treatments for the agents handled or potentially present in the laboratory.
- 11) Biological safety cabinets (Class I/II) or other appropriate protective devices shall be used whenever the employee may be at risk, i.e., when conducting procedures with potential for creating infectious aerosols or any handling of known infectious agents.
- 12) As per CDC, specific precaution shall be used for all human serum-derived reagents, including those used as controls. This includes all commercially available reagents containing human-derived materials.
- v) BSL-3 and -4 (1) require special laboratory facilities that are currently not available at the MVAHCS. Any work with agents requiring BSL-3 or -4 containment shall be addressed by the SRS and the ICC, and will likely require extensive renovation of the facilities or require work to be performed with an academic affiliate.
- vi) Select Agents. The use and storage of select agents is highly regulated. If used, researchers will need to confirm that their select agent(s) meet the CDC qualifications for exclusion from select agent regulations. See the CDC's Select Agents and Toxins Exclusions
 (<u>https://selectagents.gov/sat/exclusions/index.htm</u>), and the CDC's Exclusion Guidance Document
 (<u>https://selectagents.gov/compliance/guidance/exclusions/index.htm</u>) for information.

Permissible toxin amounts (<u>https://www.selectagents.gov/sat/permissible.htm</u>) may still require an accurate account of usage, current inventory, and written procedural SOP for each agent that includes an accepted method of disposal. If required, the above shall be part of an approved SRS protocol. The PI shall consult with the Research Safety Coordinator to determine the specific requirements for each agent and, if required, to develop a compliant SOP, review inventory record keeping requirements, and schedule for inventory audits. For additional information on requirements, see the VHA Directive 1200.08 *Safety of Personnel and Security of Laboratories Involved in VA Research* (5).

3. ADDITIONAL PRACTICES AND PRECAUTIONS WHEN WORKING WITH ANIMALS:

- a) Animal Handler Occupational Health Program.
 - i) Participants: All personnel who work in animal facilities at the Veterinary Medical Unit (VMU), or who have contact with laboratory animals or animal tissue shall be enrolled in the Medical Surveillance program through MVAHCS Occupational Health Services. Persons included are those involved in the care and maintenance of animals, as well as those individuals who have direct contact with animals (live or dead), their tissues, body fluids, or wastes. This includes all VMU staff, some investigators, some laboratory technicians, and anyone who meets criteria listed above.
 - ii) All personnel who sustain an injury related to animal exposure or care shall report to Occupational Health or to the Emergency Department during off-hours. Exposure work-up shall include routine care and could include additional serum titer evaluation. Persons who experience acute illness that could be related to animal exposure shall be evaluated by Occupational Health.

- b) The appropriate Animal BSL (ABSL) will be determined by the PI, in consultation with the Veterinary Medical Officer, Institutional Animal Care and Use Committee (IACUC) and SRS. In general, the BSL recommended for working with infectious agents *in vivo* and *in vitro* are comparable. All research work shall meet vertebrate animal biosafety precautions.
- c) ABSL 1-4 procedures from *CDC-NIH Manual* (1) shall be followed. Enforcement shall continue to be the responsibility of the IACUC and SRS. Minneapolis VMU is limited to ABSL levels of 1 & 2.
- d) Animal carcasses for disposal shall be sealed in plastic bags. BSL2 animals should be double-bagged with the outer bag appropriately labeled as biohazard. All carcasses must then be placed in the approved freezer/refrigerator (49-40), walk-in cooler (49-18), or freezer (70, 4P-103). Final disposal is by contracted collection and incineration. Radioactive animals shall be disposed of according to the Radiation Safety Officer's instructions.

4. OTHER PRACTICES AND PRECAUTIONS:

- a) Immunoprophylaxis An additional level of protection for at-risk personnel may be achieved with appropriate prophylactic vaccinations (11). The PI, in consultation with the Occupational Health physician, shall define at-risk personnel and develop recommendations which specify risks as well as benefits of specific vaccines, and which distinguish between required and recommended vaccines. A complete record of vaccines received (based on occupational requirements or recommendations) shall be maintained in the employee's permanent medical file in Occupational Health.
- b) Immunodeficient Personnel Risk assessment and BSL recommendations presuppose a population of immunocompetent individuals. Immunodeficient personnel may be at higher risk than immunocompetent personnel. It is the responsibility of the PI, in consultation with the Occupational Health physician, to ensure that immunosuppressed (hereditary, chemotherapy, splenectomy, etc.) personnel are adequately protected.
- c) Pregnancy PIs shall inform all personnel of any potential worksite risks related to pregnancy. The PI, in consultation with the Occupational Health physician, shall provide adequate protection of the pregnant worker and their fetus.
- d) Any research-study-related accidents or illnesses shall be reported to the Chair or the Coordinator of the SRS as soon as possible, but no later than 5 business days after the incident (7). The event will be reported to the SRS at an added convened meeting if needed or at the next scheduled SRS meeting.
- e) Any significant problems, e.g., violations of guidelines set forth in this document, or significant violations of the CDC-NIH guidelines, shall be reported to the appropriate MVAHCS officials (IRB, IACUC, SRS, or RDC) as soon as possible, but no later than 5 business days after becoming aware of them unless the PI has already filed a report (7, 10).
- f) General environmental cleaning/disinfection practices will comply with the EPS Sanitation Procedure Guide, whether performed by EMS employees or Research employees (8).
 - i) Specific environmental cleaning/disinfection practices for specialized areas such as the VMU located in Building 49, will comply with program-specific SOPs.

5. EDUCATION:

 a) VA-paid Research Health Care Workers (HCW) attend centralized MVAHCS Orientation. In addition, HCWs and Without Compensation employees (WOCs) complete annual training which includes infection control principles, Infection Control and Bloodborne Pathogens, TB, and Occupational Health issues. Centralized MVAHCS "Annual Mandatory Review" training is an annual review of these concepts, and any additional or changed procedures related to the above. Annual training is reviewed by MVAHCS Staff Education.

- b) A VMU Orientation is required for access to Bldg. 49 and/or prior to starting work with animals.
- c) Laboratory-specific infection control procedures are reviewed by the PI. Annual laboratory-specific safety training (specified in the Safety Training Checklist) is conducted by the PI or laboratory coordinator and documented.
- d) All Research Personnel (clinical and non-clinical) must attend the Semi-Annual General Research Safety meetings, or review the materials presented at the meeting.

6. <u>REFERENCES:</u>

- CDC, National Institutes of Health. Biosafety in Microbiological and Biomedical Laboratories, 6th Edition. Bethesda, MD: US Department of Health and Human Services, Public Health Service, 2020; HHS publication No. (CDC) 300859. <u>http://www.cdc.gov/biosafety/publications/bmbl5/index.htm</u>
- 2. NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, April 2019, Section III. <u>https://osp.od.nih.gov/biotechnology/nih-guidelines/</u>
- Occupational Safety and Health Standards, 29 CFR Part 1910. <u>http://www.osha.gov/pls/oshaweb/owastand.display_standard_group?p_toc_level=1&p_part_number</u> <u>=1910</u>
- 4. MVAHCS Policy IC-09F, Needle and Syringe Storage and Disposal, July 2, 2019. https://dvagov.sharepoint.com/sites/vhaminmcpsop/MCP/Forms/IC.aspx
- VHA Handbook 1200.08, Safety of Personnel and Security of Laboratories Involved in VA Research. April 24, 2019 (Amended January 8, 2021). https://www.va.gov/vhapublications/publications.cfm?pub=1&order=asc&orderby=pub Number
- 6. MVAHCS Policy IC-01I, Infections Precautions Policy, May 3, 2019. https://dvagov.sharepoint.com/sites/vhaminmcpsop/MCP/Forms/IC.aspx
- 7. VHA Handbook 1058.01. Research Compliance Reporting Requirements. https://www.va.gov/vhapublications/publications.cfm?pub=1&order=asc&orderby=pub_Number
- 8. VA Environmental Services Sanitation Procedure Guide. http://vaww.hefp.va.gov/resources/eps-sanitation-procedure-guide
- 9. Environment of Care Plans, including Hazardous Waste Materials Plan. <u>https://dvagov.sharepoint.com/sites/min/SiteDirectory/ECare/Environment%20of%20Care%20Plans/Forms/AllItems.aspx</u>
- 10. ECOMP. <u>https://www.ecomp.dol.gov/</u>
- 11. Recommended Vaccines for Healthcare Workers. <u>https://www.cdc.gov/vaccines/adults/rec-vac/hcw.html</u>
- 7. SRS Reviewed: August 29, 2023
- 8. <u>RESCISSIONS</u>: Guidelines for Handling Biological Hazards dated April 3, 2018
- 9. **FOLLOW-UP RESPONSIBILITY:** Subcommittee on Research Safety (SRS)

Minneapolis VA Health Care System August 29, 2023

10. Appendices:

- A. Abbreviations
- B. Addresses of Relevant Offices and Websites with Links to Resources

11. APPENDIX A: Abbreviations

ACOS	Associate Chief of Staff
BSL	Biosafety Level
CDC	Centers for Disease Control (and Prevention)
CFR	Code of Federal Regulations
DNA	Deoxyribonucleic Acid
DOT	Department of Transportation
ECOM	Employees' Compensation Operations and Management
EMS	Environmental Management Service
EPS	Environmental Programs Service
GEMS	Green Environmental Management System
HAD	Hospital-Approved Disinfectant
HCW	Health Care Worker
HIV	Human Immunodeficiency Virus
IACUC	Institutional Animal Care and Use Committee
IATA	International Air Transport Association
IBC	Institutional Biosafety Committee
ICC	Infection Control Committee
IHO	Industrial Hygiene Officer
MVAHCS	Minneapolis Veterans Affairs Health Care System
NIH	National Institutes of Health
OSHA	Occupational Safety and Health Administration
PI	Principal Investigator
PPE	Personal Protective Equipment
RDC	Research and Development Committee
SDS	Safety Data Sheet
SRS	Subcommittee on Research Safety
ТВ	Tuberculosis
TMS	Talent Management System
VMU	Veterinary Medical Unit
WOC	Without Compensation

12. APPENDIX B: Addresses of Relevant Offices and Websites with Links to Resources

- Centers for Disease Control and Prevention Attention: External Activities Program Atlanta, GA 30329 Tel: (888) 232-6348
- Occupation Safety & Health Administration (OSHA) Federal OSHA, Region V Eau Claire, WI 54701 Tel: (715) 832-9019
- National Animal Disease Center U.S. Department of Agriculture Ames, IA 50010 Tel: (515) 337-7201

13. WEBSITES FOR FURTHER INFORMATION

- 1. Centers for Disease Control and Prevention Websites
 - a) Tuberculosis: <u>www.cdc.gov/tb/</u>
 - b) Recommended Immunizations for HCW: <u>https://www.cdc.gov/vaccines/adults/rec-vac/hcw.html</u>
 - c) Healthcare-Associated Infections: http://www.cdc.gov/hai/
 - d) HIV Prophylaxis: <u>http://www.cdc.gov/hiv/basics/pep.html</u>
- 2. OSHA Websites:
 - a) Bloodborne Pathogens and Needlestick Prevention: http://www.osha.gov/SLTC/bloodbornepathogens/index.html
 - b) Occupational Safety and Health Standards. 29 CFR Part 1910: http://www.osha.gov/pls/oshaweb/owastand.display_standard_group?p_toc_level=1&p_part_number=1910
- 3. NIH Websites:
 - a) Division of Occupational Health and Safety:

http://www.ors.od.nih.gov/sr/dohs/Pages/default.aspx

- 4. USDA Websites:
 - a) National Animal Disease Center: http://www.ars.usda.gov/main/site_main.htm?modecode=36-25-30-00
- 5. VA Websites:
 - a) ORD Policies and Guidance Documents:

https://www.research.va.gov/resources/policies/default.cfm

- 6. MVAHCS Research Resources List of VA Handbooks and Directives:
 - a) <u>https://www.va.gov/vhapublications/publications.cfm?pub=1&order=asc&orderby=pub_Number</u>
- 7. VHA Directives https://www.va.gov/vhapublications/index.cfm
- 8. MVAHCS Research Service Directives https://www.research.va.gov/resources/policies/handbooks.cfm