LOUIS STOKES CLEVELAND VA MEDICAL CENTER Medical Research Service Subcommittee on Research Safety Policy

Effective Date: DECEMBER 8, 2021

SOP Title: BIOSAFETY POLICY

SOP Number: SRS--002

SOP Version: .10

Author:

Name:	John M. Schaffer, B.A				
Title:	Research Safety Coordinator				
Department:	Medical Research Service				

John M. Schaffer, B.A.

Reviewed By:

Chair/Subcommittee on Research Safety:

Krisztina M. Papp-Wallace, Ph.D.

Approved By:

Associate Chief of Staff/Research

Neal S. Peachey, Ph.D.

LOUIS STOKES CLEVELAND VA MEDICAL CENTER Medical Research Service Subcommittee on Research Safety Policy

Effective Date: DECEMBER 8, 2021

SOP Title: BIOSAFETY POLICY

SOP Number: SRS--002

SOP Version: .10

1. PURPOSE: To establish guidelines and practices to prevent transmission of infectious diseases to Medical Research employees.

2. POLICY: To protect employees from, and prevent the transmission of, infectious diseases in Medical Research Service.

3. PROCEDURE:

a. Employee Health Issues

(1) Refer to Medical Center Policy COPS-002, <u>Personnel Health Infection Prevention and Control</u> <u>Policy</u>.

(2) Based on risk assessment, laboratory personnel receive appropriate immunizations and/or clinical testing for agents of concern, i.e., Human Immunodeficiency Virus (HIV), if applicable, Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), Hepatitis A Virus (HAV), and Purified Protein Derivative (PPD) tuberculin testing. This may involve base-line serum samples for all at-risk personnel.

(3) The influenza vaccine is required annually for all employees, is free of charge to VA employees, and is available through Personnel Health.

(4) The SARS-CoV-2 vaccine is required for all employees; the SARS-CoV-2 booster is recommended for all employees; is free of charge to VA employees; and is available through Personnel Health.

(5) Incidents involving infectious materials must be reported to the Principal Investigator or laboratory director. Personnel at risk must immediately report to Personnel Health Services for medical monitoring and appropriate care. Incidents are documented in the Automated Safety Incident Surveillance and Tracking System (ASISTS) as per Medical Center Policy OOS-002, <u>Electronic Reporting of Accidents, Injuries, and Occupational Illnesses</u>.

(6) For work involving SARS-CoV-2, refer to SRS Policy 27, <u>Infection Control Procedures</u> for Work Involving SARS-CoV-2.

b. Isolation and Infection Control Precautions

(1) Refer to Medical Center Policy 011-056, Isolation and Infection Control Precautions.

(2) The Principal Investigator and/or laboratory director incorporate biosafety procedures into laboratory standard operating procedures.

(3) Laboratories that house biological material(s) and/or animal rooms that house infected animals (Animal Biosafety Level-2) must have entry signage that includes the following information:

- A. Agent(s) being used and/or being stored.
- B. Biosafety level(s) for each agent.
- C. Required PPE.
- D. Immunization requirements, when applicable.
- E. Principal Investigator's and laboratory supervisor's name and emergency contact information.
- F. Entry and exit procedures.

(4) Laboratories are constructed and equipped to facilitate the cleaning and decontamination of work surfaces. Bench tops are impervious to water and resistant to being damaged by moderate heat and/or chemicals. Laboratory chairs are covered with a non-fabric material that can be wiped-down and easily decontaminated. Carpeting and/or rugs are prohibited.

(5) Do not consume or store food, beverages, or personal medications in laboratories and animal housing and use areas; storage, application of cosmetics (lip balm), and the handling of contact lenses are also forbidden. Refer to Medical Research Standard Operating Procedure SRS-07, <u>Eating And Drinking Policy</u>.

(6) Animals and plants not involved in research are not allowed in the laboratory.

(7) When working in the Animal Biosafety Level-2 (ABSL-2) Room, refer to the Institutional Animal Care and Use Committee's ABSL-2 SOP. Also, refer to SRS-024, <u>Infection Control Procedures for the Animal Research Facility</u>.

c. Sharps Safety

(1) Refer to Medical Center Policy 011-093, <u>Bloodborne Pathogen Exposure Control Plan</u>.

d. Specimen Handling (biological fluids, cells, tissues, organs, etc.)

(1) Standard (Universal) Precautions will be taken. Appropriate personal protective equipment (PPE), as determined by risk assessment, includes barriers such as gloves, lab coat, and protective eyewear. Open-toed shoes and sandals are prohibited. Laboratory coats and appropriate disposable gloves will be worn when working with potentially infectious material. If aerosol formation or splashing of the material is anticipated, use additional personal protective equipment, such as eye and respiratory protection. Disposable PPE, e.g. plastic gown, latex/nitrile gloves, etc. must be disposed of after use/completion of procedure, and hands decontaminated. PPE used in the laboratory must remain in the laboratory upon exiting.

(2) Biological samples, i.e. bodily fluids, cells, potentially and /or known contaminated materials, etc., must be collected into compatible leak-proof containers, e.g. capped/secured centrifuge tubes, and are properly

labeled during collection, handling, processing, storage, and shipping. This will help reinforce awareness of the contents throughout a laboratory procedure.

(3) An employee may not ship infectious or biological samples without first completing relevant Department of Transportation (DOT) training. DOT training instructions are available from the RSC.

(4) The transfer of any biological agent from one lab to another must be approved by the Subcommittee on Research Safety and reported to the Associate Chief of Staff/Research.

(5) For Sharps safety/injury, refer to Medical Center Policy 011-039, <u>Bloodborne Pathogen Exposure</u> <u>Control Plan</u>.

(6) Perform all manipulations of potentially infectious material carefully to minimize the creation of droplets and aerosols:

- (a) Uncap tubes <u>away</u> from the body. Cap all specimens prior to centrifugation* and transportation. *All centrifugations must be performed within a closed system.
- (b) Mix, shake, or vortex with extreme caution. Use a biological safety cabinet or primary containment device for these procedures. See Appendix A for additional information concerning Biological Safety Cabinets.
- (c) Prior to use, inspect centrifuge tubes and bottles for their integrity, i.e. hair-line cracks, striations, and/or discoloration due to repeated use.
- (d) Dispense infectious materials close to the bottom of all vessels to minimize splatter.

(7) Cover work areas with absorbent paper whenever working with potentially infectious material. Dispose of contaminated paper in a red infectious waste barrel after each use.

(8) Decontaminate equipment and work surfaces that come into contact with potentially infectious materials. This must be done at the end of each workday with an approved hospital cleanser or a 10% bleach solution, as required by local, state, and/or federal regulations.

(9) Wash hands frequently, especially after removing gloves, at the completion of every procedure, and before leaving the laboratory or biohazardous animal housing or use space. All laboratories must have an operational sink for hand washing.

- e. Infectious Material Spills
 - (1) Refer to Medical Center Policy 137-010, Cleanup of Infectious Waste Spills and Accidents.
 - (2) Use disposable towels to cover the spilled material.

(3) Always blot (do not wipe) a spill. Decontaminate/soak the spill area for 10 minutes with a hospital-approved cleanser or a 10% bleach solution. Pick up the soaked towels using a blotting motion, working from the spill perimeter inward, and dispose of the contaminants in an infectious waste barrel.

- f. Infectious Waste Disposal
 - (1) Refer to Medical Center Policy 137-011, Refuse And Infectious Waste Management Program.

(2) Be prudent when discarding waste since processing infectious waste is expensive. Place contaminated sharp waste in an impervious red sharps container, i.e., needles, syringes, scalpel blades. Place non-sharp infectious articles and/or waste in designated red biohazard barrels located in designated Cold Rooms. Place infectious animal carcasses in red biohazard bags and dispose in red biohazard barrels in the ARF Necropsy Room B-F463 Cold Room. Environmental Management Service (EMS) removes, autoclaves, and disposes contaminated articles and/or waste as required by local, state, and/or federal regulations.

(3) Close sharps boxes when not in use or when 75% full. When 75% full, sharps boxes are removed weekly from each lab by an outside contractor or Environmental Management Service on an as needed basis.

g. Environmental Precautions

(1) Refer to the SRS Standard Operating Procedure SRS-024, <u>Infection Control Procedures for</u> <u>Infectious Diseases Research</u>.

g. Equipment Repair

(1) Decontaminate and thoroughly clean all equipment with a hospital-approved cleanser or a 10% bleach solution before releasing the unit to an engineer, service representative, or before transporting equipment for repair.

(2) Provide appropriate protective barriers to engineers or service representatives when equipment is repaired on site.

h. Laboratory Security

(1) Close and lock doors to all laboratories which contain potentially infectious material every time the room is unattended.

(2) Place warning labels on laboratory doors to alert individuals entering of the hazards that are present. The Research Safety Coordinator/Chemical Hygiene Officer in room K-117 (WP) will provide the labels.

4. REFERENCE: "Biosafety in Microbiological and Biomedical Laboratories" by the U. S. Department of Health and Human Services, May 1999, 5th Edition.

5. RESCISSION: Medical Research Service Policy 151-H dated February 14, 1993. The rescission date of this policy is December 9, 2026.

6. FOLLOW UP: Research Safety Coordinator/ Chemical Hygiene Officer

APPENDIX A. Biological Safety Cabinets

Biological Safety Cabinets (BSCs) are the most common containment devices used in laboratories working with infectious agents. BSCs are used for laboratory procedures that involve aerosols, potential splashes, and manipulations involving high concentrations and/or large volumes of infectious agents.

Each BSC is equipped with an adjustable windowed-sash that offers additional protection for personnel. Adequate illumination must be provided to minimize reflection and glare, which may impede vision.

BSCs are available in Class I, Class II and Class III designs.

Class I and II BSCs must be tested and certified *in situ* at the time they are installed in the laboratory. Cabinets must be re-certified if they are moved, and at least annually thereafter*. Certification at locations other than the final site may attest to the performance capability of the individual cabinet or model but it does not supersede the critical certification prior to use in the laboratory.

*The Baker Company BIOPROtect II Containment Hood, FACSAria Core Facility – Room K-203/Wade Park, requires semi-annual re-certification due to work with airborne pathogens.

NOTE: The use of natural gas in BSCs and Laminar Flow Hoods is prohibited at the Louis Stokes Cleveland Department of Veterans Affairs Medical Center.

(1) Class I Biological Safety Cabinets are negative pressured and ventilated. They are usually operated with an open front and have a minimum face velocity of at least 75 linear feet per minute. All of the air from the cabinet is exhausted through a HEPA filter, either into the laboratory, or to the outside.

The Class I cabinet is designed for general microbiological research with low to moderate risk agents. This cabinet is also useful for housing mixers, blenders, vortexers and other equipment that may produce a splash.

This cabinet is not appropriate for the handling of research materials that are vulnerable to airborne contamination. The inward flow of air from the laboratory can carry microbial contaminants into the cabinet.

The Class I BSC can also be used with an installed front closure panel. This panel may be used with or without attachable arm-length rubber gloves on the front panel entry holes. Without the attachable gloves, the inward flow velocity increases to approximately 150 linear feet per minute. An inlet air pressure release is necessary when attaching the arm-length rubber gloves to the front of the panel.

(2) The Class II BSC is designed with inward air flow at a velocity of 75-100 linear feet per minute to protect personnel. The unit has a HEPA-filtered vertical laminar airflow for product protection, and HEPA-filtered exhaust air for environmental protection. Design, construction and performance standards for Class II BSCs, as well as a list of products that meet these standards are available from the National Sanitation Foundation International, Ann Arbor, Michigan. Utilization of this standard and list should be the first step in the selection and purchase of a Class II BSCs.

Class II BSCs are of two types (A and B) based on construction, airflow velocities/patterns, and exhaust systems. Basically, Type A cabinets are suitable for work with microbiological research in the absence of volatile or toxic chemicals and radionuclides, since air is re-circulated within the work area. Type A cabinets may be exhausted through HEPA filters into the laboratory, or to the outside via a "thimble" connection to the exhaust ductwork.

Type B cabinets are hard-ducted to the exhaust system and are negative pressured. This provides an enclosure in which the air is at a pressure greater than that outside the cabinet. These features, plus an increased face velocity of 100 linear feet per minute, allow work to be done with toxic chemicals or radionuclides.

Personnel must be trained in the proper use of the BSCs. Of particular concern are those activities that may disrupt the inward directional airflow through the work opening of Class I and II BSCs. The following can result in the escape of aerosolized particles from within the cabinet:

- (a) Repeated insertion and withdrawal of the workers' arms into and out of the work chamber.
- (b) Opening and closing doors to the laboratory or isolation cubicle.
- (c) Improper placement or operation of materials or equipment within the work chamber.
- (d) Brisk walking past the cabinet while it is in use.

Class I and II BSCs should be located away from traffic patterns and doors. Fans, heating and air conditioning registers, and other air handling devices can also disrupt airflow patterns if located adjacent to the cabinet. Strict adherence to recommended practices for the use of BSCs and their proper placement in the laboratory are important in attaining the maximum containment capability of the equipment.

APPENDIX B. Select Agent Control Plan

Select Agents are the disease-causing agents and toxins that might be used for terrorism and which have been identified as such by the Centers for Disease Control and Prevention (CDC). The identified select agents and select agent toxins listed below are forty-two potential weapons whose transfer in the scientific and medical communities is regulated to keep them out of unfriendly hands. Select agents and select agent toxins are comprised of viruses, bacteria, rickettsiae (micro-organisms that have traits common to both bacteria and viruses), fungi and biological toxins. The USA Patriot Act of 2001, Public Law 107-56, places restrictions on the possession, shipment, and transporting of certain biological agents, toxins, and chemicals. Below is a list of agents and toxins that are covered by this law:

Viruses		Toxins	
1.	African horse sickness virus	1.	Abrin
2.	African swine fever virus	2.	Botulinum neurotoxins
3.	Akabane virus	3.	Clostridium perfringens epsilon toxin
4.	Avian influenza virus (highly pathogenic)	4.	Conotoxins
5.	Blue tongue virus (exotic)	5.	Diacetoxyscirpenol
6.	Camel pox virus	6.	Ricin
7.	Cercopithecine herpes virus (Herpes B virus)	7.	Saxitoxin
8.	Classical swine fever virus	8.	Shigatoxin and Shiga-like ribosome inactivating proteins
9.	Crimean-Congo haemorrhagic fever virus	9.	Staphylococcal enterotoxins
10.	Eastern equine encephalitis virus	10.	Tetrodotoxin
11.	Ebola viruses	11.	T- 2 toxin
12.	Foot and mouth disease virus	<u>Bacteria</u>	
13.	Goat pox virus	1.	Bacillus anthracis
14.	Japanese encephalitis virus	2.	Botulinum neurotoxin producing strains of Clostridium
15.	Lassa fever virus	3.	Brucella abortus
16.	Lumpy skin disease virus	4.	Brucella melitensis
17.	Malignant catarrhal fever	5.	Brucella suis
18.	Marburg virus	6.	Burkholderia mallei
19.	Menangle virus	7.	Burkholderia pseudomallei
20.	Monkeypox virus	8.	Cowdria ruminantium (Heartwater)
21.	Newcastle disease virus (exotic)	9.	Coxiella burnetii
22.	Nipah and Hendra complex viruses	10.	Francisella tularensis
23.	Peste des petits ruminants	11.	Liberobacter africanus
24.	Plum pox potyvirus	12.	Liberobacter asiaticus
25.	Rift Valley fever virus	13.	Mycoplasma capricolum / M. F38/ M. mycoides capri (contagious
26.	Rinderpest virus		caprine pleuropneumonia agent)
27.	Sheep pox	14.	Mycoplasma mycoides mycoides (contagious bovine
28.	South American haemorrhagic fever viruses:		pleuropneumonia agent)
	Junin, Machupo, Sabia, Flexal, and Guanarito.	15.	Ralstonia solanacearum Race 3
20	Swine vericular disease virus	16.	Rickettsia prowazekii
29.	Swille vesicular disease virus	17.	Rickettsia rickettsii
30	Tick-horne encenhalitis complex (flavi) viruses:	18.	Xanthomonas oryzae pv. oryzicola
50.	Central European Tick borne encephalitis	19.	Xylella fastidiosa (citrus variegated chlorosis strain)
	Ear Eastern Tick borne encephalitis	20.	Yersinia pestis
	(Pussion Spring and Summer encephalitis)	Fungi	
	(Russian Spring and Summer enceptiantis)	1.	Coccidioides immitis
	Omsk Hemorrhagic Fever	2.	Coccidioides posadasii
	onisk nemonnagie rever	3.	Peronosclerospora philippinensis
31.	Variola major virus (Smallpox virus)	4.	Phakopsora pachyrhizi
32.	Variola minor (Alastrim)	5.	Sclerophthora rayssiae var zeae
33.	Venezuelan equine encephalitis virus	6.	Synchytrium endobioticum
34.	Vesicular stomatitis virus (exotic)	Prions	
		1.	Bovine spongiform encephalopathy agent.

(1) Control and Security of Select Agents:

(a) Only authorized investigators may purchase select agents. Approval from the Research and Development Committee must be obtained prior to the ordering/use of select agents. Investigators and laboratory personnel must complete the following documents:

- 1) Ordering of Select Agents.
- 2) Requests for Articles and Manuscripts.
- 3) Statement of Eligibility to Handle Biological Agents or Toxins (form 3000).

4) When the quantity of any select agent or toxin exceeds the Animal and Plant Health Inspection Service (APHIS) and/or the CDC exemption amount, a Certificate(s) of Registration from APHIS or CDC for use or storage of select agents or toxins is required. When non-exempt quantities of toxins are used or stored for research purposes, the Medical Center Director (Responsible Official) and Alternate Responsible Official(s) must have an approved Security Risk Assessment as required in 42 CFR 73.7, or if regulated by APHIS, in compliance with 7 CFR 331.7, or 9 CFR 121.7, as applicable.

(b) See Medical Research Service Standard Operating Procedure (SOP) SRS-021 "Ordering of Select Agents or Hazardous Chemicals" for more information on ordering select agents.

(c) A select agent inventory log is kept within each laboratory. This inventory log documents amount used, date used, current amount on hand and is initialed by the user. When a select agent has a "0" balance, the inventory log is submitted to the Research Safety Coordinator (RSC). Alteration or compromise of inventories or records for select agents or toxins is forbidden and is reportable to VA Police Service and the facility safety office.

Personnel who have access to select agents must register with the APHIS and the CDC when inventories exceed limits set by APHIS and CDC (see attachments). Access to laboratories that house select agents is based upon obtaining a VA paid or Without Compensation (WOC) appointment, completing all required training, and the completing of all forms noted in part (a). The RSC conducts a semi-annual review of persons authorized to enter areas where select agents or toxins are used or stored.

(d) An Environmental Protection Agency (EPA) approved waste facility contracted by the LSCDVAMC handles the collection and destruction of select agents and toxins (including exempt quantities). Copies of the manifests which document the removal of select agents and toxins are submitted upon request to the RSC from the EPA-approved waste facility.

(e) In the event of loss, release, or theft of select agents or toxins, the investigator or laboratory personnel must notify the RSC immediately. Upon receipt of notice the RSC will contact Police Service and the facility safety office.

APPENDIX C. Recombinant or Synthetic Nucleic Acid Molecules

(1) When the use of Recombinant or Synthetic Nucleic Acid Molecules (rDNA) is cited on a Research Protocol Safety Survey, the Principal Investigator must complete the following form:

CASE

CASE WESTERN RESEVE UNIVERSITY

Institutional Biosafety Committee

As a condition of <u>National Institutes of Health</u> (NIH) funding, institutions conducting or sponsoring Recombinant or Synthetic Nucleic Acid Molecules research that is covered by the <u>NIH Guidelines for Research</u> <u>Involving Recombinant or Synthetic Nucleic Acid Molecules</u> are responsible for ensuring that the research is conducted in compliance with the provisions of the NIH Guidelines. For this purpose the Institutional Biosafety Committee (IBC) was formed. Consisting of Case Western Reserve University (CWRU) faculty and community representatives, the committee is charged with the responsibility for the oversight and approval of research activities involving Recombinant or Synthetic Nucleic Acid Molecules conducted at or sponsored by CWRU, or research conducted by CWRU faculty (this includes investigators whose laboratories are located at the Louis Stokes Cleveland DVA Medical Center - LSCDVAMC), staff or students.

Research Projects Requiring IBC Registration

Recombinant or Synthetic Nucleic Acid Molecules research conducted at the LSCDVAMC must be conducted with appropriate safeguards against environmental release and for protection of research personnel. Accordingly, VA funded and non-VA funded projects and proposals performed on-site or in leased space and which involve Recombinant or Synthetic Nucleic Acid Molecules must be registered with the Case Institutional Biosafety Committee (IBC), prior to the initiation of research. The committee shall review for approval all work requiring containment at Biosafety Level-2, Biosafety Level-3, and Biosafety Level-4. See <u>Appendix G, NIH</u> <u>Guidelines</u> and the CDC's <u>Biosafety in Microbiological and Biomedical Laboratories, 4th Edition</u>.

Please indicate if you are performing any of the procedures listed below.

Experiments that Must be Registered & Approved PRIOR to Initiation:

TTTO	<u>это</u> Г			0							100 1		
YES	N()	- I C I	oning	of DNA	encoding	molecul	es toxic to	vertehrates	within	11)5()<	<100ng/kg	r hodv	weight
LDD			onng	ULDINI	encoung	, morecur	es toxic to	venteorates	w itilli	LD30	<10011 <u>6</u> / Kg	, oouy	weight.

YES NO Cloning of total DNA from all Class 2, 3, or 4 human or animal pathogens (including HIV and related viruses, and human tumor viruses).

YES NO Experiments using as vectors more than two-thirds of the genome of infectious animal or plant viruses or defective recombinant viruses grown in the presence of a helper virus.

YES NO Cloning using human or animal pathogens as host-vector systems.

YES 🗌 NO	All experiments that	may generate transgen	ic animals, including	grodents constructed	d or purchased,
or plants which	may extend the host-ran	ge of human, or animal	pathogen or that rec	uire BL-2 or greate	r containment.

YES NO All human gene transfer experiments.

Experiments that Require Registration Simultaneous with Initiation:

YES	NO 🗌	Experiments 1	using as vector	s less than tv	vo-thirds	of the g	enome of	defective	animal or plant
viruses, fro	ee of help	per virus.	-			-			_

YES NO Cloning of DNA for more than one-half of the genome of Class 1 or Class 2 human or animal pathogens, or cloning of known oncogenes.

- YES NO Generation of transgenic animals requiring ABL-1 containment.
- YES NO Experiments involving whole plants.

Exempt Experiments that *Do Not* Require Registration:

Refer to the <u>Guidelines, Section III-F</u> for a detailed explanation of exempt experiments not requiring registration with the IBC.

Typical exempt experiments are:

YES	NO 🗌	Expression of	f proteins i	n prokaryotic	hosts as lor	ng as culture	volume is le	ess than	10 liters,	the
protein is r	nontoxic	and the source	e DNA is n	ot from a clas	ssified patho	ogen.				

YES NO Expression of genes from either prokaryotic or eukaryotic sources when introduced in vertebrate
cells in culture as long as the vector contains less than 2/3 of a viral genome, cannot be packaged into a viral particle,
and cannot replicate autonomously.

YES D NO Expression of genes in yeasts unless the source of DNA is from a classified pathogen.

YES 🗌 NO 🗌 Generation of transgenic flies or fish unless the source of DNA is from a classified pathogen.

YES 🗌 NO 🗌 Clo	oning of all other DNA in E. coli K12, S. cervisiae, and B. subtilis host-vector sy	vstems (with the
exception of DNA from	m Class 2, 3, or 4 pathogens).	

YES NO Introduction into cultured cells of any Recombinant or Synthetic Nucleic Acid Molecules containing less than half of a eukaryotic viral genome (with the exception of Class 2, 3, or 4 pathogens).

The interview of transfer of transferrer for the second transferrer to	YES [NO 🗌	Purchase or transfer	of transgenic	rodents except	those requiring	BL-2 or higher	containment.
--	-------	--	------	----------------------	---------------	----------------	-----------------	----------------	--------------

Acknowledgement of Responsibility and Knowledge of Work Involving Recombinant or Synthetic Nucleic Acid Molecules

I certify that my research studies will be conducted in compliance with and full knowledge of Federal, State and local policies, regulations and CDC-NIH Guidelines governing the use of Recombinant or Synthetic Nucleic Acid Molecules. I further certify that all technical and incidental workers involved with my research studies will be aware of potential hazards, the degree of personal risk (if any), and will receive instructions and training on the proper handling and use of rDNA.

Principal Investigator's Signature: _____

Date:	

(2) When research involves non-exempt rDNA, the Research Protocol Safety Survey and research protocol will be submitted to the IBC at CWRU for review. A Memorandum of Understating (MOU) between the LSCDVAMC and CWRU is in place.

(3) The Principal Investigator and/or Laboratory Director are responsible for assessing laboratory-risks and establishing entry/exit requirements (procedures) for personnel when non-exempt rDNA is in use or is being stored.

APPENDIX D. Biological Spill Procedures (BSL-2):

(1) Laboratories working with biohazards must have access to a basic Biological Spill Kit. A Biological Spill Kit is housed on the first floor/Research in the autoclave bay near rooms K-102 and 104, which is easily accessible.

Biological Spill Kit Includes:

- 1. Disposable coveralls (bunny suit)
- 2. Scrubs (for use only if clothes are contaminated)
- 3. De-con boots
- 4. Gloves
- 5. Goggles
- 6. Chlorhexidine Gluconate wipes (skin use only)
- 7. Bleach wipes (environmental surfaces only)
- 8. Absorbent
- 9. Disposable spatulas
- (2) The following procedures are provided as a guideline to the clean-up of a biohazardous spill:
 - A. All Spills

1. If the spill involves *Clostridium difficile* spores or another biological agent that is able to survive on surfaces for a long period of time, please follow the guidelines for wipetests found in the Research Safety SOP, SRS-024, for Infection Control Monitoring to ensure complete clean-up of the agent and contact the Research Safety Coordinator (RSC) for further assessment.

2. Take appropriate measures to prevent the spread of the contamination (e.g., drips, tracking on shoes, etc.) to additional surfaces (e.g., floors, outside the lab, etc.).

3. Use a two-step cleaning/disinfection process of first removing contents of the spill or contaminated area with an initial bleach wipe/solution, then clean/disinfect with a new wipe to prevent cross contamination.

- B. Spill Inside a Centrifuge
 - 1. Remove all personnel from the room. Wait 30 minutes for any potential biological aerosol to settle before attempting to clean-up the spill.
 - 2. Personal Protective Equipment (PPE):

a. For large spills (>100 mL), wear disposable coveralls, de-con boots, goggles, and gloves during clean-up.

b. For smaller spills (<100 mL), lab coat, goggles and gloves are sufficient for clean-up.

3. Remove rotors and buckets to the nearest biological safety cabinet using a secondary container to prevent drips.

4. Thoroughly disinfect inside of centrifuge, rotors, and buckets using disposable towels and 10% bleach, or bleach wipes using the two-step cleaning process. Place all contaminated wipes and paper towels into solid biohazardous waste containers for further processing by Environmental Management Service.

5. Remove contaminated debris, including PPE (disposable coveralls, de-con boots, and gloves) after disinfection, place into solid biohazardous waste containers for further processing by Environmental Management Service, and wash hands. Autoclave any reusable items (i.e., centrifuge tubes) after they are initially cleaned with bleach.

6. Remove and discard PPE at point of use and wash hands.

C. Spill Inside the Laboratory

1. Remove all personnel from the room. Wait 30 minutes for any potential biological aerosol to settle before entering the spill area.

2. Remove any contaminated clothing and footwear and place into a biohazard bag and sequester, then contact the RSC for further assessment on measures to take. Change into scrubs and/or de-con boots.

3. If the spill made any contact with the person's skin, even thru clothing, first wipe the affected area thoroughly with a disposable towel, soap and water to remove any excess contamination, dry, then wipe with Chlorhexidine Gluconate wipes and allow to air dry to ensure germicidal action of disinfectant. Dispose all towels/wipes into solid biohazardous waste containers for further processing by Environmental Management Service.

4. PPE:

a. For large spills (>100 mL), wear disposable coveralls, de-con boots, goggles, and gloves during clean-up.

b. For smaller spills (<100 mL), lab coat, goggles and gloves are sufficient for clean-up.

5. Clean-up:

a. For large spills (>100 mL), cover and encircle the spill with absorbent and use a disposable spatula to scoop up waste into a biohazard bag, being careful to minimize aerosolization, and dispose into solid biohazardous waste containers for further processing by Environmental Management Service.

b. For smaller spills (<100 mL), cover and encircle the spill with paper towels being careful to minimize aerosolization, and dispose into solid biohazardous waste containers for further processing by Environmental Management Service.

6. All items that were contaminated must be removed from the spill area; wiping each item thoroughly with bleach wipes using the two-step cleaning process. Autoclave any reusable items (i.e., centrifuge tubes, porous materials) after they initially cleaned with bleach. Broken glassware must be picked-up with forceps and disposed into a red hard-sided sharps box.

Note: Do not pick up any contaminated sharp object with your hands.

7. Wipe equipment with bleach wipes for designated contact time and rinse with water, if necessary, using two-step cleaning process. Dispose of all wipes into solid biohazardous waste containers for further processing by Environmental Management Service.

8. Wipe off any residual spilled material, and clean/disinfect with the area, including the floor, with a new bleach wipe, using two-step cleaning process. Dispose of all wipes into solid biohazardous waste containers for further processing by Environmental Management Service.

- 9. Remove and discard PPE at point of use and wash hands.
- 10. Re-open lab when decontamination is complete.

D. Spill Outside the Laboratory

1. Always transport biohazardous materials in an unbreakable well-sealed primary container placed inside a leak-proof, closed and unbreakable secondary container, labeled with the biohazard symbol (plastic cooler, bio-specimen pack, etc.).

2. Should a spill occur outside the laboratory, secure the area to ensure that the spill remains contained.

3. Contact the RSC at ext. 4263.

4. Do not attempt to clean up the spill without the proper PPE and spill clean-up materials.

E. After a Spill

1. Inform lab personnel, laboratory supervisor, the Principal Investigator, and the RSC about the spill and the decontamination process that took place.

2. Determine the root cause of the spill and propose a method to prevent this from happening in the future. This information must also be shared with lab personnel, laboratory supervisor, the Principal Investigator, and the RSC.