Samuel Merritt University

Biosafety Manual

For SMU Teaching, Research Laboratories

and George Riess Anatomy Lab

Ver 1.2 October, 2018

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CONTACT INFORMAITON

Emergency	
Barb Puder, Ph.D. (Chair)	(510) 879-9286
Matthew Smith, Lab Coordinator	(510) 879-9200 ;7371, Cell: (510) 828-2732
G587 Teaching Lab	
Matthew Smith, Lab Coordinator	(510) 879-9200 ;7371
Barb Puder, Ph.D. (Chair)	(510) 879-9286
Mary Premenko-Lanier, Ph.D.	(510) 879-9200; 7531
Rhea Kimpo, Ph.D.	(510) 879-9200 ;7357
G597/G598 Research Lab	
Richard Rocco, Ph.D., (Chair)	(510) 879-9200 ;7514
Mary Premenko-Lanier, Ph.D.	(510) 879-9200; 7531
Christina Lewis, Ph.D., Basic Sciences	(510) 879-9200 ;7512
SMU Biosafety Committee	
Richard Rocco, Ph.D., (Chair)	(510) 879-9200 ;7514
Barb Puder, Ph.D., Chair, Basic Sciences	(510) 879-9286
Karissa Legleiter, MA	(510) 879-9200 ;7358
Mary Premenko-Lanier, Ph.D.	(510) 879-9200;7531
Matthew Smith, Lab Coordinator	(510) 879-9200 ;7371
Tim Parker, SMU Facilities	(510) 907-2432
Erick Wilkinson, ABSMC Safety Officer	(510) 869-8724
Anatomy Lab	
Barb Puder, Ph.D., Chair, Basic Sciences	(510) 879-9286
Matthew Smith, Lab Coordinator	(510) 879-9200 ;7371
Kamla Ahluwalia, Ph.D., Basic Sciences	(510) 879-9200 ;7513
Barbara Guzman, DPM, CSPM	(510) 879-9200; 7533
Rhea Kimpo, Ph.D., Basic Sciences	(510) 879-9200 ;7357

Karissa Legleiter, M.A., Basic Sciences	(510) 879-9200 ;7358
Christina Lewis, Ph.D., Basic Sciences	(510) 879-9200 ;7512
Reed Rowan, Ph.D., CSPM	(510) 879-9200 ;7511

INTRODUCTION

1.0 BIOHAZARD DEFINITION

Biohazards are defined as any disease-causing agent derived from biological origin. These agents may be derived from humans, animals, plants, human derived materials, recombinant DNA and any material potentially contaminated by them. Biohazard agents include but are not limited to: certain bacteria, fungi, viruses, parasites, recombinant products, and cultured human or animal cells.

1.1 PURPOSE OF THIS MANUAL

The purpose of this Samuel Merritt University (SMU) Biosafety Manual is to provide biosafety guidelines and requirements for the handling of infectious microorganisms, recombinant DNA, human or animal tissues or body fluids. The guidelines in this Manual are intended to cover all activity with the above defined biohazardous disease-causing agents. This Manual applies to all work with potentially biohazardous agents in the SMU Multi-Use Teaching Lab and Faculty Research Lab both in Providence Pavilion Room G587 and the SMU George H. Riess Human Anatomy Lab.

1.2 ROLES AND RESPONSIBILITIES

Ensuring biosafety for faculty, staff and students is a co-operative effort between the SMU Biosafety Committee and all personnel utilizing the SMU teaching and research facilities. All faculty and staff utilizing SMU laboratory facilities must file a “Faculty and Staff Biological Authorization” form (attached) prior to the start of a course, or teaching event. This requirement includes full semester courses, single day or multiple day teaching seminars that will be conducted in any of the three above mentioned laboratories. The Authorization of this form must be submitted to the SMU Laboratory Manager who will forward it to the SMU Biosafety Committee for approval prior to scheduled semester course or teaching seminar.

Principal Investigators, Supervisors, Teachers of Record for a particular course are all responsible for maintaining a safe work environment for SMU personnel, students, research participants, and visitors. They are also responsible for providing the training, safety equipment that are necessary for all faculty, staff and students to perform their tasks safely and in compliance with this SMU Biosafety Manual.

1.3 REGULATIONS

SMU has adopted the following two documents as the basis for the regulations presented detailed in this SMU Biosafety Manual:

Biosafety in Microbiological and Biomedical Laboratories
5th Edition, December 2009, HHS Publication No. (CDC) 21-1112
U.S. Department of Health and Human Services, Public Health Service
Centers for Disease Control and Prevention,
National Institutes of Health

Guidelines for Biosafety in Teaching Laboratories, 2012 Edition
and
Appendix to the Guidelines for Biosafety in Teaching Laboratories, 2012 Edition
American Society for Microbiology
Washington, DC

1.4 BIOSAFETY LEVELS

The SMU General Teaching Lab and Faculty Research Lab are required to meet all the requirements of a Biosafety Level 2 laboratory (BSL-2) as defined in the NIH manual (cited above). The George Riess Human Anatomy Lab is required to meet all the requirements of a Biosafety Level 1 laboratory (BSL-1).

BSL-2 requirements are applicable for any agents being used that have a moderate potential hazard to cause disease in healthy adult humans and pose a moderate risk to the environment. If a worker contracts a disease related to any

BSL-2 agents, treatment is generally available. A list of potentially infectious agents that may be in use in these laboratories is posted on the front door to the G587 Teaching Laboratory. The George Riess Human Anatomy Laboratory is a BSL-1 laboratory which means that no infectious agent of any kind may be used in this lab. Only embalmed tissues may be used in this lab.

BMBL Section 1 Biosafety (Biocontainment) Plan Document 7 CFR 331: Section 12 (a); (b) and (c) (1)

CFR: Sec 12(a)

- Not applicable; no select agents or toxins are used in the laboratory

CFR: Sec 12(b)

- The biosafety and containment procedures must be sufficient to contain the select agent or toxin. Not applicable per above Sec 12(a)

CFR: Sec 12(c)

- Samuel Merritt University is committed to preserving the health and safety of its students, staff, and faculty, and to protecting the environment and the community. It is recognized that use of potentially pathogenic microorganisms is necessary in some teaching and research laboratories. To ensure safe handling of these organisms, the University requires compliance with National Institutes of Health (NIH) and Code of Federal Regulations (CFR) Guidelines, and with the recommendations in the Biosafety in Microbiological and Biomedical Laboratories (BMBL), 5th edition and the 2012 ASM Guidelines for Biosafety in Teaching Laboratories (American Society for Microbiology). The Appendix to the ASM Guidelines provides additional explanatory notes. Compliance with other applicable federal, state, and local regulations is also required.

BMBL Section 2 Occupational Health Program ***9 CFR 121: Section 12(d); (e)***

CFR: Sec 12(d)

- Occupational health training is required for laboratories that utilize Tier 1 select agents. These include Bacillus anthracis, Botulinum neurotoxin, Ebola virus and similar agents. None of these nor others are being utilized in the G587 Laboratory.
- The list of Tier 1 select agents is at www.selectagents.gov/faq-general.html

CFR: Section 12(e)

- The plan must be reviewed and revised, as necessary, after any drill or exercise and after any incident. Not applicable per above Sec 12(d)

42 CFR 73: Section 13(a)

- Resistant and/or recombinant organisms and select agents are not used in the laboratory.

42 CFR 73: Section 13(a)

- In addition, an individual or entity may not conduct or possess products resulting from a restricted experiment with an overlap select agent or toxin. Not applicable per above 42 CFR 73: Section 13(a)

9 CFR 121: Section 13(a)

- An individual or entity may not conduct or possess products resulting from, the following experiments with recombinant or select agents unless preapproved. Not applicable per above 42 CFR 73: Section 13(a)

Section 3: Standard Practice Document BMBL Section IV BSL-2, p33

A1 Detailed description of how access to the laboratory is controlled (key card entry etc.)

- Access to the multi-use lab is controlled by a keypad entry. The Lab Coordinator and instructors are given access to enter.

A2 Hand washing procedure for all persons working in the lab.

- Personnel wash their hands after working with potentially hazardous materials and before leaving the laboratory.

A3 Eating, drinking, smoking, handling contact lenses, applying cosmetics, and storage of food is not permitted in laboratory areas.

A4 Mouth pipetting is forbidden

A5 Policy for sharps, broken glass, needles etc. must be written and designed to reduce risk from these hazards

- Sharps can lead to accidental infections and can introduce aerosols.

a) Safety needles and syringes must be used whenever possible.

b) Sharps must never be bent, sheared, or recapped. Safety devices must not be modified.

c) A sharps container must be available and used for their disposal. Do not overfill sharps containers.

A5-a Detailed procedure for handling and disposal of needles

- Sharps should be avoided whenever possible in a BSL-2 laboratory. Plastic transfer pipettes (e.g., Corning cat. #4975; Falcon cat. #3575; Fisher Cat. #13-675-123) should be substituted for glass Pasteur pipettes. Needles with safety devices are recommended wherever possible. If conventional needles are required, they must *never* be re-capped, and must be disposed of in a rigid, red sharps waste container.

- *Never* reach into a sharps container to retrieve discarded items. Do not allow a sharps container to become more than ¾ full.
- Reminder: syringes without needles can be discarded in either a biohazard bag or a biohazardous sharps container, but must never be discarded in regular trash.

A5-b Describe use of sharps/needle disposal containers

- Sharps (glass slides, glass cover slips, glass pipettes, scalpel blades, serum tubes, syringes, needles, etc.) must be placed in rigid sharps containers immediately after use. In the rare circumstance where it is not possible to immediately place sharps into sharps containers, a temporary container may be used provided that no personnel exposure to the sharps can occur during the eventual transfer to a sharps container. Sharps containers must be sealed when they become no more than ¾ full and a new sharps container provided.

A5-c Describe use of containers for non-disposable sharps.

No non-disposable sharps are used in the laboratory.

A5-d Describe use of brush and dustpan for broken glass, provide plasticware where possible.

- A container for uncontaminated broken glass is available in the lab. “Non-Infectious Broken Glass” includes all broken glassware, which has not come into contact with potentially infectious agents. These materials may include such items as: glassware broken during or after cleaning, glassware broken while containing noninfectious materials (water, buffers et. al.), broken coffee cups, broken soda bottles etc. Glass Pasteur pipettes, pipette tips, glass and plastic serological pipettes, test tubes, flasks and petri dishes which have not come into contact with potentially infectious agents may also be classified as non-infectious broken glass, if handled accordingly as detailed below:

a) Place all noninfectious broken glass items into puncture resistant containers (e.g. sturdy cardboard/fiberboard box) which has been lined with plastic bag (do not use a red or orange bag).

b) Do not fill above the top of the box, when approaching full, seal box and wrap box with several strips of packing or duct tape.

c) Clearly label box "NONINFECTIOUS BROKEN GLASS" (use an indelible black marker or other clearly visible permanent pen type).

d) Dispose of noninfectious broken glass box through housekeeping (or place in regular "domestic" trash dumpster).

A6 Describe procedure to minimize splashes and/or aerosols

- Aerosol formation has the potential to contaminate work surfaces, exposed skin and garments, and air. Thus, aerosols can result in topical, oral, and respiratory exposures for workers. Manipulation of a biological sample has the potential for releasing a portion of the sample in microdroplet form to the air and work surfaces.
- Good work practices for some common laboratory procedures are provided here:
- Pipetting can introduce aerosols and splashes. Micropipettors can also introduce aerosols.

a) Mechanical pipettors should be used. No mouth pipetting.

b) Using pipette tips with cotton plugs when transferring biohazardous material.

c) “To deliver” pipettes should be used instead of pipettes requiring blowout.

d) To avoid splashes the material should be dispensed such that the tip of the pipette is placed against the wall of the receiving container.

- Centrifugation can introduce aerosols.

a) Prevent leaks by not overfilling centrifuge tubes.

b) Use sealed tubes, O-ring sealed rotors or safety buckets and check for damage before use.

c) Rotors must be balanced before use.

- Sharps can lead to accidental infections and can introduce aerosols.

a) Safety needles and syringes must be used whenever possible.

b) Sharps must never be bent, sheared, or recapped. Safety devices must not be modified.

c) A sharps container must be available and used for their disposal. Do not overfill sharps containers.

- Open Flames can produce aerosols when used to sterilize inoculating loops. They are also a fire hazard.

a) Gas flames and electric incinerators have been replaced with disposable inoculating loops.

b) Use plastic disposable inoculating loops at all times.

c) Open flames can disrupt the airflow of a biosafety cabinet.

- Blending, Grinding, Sonicating, Lyophilizing, and Freezing can all result in aerosol production.

a) Whenever possible blenders, grinders, sonicators and similar equipment should be operated in a biosafety cabinet. Shielding should be used to minimize aerosols and splatters.

b) Lyophilizer vacuum pump exhaust must be HEPA filtered or vented into a biosafety cabinet.

c) Tubes stored in liquid nitrogen have the potential to explode or rapidly vent upon removal and thawing.

A7 Describe name and use of disinfectant of work surfaces

- Disinfection of work surfaces can utilize fresh 10% household bleach (~5,000 ppm hypochlorite concentration), 70% ethanol, or appropriately diluted quaternary ammonium disinfectant cleaner (Lysol, Simple Green). Bleach wiping can be corrosive to some metallic surfaces and should be followed with a 70% ethanol rinse.

A8 Describe decontamination of cultures, stocks, and infectious materials and disposal of these items.

- Liquid infectious cultures should be inactivated by autoclaving or with concentrated bleach solution, added to ~5,000 ppm (1:10 dilution) for 10 minutes. Inactivated liquid cultures may be disposed of in the sink with a 10-fold volume of water. All solid infectious and disinfected materials should be discarded into red Biohazard waste bags for autoclaving off-site.

A8-a Describe use of disposal bags for transport of material to be decontaminated outside the laboratory

- Dedicated red Biohazard-labelled waste bags must be used in red Biohazard receptacles. These will be collected by the janitorial service for autoclaving and disposal.

A8-b Pack all material for decontamination in accordance with all local, state, and federal regulations. See Chapter 6 of the ABSMC Safety Manual for more information

All infectious material is to be disposed in red Biohazard bins and autoclaved off-site.

A9 Reference sign posted on the laboratory entrance door, which includes:

a) Universal biohazard symbol

b) Biosafety level BSL2

c) Lab Coordinator’s name and phone number

d) Principal Investigators’ names and telephone number

e) Procedure for entering and exiting the laboratory

- Enter key code or ring doorbell for access.
- Information on the infectious agents in use must be posted in accordance with institutional policy and are included in the guidelines set forth in the guide to **ASM Biosafety in Microbiology Teaching Laboratories** (attached).
- Microorganisms on-site listed on the proposed Biohazard placard. Instructor should provide important strain notes.

A10 Reference the Sutter pest control program

- Sutter Health maintains a pest control program for the University.

A11 Instructors are to ensure that all students and users are trained with regard to all of the above. The **Laboratory Policy Agreement** (attached) must note the importance of personal health status and the impact on susceptibility to infection (pregnancy, immune compromise).

- Instructors provide a **Microbiological Protocols** document.

Section 4: Special Practices Section ***BMBL Section IV BSL-2, p35***

B1 All persons entering the BSL2 G587 laboratory receive and are required to sign the acknowledgment of the potential hazards that describes the specific entry and exit requirements as specified in the **Laboratory Policy Agreement** (document attached).

B2 All persons working in the G587 laboratory must have received immunizations for agents handled or potentially present in the laboratory.

B3 Serum samples of students and personnel working in the lab are not required to be stored for reference.

B4 This SMU Biosafety Manual constitutes a policy manual that governs all biosafety issues with regard to the G587 Laboratory.

B4 A copy of the SMU Biosafety Manual is on file electronically at

www.samuelmerritt.edu

B5 All laboratory personnel and students working in the G587 laboratory receive and must sign the **ASM Biosafety in Microbiology Teaching Laboratories** (copy attached). All faculty teaching a laboratory course and principle investigators (PIs) conducting research in the G587 Laboratory that utilize biological agents must review, complete and sign the **SMU Biological Use Authorization (BUA)** form (attached).

B6 All potentially infectious materials (cultures etc.) are placed in durable, leak proof containers during storage, transport, and handling. Petri dishes ad vials with live cultures are transported in leak proof plastic bags for transfer for incineration and disposal.

B7 All laboratory equipment is routinely decontaminated according the requirements specified by the manufacture. All spills, splashes or other potential contamination are decontaminated with freshly made ~5,000 ppm bleach in DI water or according to procedures specified by the manufacturers of the laboratory equipment.

B7a Spills involving infectious material must be contained, decontaminated, and cleaned up by laboratory personnel or the teacher of record for the class in which in the spill occurred. *If the spill is too large to clean up*, the laboratory should be evacuated and ABSMC Summit Operator (510 655-4000 x5555) notified of a **CODE ORANGE – Hazardous Spill**.

B7b Equipment removed from the laboratory for repair, maintenance or disposal must be decontaminated as specified in BMBL:B7 above.

B8 Incidents that result in potential exposure to infectious materials to students and/or personnel must be reported immediately to the laboratory supervisor or his/her designate. The procedures in the **Incident Report** (copy attached) must be followed, signed and a copy forwarded to the SMU Biosafety Committee and the Laboratory Supervisor.

B8a Students and or personnel involved in a potential exposure will be required to follow the Incident Report document as specified in BMBL:B8 above.

B9 Animals and plants are not allowed in the G587 Laboratory. This is also stated in the **Laboratory Policy Agreement** specified in B1 above.

B10 All procedures involving the manipulation of infectious materials that may generate an aerosol must be conducted within the laminar biosafety hood found in the G587 laboratory.

- Note: The following documents are referenced in the above and attached:

(1) Laboratory Policy Agreement

(2) ASM Biosafety in Microbiology Teaching Laboratories

(3) Incident Report

(4) SMU Biological Use Authorization form.

Section 5: Safety Equipment Document ***BMBL Section IV BSL-2, p36***

C1 Properly maintained Biological Safety Cabinets (BSCs), other appropriate personal protective equipment, or other physical containment devices must be used whenever:

a) Procedures with a potential for creating infectious aerosols or splashes are conducted in a certified BSC hood. These may include pipetting, centrifuging, grinding, blending, shaking, mixing, sonicating, opening containers of infectious materials, inoculating animals intranasally, and harvesting infected tissues from animals or eggs.

b) Sealed rotor heads or centrifuge safety caps must be used when centrifuging any infectious agents in the open laboratory.

C2 Protective laboratory coats, aprons, gowns, smocks, or uniforms designated for laboratory use must be worn while working with hazardous materials. Protective clothing and/or attire must be removed before leaving laboratory areas and must not

be worn in non-laboratory settings (*e.g.,* cafeteria, library, and administrative offices). Dispose of protective clothing appropriately, or deposit it for laundering by the institution. It is required that laboratory clothing not be taken home.

C3 Eye and face protection (*i.e.,* goggles, mask, face shield or other splatter guard) must be worn when infectious material must be handled outside the biosafety hood. Personal eye and face protection equipment must be disposed of or decontaminated. The use of contact lenses in the laboratory is discouraged, but, if necessary, must always be accompanied by additional eye protection (*i.e.,* safety glasses or goggles).

C4 Gloves must be worn to protect hands from exposure to hazardous materials. Glove type selection should be based on an appropriate risk assessment. Alternatives to latex gloves (nitrile) are available. Gloves must not be worn outside the laboratory. Additionally, the following precautions must be practiced when working with hazardous materials:

a) Gloves should be changed in the event of contamination, when glove integrity is compromised, or when otherwise necessary.

b) Hands should be washed after glove removal before leaving the laboratory.

c) Disposable gloves must not be washed or reused, and should be disposed of with other contaminated laboratory waste.

d) Hand washing protocols must be rigorously followed.

Section 6: Laboratory Worker Document ***<u>BMBL Section IV</u> BSL-2, p37***

C4-a Change disposable gloves when integrity has been compromised

- Change gloves when contaminated, integrity has been compromised, or when otherwise necessary. Wear two pairs of gloves when appropriate.

C4-b Wash hands after removing gloves

- Remove gloves and wash hands when work with hazardous materials has been completed and before leaving the laboratory.

C4-c Do not reuse gloves. Dispose of gloves with other contaminated laboratory waste. Hand washing protocols (**Laboratory Policy Checklist**) must be followed.

a) Glove selection should be based on an appropriate risk assessment, contact your campus Research Safety Program (ABSMC Safety Manual) if you are uncertain about appropriate glove selection.

b) Nitrile gloves are available and have replaced latex gloves.

c) Do not wash or reuse disposable gloves. Dispose of potentially contaminated gloves with other contaminated laboratory waste.

d) Gloves must not be worn outside the laboratory.

Section 7: Laboratory Facilities Document BMBL Section IV BSL-2, p37

D1 Laboratory doors should be self-closing and have locks in accordance with the institutional policies.

D2 Laboratories must have a sink for hand washing. The sink may be manually, hands-free, or automatically operated. It should be located near the exit door.

D3 The laboratory should be designed so that it can be easily cleaned and decontaminated.

D3 Carpets and rugs in laboratories are not permitted.

D4 Laboratory furniture must be capable of supporting anticipated loads and uses.

D4 Spaces between benches, cabinets, and equipment should be accessible for cleaning.

D4-a Bench tops must be impervious to water and resistant to heat, organic solvents, acids, alkalis, and other chemicals.

D4-b Chairs used in laboratory work must be covered with a nonporous material that can be easily cleaned and decontaminated with appropriate disinfectant. Lab furniture is covered with non-porous vinyl material.

D5 Laboratory windows that open to the exterior are not recommended. However, if a laboratory does have windows that open to the exterior, they must be fitted with screens.

- G587 windows do not open

D6 Biological Safety Cabinets (BSCs) must be installed so that fluctuations of the room air supply and exhaust do not interfere with proper operations.

D6 BSCs should be located away from doors, windows that can be opened, heavily traveled laboratory areas, and other possible airflow disruptions.

D7 Vacuum lines should be protected with liquid disinfectant traps.

- A vacuum trap is installed in the existing chemical fume hood. Other existing vacuum and gas outlets will not be used

D8 An eyewash station must be readily available.

- An eyewash and safety shower is available.

D9 There are no specific requirements on ventilation systems. However, planning of new facilities should consider mechanical ventilation systems that provide an inward flow of air without recirculation to spaces outside of the laboratory.

D10 HEPA filtered exhaust air from a Class II BSC can be safely recirculated back into the laboratory environment if the cabinet is tested and certified at least annually and operated according to manufacturer's recommendations. BSCs can also be connected to the laboratory exhaust system by either a thimble (canopy) connection or directly exhausted to the outside through a hard connection.

D10 Provisions to assure proper safety cabinet performance and air system operation must be verified.

D11 All laboratory waste will be disposed of in appropriate biohazardous waste containers and/or using the appropriate disinfectants. The use of sharps will be minimized and all sharps will be disposed of in biohazard-labelled sharps containers. Solid waste will be collected in a red biohazard waste bin with appropriate red biohazard bags. All solid waste containers including sharps containers will be picked up and autoclaved off-site. Infectious liquid waste will be disposed in the sink with a ten-fold volume of water after adding fresh bleach (~6%, 60,000 ppm) to at least 10% of the waste volume (~5,000 ppm final hypochlorite concentration) and standing for 10 minutes.

Appendix 6A. Student Policy Agreement, Ver 1.1 October 2018

All students and personnel working in the BSL-2 G587 Multi-Use Teaching Laboratory must check off all items in this list. On the last page, sign and date, which will confirm that this signature constitutes understanding and compliance with all of the items in the checklist. This checklist must be completed, signed, and submitted to the instructor of record by all students on or before the first day of a class. Faculty only need to review and sign once for each class taught in this laboratory. Initial all below to acknowledge agreement.

Faculty Only:

All faculty and laboratory personnel are required to complete the **SMU Biological Use Authorization (BUA)** form (attached) when biological agents are being used in the course. Faculty not using biological agents in their laboratory course work, for example, the use of slides and computers only, are required to fill out this form for their course only for the first time it is being taught in this laboratory or only when biological agents are being used in the course.

Initial here: _____

Faculty and Students Initial Each Below:

1) Access to the laboratory is limited at the discretion of the Laboratory Coordinator, principal investigator on a research project being conducted in the laboratory or instructor of record for a course in which biological agents are being used.

Initial here: _____

2) All of the following are prohibited at all times in the laboratory irrespective as to whether or not biological agents are being used:
    a) Eating or consuming of liquids of any kind.
    b) Smoking
    c) Handling or applying contact lenses
    d) Applying cosmetics, lip balms, lipstick etc.

e) Storing food and liquids intended for human use.

f) Mouth pipetting for any reason.

g) “Street” jackets, hats, scarfs, gloves, back packs, shoulder bags, brief cases etc. are not allowed to be brought into the laboratory at any time. These items must be stored in lockers outside the laboratory. Computers, notebooks and limited stationary supplies are allowed. The purpose of this regulation is to prevent the contamination of these items from a laboratory bench that may not have been properly decontaminated.

Initial here: _____

3) All of the following items are prohibited at all times when biological agents are in use (live microorganisms, live human and/or animal tissue cultures, toxins known to affect humans, human genes, body fluids and unfixed or fixed human tissues).

a) All of the items in 2) above.

b) Open toe shoes, sandals of any kind, flip flops etc.

Initial here: _____

4) All of the following are required when biological agents are in use. For courses in which no biological agents are used, these items are at the discretion of the instructor of record:

a) Gowns, aprons or other protective coverings are required. These items may be disposable or non-disposable. For non-disposable items they must be put into a labeled hamper and sent to a laundry facility. None of these lab coat or apron items of either disposable or non-disposable may be worn outside the laboratory or taken out of the laboratory for any reason at any time.

Initial here: _____

b) Safety eyeglasses must be worn at all times while in the laboratory.

Initial here: _____

c) Disposable latex or vinyl gloves must be worn at all times while in the laboratory. Gloves are single-use and must be disposed of in the red biohazard-labeled containers.

Initial here: _____

d) Hands must be washed after removing the gloves and again before leaving the laboratory.

Initial here: _____

e) All sharps must be placed in the red sharps containers labeled with the Biohazard sign and found on the benches in the laboratory.

Initial here: _____

f) When handling biological agents in such a way that aerosols may be formed, then all this must be done on the laboratory laminar flow hood.

Initial here: _____

g) All students and personnel must know the location of the eye wash station and safety shower.

Initial here: _____

h) Spills and accidents involving biological agents must be reported immediately to the laboratory supervisor, instructor of record, or principal investigator. An Incident Report must be filled out by one of those to whom the accident is reported and a copy submitted to the SMU Basic Sciences Biosafety Committee (BSBC). The Incident Report form is attached.

Initial here: _____

i) All workbench surfaces must be cleaned with 10% (v/v) bleach in tap or DI water at the end of the class period or following any accident or spill.

Initial here: _____

j) All biological agents (serums, urines, cultures, tissues etc.) are required to be placed into leak proof bags when being transported within or outside of the laboratory. These bags are then to be placed into labeled floor buckets for disposal if required. These are taken away for incineration by a contract company.

Initial here: _____

k) All laboratory entrance and exit doors must be locked at all times when biological agents are present. Entrance by students and/or faculty will be only through key card entry using the faculty or student SMU identification badge.

Initial here: _____

Print Name

Signature Date

Appendix 6B. ASM Biosafety in Microbiology Teaching Laboratories

The G587 Multi-Use Teaching Laboratory adheres to the requirements of the "*Biosafety in Microbiological and Biomedical Laboratories (BMBL)* ." 5th edition, December 2009, US Department of Health and Human Services, National Institutes of Health. In addition, the G587 Laboratory follows the requirements of the American Society of Microbiology (ASM) *Guidelines for Biosafety in Teaching Laboratories* and *Appendix to the Guidelines for Biosafety in Teaching Laboratories*, ASM, Washington, DC, both published in 2012.

The ASM Guidelines follow very closely the BMBL manual. Below is a checklist of some items unique to the ASM Guidelines and which apply specifically to a microbiology teaching laboratory at the college and graduate school level. Page number references below refer to ASM Guidelines (2012) and ASM Guidelines Appendix (Version 3.3A, 2012).

1) The use of any of these organisms requires a BSL-2 Laboratory (Appendix pg. 8, 11):

    - *Enterococcus faecalis*
    - *Klebsiella pneumonia*
    - *Pseudomonas aeruginosa*
    - *Salmonella enterica*
    - *Morganella morgana*
    - *Mycobacterium smegmatis*
    - *Proteus vulgaris*
    - *Staphylococcus aureus*
    - *Streptococcus pyogenes*

    These and other organisms that require a BSL-2 laboratory are likely to be present in the environment and in student throat and skin cultures.

2) These procedures, if used, require a BSL-2 laboratory (Appendix pg. 7)

   - acid-fast staining
   - animal cell cultures
   - CAMP test for group B beta-streptococci
   - coagulase testing
   - hemolysis testing

   The last two tests in the above list are performed in the G587 teaching laboratory. Other procedures, not listed, may also be included in the curriculum.

3) Personal Protective Equipment: (Appendix pg. 1-3)

   a) Safety glasses must be worn at all times

   b) Lab coats are required at all times (Note: plastic aprons with no protective sleeves do not meet these requirements).

   c) Closed-toe shoes required at all times.

   d) Gloves are required when handling infectious materials and when performing a Gram stain.

4) Use of the G587 Teaching Lab for courses that do not utilize infectious agents (for example, a course in Neurology) requires that all BSL-2 biohazardous waste must be removed to a storage area before the laboratory is used for other non-BSL-2 courses (Appendix pg. 2).

5) In a BSL-2 laboratory, any procedure known to generate aerosols must be performed in a biological safety cabinet (laminar flow hood) (Appendix, pg. 3).

6) Electrical micro-incinerators must be used instead of gas open-flame Bunsen burners (Appendix, pg. 4)

7) Fresh 10% household bleach (~5,000 ppm) in water (prepared monthly, stored in dark) is the preferred disinfectant for equipment and bench tops (Appendix pg. 4)

8) Collecting environmental samples (student hands, doorknobs, soil, skin or mouth swabs etc.) all require a BSL-2 laboratory (Appendix pg. 5).

9) The following rules must be observed at all times when infectious agents are being used to prevent accidental injury and infection to yourself and others and to minimize contamination of the laboratory environment (Appendix pg. 9)

   a) Backpacks, purses, books etc. must be stored outside the laboratory in lockers or cubicles located outside the BSL-2 laboratory.

   b) Electronic devices (iPhones, iPads, laptops, cell phones etc.) must not be brought into the laboratory.

   c) Bench tops must be cleaned before and after use with diluted bleach solution.

   d) Hands must be washed on entering and leaving the laboratory.

   e) Lab coats, gloves, eye goggles are required at all times.

   f) Open-toed shoes and sandals are not allowed.

   g) Long hair must be tied back.

10) Persons who are immune compromised (including those who are pregnant or may become pregnant) and students living with or caring for an immune compromised individual are advised to consult with your physician to determine the appropriate level of participation in the lab (Appendix pg. 10-11)

Appendix 6C. Laboratory Incident Report, Ver. 1.0

This report is to be completed and signed by the Laboratory Supervisor, or the Teacher of Record or the Principle Investigator (PI). Copies must be given to the Laboratory Supervisor and the SMU Biosafety Committee.

(1) Date of the incident_____Time_____AM PM

Name of Person(s) Involved_____

_____

(2) Specific Location of the Incident Within the G587 Laboratory:

(3) Describe the Incident including the biological agents involved if applicable (use additional pages if required):

(4) Describe the mechanism and route of exposure to a biological agent (percutaneous, splash to mucous membranes or skin, aerosol etc)

(5) Print the name (s) of all of the following:

Individual(s) exposed or injured_____

Witnesses_____

(6) Describe in detail what medical attention was provided for those who may have been injured, for example, called 911, referred individual to SMU Health Services, first aid provided etc.

(7) Describe the material(s) and/or laboratory equipment that were involved in the accident, for example, broken glass, sharps etc:

(8) Describe the clean-up and decontamination procedure that was used:

(9) Describe and list the personal protective equipment that was used at the time of the accident:

(10) Sign and Date of the person(s) completing this Incident Report (Teacher of Record or PI or Supervisor)

_____	_____	_____
Print name	Sign	Date

_____	_____	_____
Witness Print name	Sign	Date
_____	_____	_____
Name of Individual Injured or exposed	Sign	Date

Appendix 6D. Faculty and Staff Biological Use Authorization

SAMUEL MERRITT UNIVERSITY

Biological Use Authorization

PRINCIPAL INVESTIGATOR INFORMATION:

Name _____
Last First Title

Phone _____ Fax _____ Email _____

Department _____ Building _____ Room _____

Project Title _____

Application Status: Initial ◯ Renewal of BUA ◯

OTHER PERSONNEL ASSOCIATED WITH THE PROJECT:

Use continuation page, if necessary.

Last First Phone

Name _____

Name _____

Name _____

PRINCIPAL INVESTIGATOR'S CERTIFICATION:

By signing below, I certify that I and the listed participants will abide by all Samuel Merritt University laboratory safety policies and by the policies and procedures governing the use of infectious agents, recombinant DNA, and other biological materials as outlined in CDC and NIH publication "Biosafety in Microbiological and Biomedical Laboratories". (https://www.cdc.gov/biosafety/publications/bmbl5/index.htm).

I will:

- ensure that listed personnel receive appropriate training in safe laboratory practices and the procedures for these protocols prior to any work beginning.
- inform the University Biosafety Officer of any significant research related accident or illness as soon as possible after its occurrence.
- submit in writing a request for approval from the Biosafety Committee of any significant modifications to the study, facilities, or procedures.

Signature of Principal Investigator _____ Date _____

For BSC use only

☐ Biosafety Committee Approval _____
Biosafety Committee Chair

Approval Date _____ Expiration Date _____

FUNDING INFORMATION:

This study will be funded Yes ◯ No ◯

Check all that apply:

- ☐ Federal Government
- ☐ Other Government (State, City, WHO)
- ☐ Pharmaceutical/Device Company
- ☐ Other private
- ☐ Campus/University-wide programs
- ☐ Departmental

Funding source name (and grant/contract #, if known) _____

SPECIFIC LOCATIONS WHERE RESEARCH WILL BE PERFORMED:

Location(s) of biohazardous materials _____

Location(s) of biosafety cabinet(s) _____

Location(s) of autoclave(s) _____

PART A: INFECTIOUS AGENTS AND TOXINS

1. Please indicate "Yes" or "No" to each of the following. I am working with:

◯ Yes	◯ No	a. an RG1 organism.
◯ Yes	◯ No	b. an RG2 organism.
◯ Yes	◯ No	c. sheep tissue or sheep cell lines.
◯ Yes	◯ No	d. Old World primate tissues or cell lines.
◯ Yes	◯ No	e. toxins known to affect humans.
◯ Yes	◯ No	f. human genes, blood, body fluids, unfixed tissue, or cell, tissue, organ cultures derived from humans.

2. If you answered “Yes” to any of the above statements, please complete the following Infectious Agents and Toxins Information section.

Use continuation page if necessary.

Note: Information about Biosafety Risk Levels of Biologic Organisms is located at (http://ehs.ucsf.edu/risk-group-summary).

If you are working with human genes, blood, body fluids, unfixed tissue, or cell, tissue, or organ cultures derived from humans, list the potential blood-borne pathogens, the specific material being used, and enter "2" under Risk Group.

INFECTIOUS AGENT OR TOXIN	RISK GROUP

3. Please attach a written description for the following:

- The experimental design and goals of the research, including a brief description of the experimental procedures. Provide sufficient detail to allow the committee to assess the hazardous potential of the experiments.
- An assessment of the hazardous potential, including a brief description of the agents, its hosts, modes of transmission to humans, and pathogenicity. Also, describe the implications if the organism were to be released outside the laboratory.
- A description of your plan for biosafety for the research, including a description of the biosafety training you will provide related to this work for all personnel involved in the project.

4. Please indicate "Yes" or "No" to the following statement:

Yes ◯ No ◯ I will use one or more of the **DHHS Select Agents** in this study.

A List of DHHS Select Agents is located at:
(https://www.selectagents.gov/SelectAgentsandToxinsList.html)

If "Yes" please attach one-paragraph descriptions of the agent(s), the quantities in which you will be handling and storing them, storage locations, security precautions and mechanisms by which you will ensure their safe usage and disposal.

PART B: RECOMBINANT DNA

1. Please indicate "Yes" or "No" to each of the following.

Yes ◯ No ◯ a. I am inserting foreign DNA into a vector or organism for cloning.

Yes ◯ No ◯ b. The DNA to be cloned is from a RG3 agent, represents more than two-thirds of the genome of a RG1 or 2 organism, encodes a known oncogene, or encodes molecules known to be toxic to vertebrates at concentrations less than 1 mg/mL.

Yes ◯ No ◯ c. The vector I am using for introduction of foreign DNA into the host is from an RG3 agent, is a RG1 or 2 virus that infects eukaryotic cells and contains more than two-thirds of the viral genome.

Yes ◯ No ◯ d. The host into which I am introducing the DNA is a cell or organism other than *E. coli* K12 or its derivatives, *Saccharomyces cerevisiae*, *S. uvarum*, *Bacillus subtilis*, or *B. licheniformis*.

---

2. If you indicated "Yes" to any of the above statements, please complete the following Recombinant DNA Information.

Please provide specific names: Risk Group

Host(s)

Vector(s)

Gene(s) to be cloned

DNA source(s)

3. Please attach one paragraph descriptions of the following:

- The experimental design and goals of the research, including a brief description of the experimental procedures. Provide sufficient detail to allow the committee to assess the hazardous potential of the experiments.

- Assessment of the hazardous potential of cloning any DNA segments encoding pathogenic, oncogenic, or toxic substances.
- Containment conditions that will be implemented.

PART C: STANDARD OPERATING PROCEDURES FOR ALL APPLICANTS:

Please initial to acknowledge agreement with each of the following:

_____ a. Decontamination Procedures: I will use 0.5% sodium hypochlorite (a 1:10 dilution of household bleach) to decontaminate equipment and work surfaces. In locations where bleach would cause corrosion, I will decontaminate with an iodophore (e.g., Wescodyne).

_____ b. Local Transport of Infectious Materials: All infectious materials transported to and from my laboratory will be enclosed in a primary container with sealed top, which will then be enclosed in a secondary leak-proof, non-breakable container (such as a Coleman cooler) appropriately labeled with the biohazard symbol.

_____ c. Storage: All infectious materials to be stored will be clearly labeled with the universal biohazard symbol as well as the storage space (e.g., freezer, refrigerator).

_____ d. Human Origin: If I am using human genes, blood, body fluids, unfixed tissue, or cell, tissue, or organ cultures derived from humans, I will handles all such cultures under BSL2 conditions and in accordance with Blood-borne Pathogen Standards unless the Biosafety committee has specifically approved a lower level of containment.

_____ e. Shipment of Biological Materials: I will follow all applicable state, Federal, and international regulations whenever I ship biologic materials domestically and internationally. I will also obtain the proper importation or exportation permits/licenses before shipping or receiving any biologic material.

_____ f. Containment of Aerosols or Splashes: All manipulations having a potential for generating aerosols (e.g., homogenization, centrifugation, and sonication) will be conducted in a properly certified biosafety cabinet or in a centrifuge equipped with sealed rotor heads or safety cups. Screw-cap centrifuge tubes will be no more than three-fourths filled.

_____ g. Disposal: I will post in my laboratory the procedures for disposal of biologic waste, as determined by the Biosafety committee.

Appendix 6E. Biological Use Authorization (BUA) – Amendment Application Form

Protocol Title:

1. Briefly indicate the proposed change/amendment.

☐ Change in personnel (see Tables 1 & 2 below)
☐ Change in procedures
☐ Add Procedures
☐ Other:

2. Indicate the reason and justification for the amendment.

3. Provide details of the proposed changes/procedures (reference BUA page number)

Table 1: Addition of personnel

			For use by Biosafety Committee only	
Name	**Employee #**	**Phone**	**Medical surveillance current and appropriate?**	**Training current and appropriate?**
			☐	☐
			☐	☐
			☐	☐
			☐	☐

Table 2: Deletion of personnel

Name

Please certify the following statement from the original BUA by signing below:

"The Principal Investigator will ensure that listed personnel have received or will receive appropriate training in safe laboratory practices and the procedures for this protocol *before any work begins* and at least annually thereafter. In addition, all listed personnel who have occupational exposure to bloodborne pathogens will take an online bloodborne pathogen training sessions conducted by SMU.

Principal Investigator _____Date _____
(sign)

_____
(print name)

Approval

Biosafety Chair _____Date _____

Appendix 6F. Biological Use Authorization (BUA) – Continuing Review Form

Project Title:

Principal Investigator (Last, first)
_____Ext._____
Co-Investigator / Study Director _____Ext.
_____
Co-Investigator / Study Director _____Ext.
_____

Project Status
Request Protocol Continuance

A. ☐ **Active** – project ongoing
   1. ☐ No changes are planned and the project will continue as previously approved by the Biosafety Committee.
      a. Please provide a summary (approximately 1 page) of work done since last BUA submission, including any relevant findings that affect risks (e.g. dosing change) and any problems encountered.
   2. ☐ Changes are planned. Please provide a summary (approximately 1 page) of work done since last BUA submission, including any relevant findings that affect risks (e.g. dosing change) and any problems encountered.
      i. ☐ Fill out second page of this Review form for Personnel Change only.
      ii. ☐ BUA Amendment Application Form for minor modifications.
      iii. ☐ New BUA Application Form for significant modifications.
   3. Other. Provide a brief explanation.
      e

B. ☐ **Currently Inactive** – project was initiated but is presently inactive.
   1. ☐ No changes are planned and the project will continue as previously approved by the Biosafety Committee.
   2. ☐ Changes are planned. Provide a full description and justification for the proposed changes. (A copy of the BUA Amendment Form can be provided by Biosafety Committee).
      i. ☐ Fill out second page of this Review form for Personnel Change only.
      ii. ☐ BUA Amendment Application Form for minor modifications.
      ii. ☐ New BUA Application Form for significant modifications.

   3. ☐ Other. Provide a brief explanation.
      _____
      _____

C. ☐ **Inactive** – project never initiated but anticipated start date is_____.
1. ☐ No changes are planned and the project will continue as previously approved by the Biosafety Committee.
2. ☐ Changes are planned. Provide a full description and justification for the proposed changes. (A copy of the BUA Amendment Form can be provided by Biosafety Committee).
   i. ☐ Fill out second page of this Review form for Personnel Change only.
   ii. ☐ BUA Amendment Application Form for minor modifications.
   ii. ☐ New BUA Application Form for significant modifications.

3. ☐ Other. Provide a brief explanation.
_____
_____

D. ☐ Request BUA Termination **(**Please sign bottom of form and return it to Biosafety Committee).
1. ☐ Project never initiated.
2. ☐ Project initiated but project has not/will not be completed.
3. ☐ Project has been completed, no further activities with biological agents will be used.

Project Personnel: Have there been any personnel/staff changes since the last BUA approval (including Amendments) was granted? ◯ No ◯ Yes (If yes, please fill out the table below or use Amendment Form)

Table 1: Addition of personnel

			For use by Biosafety only	
Name	**Employee #**	**Phone**	**Medical surveillance current and appropriate?**	**Training current and appropriate ?**
			☐	☐
			☐	☐
			☐	☐
			☐	☐

Table 2: Deletion of personnel

Name

Please certify the following statement from the original BUA by signing below:
"The Principal Investigator will ensure that listed personnel have received or will receive appropriate training in safe laboratory practices and the procedures for this protocol *before any work begins* and at least annually thereafter. In addition, all listed personnel who have occupational exposure to bloodborne pathogens will take an online bloodborne pathogen training sessions conducted by SMU.

Principal Investigator _____Date _____
(sign)

_____
(print name)

Approval

Biosafety Chair _____Date _____

Appendix 6G. Laboratory Inspection Checklist

Inspection Check List **G587 Teaching Lab** **3100 Summit St.**

Inspector_____ Date_____

This Inspection List follows all the steps required for BSL-2 Laboratories as specified in BMBL 5th edition.

	Yes	No
(1) CFR: Section 12(a): An SMU Biosafety Manual is on file	◯	◯
(2) CFR: Section 12(e): SMU Biosafety Manual is reviewed yearly	◯	◯
(3) 42 CFR 73:Sec 13 (a): Confirm that disease agents that acquire resistance are not being used	◯	◯
(4) BMBL:A1: Confirm that lab has limited, controlled access	◯	◯
(5) BMBL:A2: Confirm that a sink is close to exit and contains a disinfectant	◯	◯
(6) BMBL:A3: Confirm procedure in place that forbids eating, applying cosmetics, storing food in the lab is prohibited	◯	◯
(7) BMBL:A3: Confirm that student storage lockers are outside the lab	◯	◯
(8) BMBL:A4: Confirm procedure in place to forbid pipetting by mouth	◯	◯

	Yes	No
(9) BMBL:A5: Confirm a procedure in place for sharps and broken glassware	○	○
(10) BMBL:A6: Confirm that the laminar flow hood is certified, inspected and up to date	○	○
(11) BMBL:A6: Confirm that the chemical hood is certified, inspected and up to date	○	○
(12) BMBL:A7: Confirm that all lab work surfaces are decontaminated with in-date 10% bleach	○	○
(13) BMBL:A8: Confirm a procedure on decontamination of cultures, stocks and related materials is in on file	○	○
(14) BMBL:A8a: Confirm the use of red decontamination bags for all for all transport outside the lab	○	○
(15) BMBL:A9: A biohazard sign is posted outside the lab door	○	○
(16) BMBL:A9: A list of all potentially hazardous bacterial agents are listed and posted on the outside lab door	○	○
(17) BMBL:A10: Sutter pest control in place	○	○
(18) BMBL:A11: Student agreement and training form in place and signed by all students	○	○
(19) BMBL:A11: Student agreement covers susceptibility of pregnant		

	Yes	No
women are informed of potential hazards	○	○
(20) BMBL:B1: Student agreement covers potential hazards	○	○
(21) BMBL:B2: Lab personnel records on TB and Hepatitis B immunization on file	○	○
(22) BMBL:B4: SMU Biosafety Manual on file and available	○	○
(23) BMBL:B5: Lab supervisor has documentation to demonstrate that lab personnel and students have been trained in microbiological safety practices	○	○
(24) BMBL:B6: Infectious agents are placed in leak proof, biohazardous red plastic containers and containers	○	○
(25) BMBL:B7: A procedure is in place for decontamination of lab equipment, lab surfaces etc. that have been exposed to splashes of potentially infectious agents	○	○
(26) BMBL:B8: Review reports of accidents resulting in potential exposure to hazardous agents or safety issues (broken glass etc)	○	○
(27) BMBL:C1: Lab safety equipment available for all students and lab personnel	○	○
(28) BMBL:C1-b: Centrifuges have sealed rotors to prevent aerosols	○	○
(29) BMBL:C2:Lab aprons or coats, gloves, eyeglasses available	○	○

	Yes	No
(30) BMBL:C2: Protective clothing is left in a specific location in the lab and never worn outside the lab	○	○
(31) BMBL:C2: Evidence of laundry facilities for protective clothing provided	○	○
(32) BMBL:C3: Eye and face protection goggles and devices are available	○	○
(33) BMBL:C3: Lab manual specifies that those wearing contact lenses must wear eye protection glasses	○	○
(34) BMBL:C4: Lab manual specifies that disposable gloves must be used	○	○
(35) BMBL: C4: Non-latex based gloves available	○	○
(36) BMBL:C4-c: Handwashing procedure in place	○	○
(37) BMBL:D1: Lab doors are self-closing	○	○
(38) BMBL:D2: Lab sink for hand washing located near exit door	○	○
(39) BMBL:D3: No carpets or rugs in the lab	○	○
(40) BMBL:D4-a: Lab chairs are impervious to liquids	○	○
(41) BMBL-D4-b: Lab chairs covered with non-porous material	○	○

	Yes	No
(42) BMBL:D5: Lab windows must not open to the outside	○	○
(43) BMBL:D6: Sutter maintains lab air and exhaust room air supply	○	○
(44) BMBL:D6: The chemical and laminar flow hoods are located away for doors and windows	○	○
(45) BMBL:D7: Vacuum lines in the chemical hood have vacuum traps	○	○
(46) BMBL:D8: Eyewash station records for checking available	○	○
(47) BMBL:D11: Procedure in place for decontamination of all lab waste is available ex autoclave, chemical disinfection, incineration, or other validated method is in place	○	○