STLCC Biological Safety Plan

September 2018

Purpose and Scope

The purpose of this program is to define the biological safety policies and procedures pertaining to research operations at STLCC BRDGPRK Campus. These policies and procedures are designed to safeguard personnel and the environment from biologically hazardous materials and to comply with: lease, federal, and state regulatory requirements. All faculty, customers, and laboratory employees must adhere to the biological safety policies and procedures in the conduct of their research and the management of their laboratories.

Biological agents include all infectious microorganisms (bacteria, fungi, parasites, prions, rickettsia, viruses, etc.) that can cause disease in humans or pose significant environmental or agricultural impact, as well as the toxins derived from such organisms. Additionally, recombinant or synthetic nucleic acid molecules; human or non-human primate tissues, fluids, cells, or cell cultures; transgenic plants or animals; and any work with animals and their tissues, which are known to be reservoirs of zoonotic diseases, are wholly or partly covered by the procedures and policies in this manual.

For information about specific biological safety programs for operations not covered in this manual, contact a member of the Intuitional Biosafety Committee or the Biosafety Officer.

Rules and Regulations

The following is a summary of federal and state regulations and guidelines that either regulate or provide guidelines covering the use of biological agents:

- Centers for Disease Controls and Prevention and the National Institutes of Health: Biosafety in Microbiological and Biomedical Laboratories (BMBL), 5th Edition, 2007. This document contains guidelines for microbiological practices, safety equipment, and facilities that constitute the four established biosafety levels. The BMBL is generally considered the standard for biosafety and is the basis for this manual.
- National Institutes of Health: Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines). This document provides guidelines for constructing and handling recombinant or synthetic nucleic acid molecules and organisms containing these molecules. Although these guidelines are not subject to regulatory enforcement, institutions that receive any NIH funding for recombinant or synthetic nucleic acid molecules research is required to comply with these guidelines as a condition of funding. This document requires that each institution establish a Biosafety Committee with the authority to approve proposed research using the NIH guidelines as the minimum standard.

- Select Agent Rule: Department of Health and Human Services: 42 CFR Parts 42 and 43 Possession, Use, and Transfer of Select Agents and Toxin; Final Rule; and the Department of Agriculture's Animal and Plant Health Inspection Service: 7 CFR Parts 331 and 9 CFR Parts 121, Agricultural Bioterrorism Protection Act of 2002: Possession, Use, and Transfer of Biological Agents and Toxin; Final Rule. These regulations require institutions that possess, use, or transfer certain biological agents and toxins ("select agents") to be registered and approved by DHHS and/or APHIS.
- U.S. Department of Agriculture, Animal and Plant Health Inspection Service, and Veterinary Services: USDA, APHIS, and VS regulate the importation of animals and animal-derived materials to ensure that exotic animal and poultry diseases are not introduced into the United States. Generally, a USDA veterinary permit is needed for materials derived from animals or exposed to animal-source materials. Materials that require a permit include animal tissues, blood, cells or cell lines of livestock or poultry origin, RNA/DNA extracts, hormones, enzymes, monoclonal antibodies for in vivo use in non-human species, certain polyclonal antibodies, antisera, bulk shipments of test kit reagents, and microorganisms, including bacteria, viruses, protozoa, and fungi. Exceptions to this requirement are human and nonhuman primate tissues, serum, and blood.
- Centers for Disease Control and Prevention: The CDC has established specific regulatory requirements for importation or transportation of etiologic agents, which include a permit application that must be submitted and approved prior to any such importations. The federal regulation governing the importation of etiologic agents is USPHS 42 CFR - Part 71 Foreign Quarantine. Part 71.54, Etiologic agents, hosts, and vectors.

Roles and Responsibilities

Faculty and Investigators are directly and primarily responsible for the safe operation of the laboratory. Their knowledge and judgment are critical in assessing risks and appropriately applying the recommendations in this Plan. Safety is a shared responsibility among all laboratory and support staff. Many resources exist to assist with these responsibilities, including the Institutional Biosafety Committee (IBC), Biological Safety Officer, and EHS Specialist.

The SR Research Scientist/CRO Coordinator

CRO Coordinator has the ultimate responsibility for the activities associated with the use of biological materials, associated devices, and the BSP. This individual has the important role of implementing and managing the BSP.

CRO Coordinator or his/her delegate is a member of the IBC. He/she should attend all committee meetings. In all programs involving the use of biological materials, the CRO Coordinator should be knowledgeable of the results or periodic audits, to ensure all activities comply with regulatory requirements and that all participants in the BSP conduct activities in a safe manner.

CRO Coordinator represents management and has the authority to delegate resources including personnel for the program and appropriate funds in a timely manner. This individual must be available to facilitate effective and immediate action on behalf of management, the IBC and the BSO, particularly in the event of an emergency. CRO Coordinator has the authority to make prompt decisions without having to consult with higher management officials, including the authority to take whatever action is necessary to ensure that all biosafety practices are in accordance with the regulations and conditions of the BSP.

CRO Coordinator is involved in selecting the chairperson and members of the IBC and the BSO, and defines the role, duties and responsibilities of each. This individual supports the IBC and the BSO, creating an atmosphere of cooperation and professionalism such that individuals feel comfortable raising biosafety concerns. A clear understanding that there is strong management support for and participation in the BSP enhances authority. Individuals should understand management's expectations regarding internal enforcement of BSP requirements and the consequences for non-compliance.

Dean/CRO Partner Supervisor

A Dean or CRO Partner Supervisor is responsible for encouraging compliance with safety, health and environmental practices and procedures in their schools or departments, respectively. Specifically, he or she shall:

- understand applicable regulations and see that requirements are met,
- enforce rules and regulations and take prompt, effective action when necessary,
- ensure compliance of principal investigators and other supervisory personnel with federal, state, and local regulations and university policies applicable to the department's work

Institutional Biological Safety Committee

The IBC is composed of such persons as the BSO, CRO Coordinator, and faculty and staff persons trained and experienced in the safe use of biological materials. The EHS Specialist is to serve as a consultant to the BSC and is a non-voting member. Membership on the IBC should represent each area of use within the facility. The primary responsibility of the IBC is to formulate policy and procedures related to the use of biohazardous agents, including: human pathogens, other infectious agents, and recombinant or synthetic nucleic acid molecules. As mandated by the NIH Guidelines, experiments involving human gene transfer, formation of transgenic plants or animals and the generation of recombinant or synthetic nucleic acid molecules must be reviewed and approved by the IBC.

CRO coordinator selects a chairperson for the committee based upon the recommendations of the faculty, staff, CRO partners, and BSO. This individual should have knowledge of BS issues, good leadership abilities, the authority and credibility by virtue of their position, and a desire to serve as chairperson, in order to facilitate the effectiveness of the IBC. The IBC establishes a charter to delegate its purpose and duties. Typically, the IBC establishes a quorum for meetings, as defined in the IBC charter. An acceptable quorum consists of at least one-half of the committee's voting members. The meeting frequency and content, as defined by the IBC charter, is sufficient to ensure that the BSP is operating in compliance with established procedures and regulations. The IBC maintains minutes of its meetings. The contents of minutes shall include, at a minimum, that which the IBC charter specifies.

Biological Safety Officer

The BSO (Rachel Berman at BRDG PRK, Mary Thoele at Meramec, Rachel Brandon-Struab, Katie Siech at Wildwood, and Virginia Naumann) is responsible for biosafety and compliance with regulations for the use of biologicals and associated devices. The BSO is a member of the IBC and works closely with the IBC and CRO Coordinator in implementing the BSP. The BSO ensures that participants in the BSP safely perform all biosafety activities according to approved policies and procedures, and that all regulatory requirements are satisfied. The BSO and his/her staff have full access to all activities involving the use of biologicals and associated devices. The BSO has the authority to terminate any activity in which health and safety appear compromised without consulting management or the IBC, if required.

The Biosafety Officer performs audits of all biological areas of use and individuals using biological materials to ensure that their work is in accordance with the regulations, and

policies and procedures. Specific duties and responsibilities of the BSO and his/her staff include:

- monitoring compliance with safety policies and procedures regarding potentially infectious and biohazardous materials
- assisting laboratory personnel in the selection of safe laboratory practices, equipment and controls
- providing technical guidance to all personnel on matters related to biological laboratory safety
- developing and conducting appropriate training programs to promote techniques for the safe handling and disposal of potentially infectious and biohazardous materials
- approving the use of biohazardous materials by PIs and sets safety criteria for the handling of those agents
- overseeing ordering and receipt of Select Agents, when necessary, as defined by the Department of Health and Human Services
- investigating all reported accidents which may result in personnel or environmental exposure to biohazardous materials
- coordinating the off-site treatment of infectious wastes
- responding to emergencies involving biohazardous materials
- attending all IBC meetings
- corresponding with all applicable regulatory agencies
- maintaining all required records

EHS Specialist

The EHS Specialist is to serve as a resource to the IBC and in short absences of the BSO, perform the biological safety officer responsibilities listed above as needed. The EHS Specialist is to ensure that a biological safety plan is in place and audit the program at least annually.

Principal Investigator or Faculty Member

A PI (or faculty member) is responsible for identifying potentially infectious and biohazardous materials and carrying out specific control procedures within their own laboratories. This responsibility may not be shifted to inexperienced or untrained personnel. A PI is also responsible for the instruction of students and staff in the potential hazards of biologically derived materials. All protocols involving work with potentially infectious agents must be submitted to the Biological Safety Officer for review and approval. Specifically, a PI has the responsibility to know and abide by the following rules:

- submit protocols involving work with potentially infectious agents, recombinant DNA, or Select Agents and/or Toxins to the Biological Safety Officer
- ensure that any research project using recombinant and/or synthetic nucleic acids be described in a protocol has been approved by the IBC
- coordinate the procurement of Select Agent and/or Toxins or biological materials requiring permits with the Biological Safety Officer
- maintain an accurate and thorough inventory for biological agents in the laboratory
- maintain an accurate and thorough Select Agent and/or Toxins inventory for the laboratory
- ensure that appropriate signage is used at the entrance(s) to and within the laboratory
- create and foster a laboratory environment that encourages open discussion of biosafety issues, problems, and modification of procedures
- ensure laboratory personnel have received all applicable training, if required, before working with biological agents
- train research personnel and students in lab specific protocols
- ensure laboratory personnel work in accordance to the university's BSP requirements
- ensure that Personal Protective Equipment (PPE) appropriate to the biohazardous agent(s) is available, is in good condition, and is utilized appropriately
- coordinate biological and infectious waste disposal with the EHS Specialist,
- notify the BSO if a laboratory-acquired infection is known or suspected
- stop work posing imminent danger
- implement corrective actions to prevent recurrence of BSP operating errors

Individual

The health and safety of each employee, CRO Partner, and student is extremely important, and the college fosters a safe learning environment. Individuals should bring their concerns to their supervisor, department head, BSO, IBC or the EHS specialist. Each individual is expected to be conscientious in assuming personal safety responsibility. Each individual is responsible for working safely and abiding by applicable safety guidelines. All individuals who might be exposed to biohazards in the course of their activities at the university shall:

- become familiar with the BSP and all laboratory procedures applicable to him/her,
- comply with safety guidelines and procedures required for the task(s) performed,
- report unsafe conditions to the PI, supervisor or the Biological Safety Officer,
- seek guidance from his/her PI, supervisor or the Biological Safety Officer when he/she is uncertain how to handle, store, or dispose of any hazardous or biohazardous material.

Ancillary Personnel

Ancillary personnel shall:

- ensure that he/she understands the designation of a biohazard symbol before entering a biological work or storage area
- obtain authorization from the laboratory supervisor or PI for initial entry into a posted biohazardous area
- notify the BSO and receive clearance prior to performing any maintenance involving plumbing, ductwork, or ventilation systems connected to biological work areas
- emergency response personnel must ensure that any action taken is appropriate for the level of hazard and inform the BSO of the response to an emergency involving biological materials

Biohazard Assessment/Communication

The Institutional Biosafety Committee (IBC) and the Biosafety Officer are responsible for conducting risk assessments of work with biohazardous materials including recombinant DNA/RNA, human materials, microorganisms, and biological toxins. Before acquiring these materials and beginning any work faculty and investigators must contact the Biosafety Officer to review the planned work and to determine what may need to be reviewed and approved by the IBC.

Communication of risks involved with work with biohazardous materials is done through a number of ways.

1. The Universal Biohazard Symbol is used to denote equipment and rooms where biohazardous materials are used and stored
2. Biosafety training is provided by for employees and students who work with biohazardous materials or have responsibilities that involve laboratory areas where biohazardous materials are used or stored
3. The PI/Faculty member is responsible for ensuring risks involved in handling biohazardous materials are communicated to his/her laboratory group

Select Agents

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Subtitle A of Public Law 107-188 (42 U.S.C. 262a), requires DHHS to regulate the possession, use, and transfer of biological agents or toxins (i.e., select agents and toxins) that could pose a severe threat to public health and safety. The Agricultural Bioterrorism Protection Act of 2002, Subtitle B of Public Law 107-188 (7 U.S.C. 8401), requires the USDA to regulate the possession, use, and transfer of biological agents or toxins (i.e., select agents and toxins) that could pose a severe threat to animal or plant health, or animal or plant products. These Acts require the establishment of a national database of registered entities and set criminal penalties for failing to comply with the requirements of the Acts. In accordance with these Acts, DHHS and USDA promulgated regulations requiring entities to register with the CDC or the APHIS if they possess, use, or transfer a select agent or toxin (42 CFR Part 73, 7 CFR Part 331, and 9 CFR Part 121). CDC and APHIS coordinate regulatory activities for those agents that would be regulated by both agencies ("overlap" select agents). The Attorney General has the authority and responsibility to conduct electronic database checks (i.e., the security risk assessments) on entities that apply to possess, use, or transfer select agents, as well as personnel that require access to select agents and toxins. The FBI, Criminal Justice Information Services Division (CJIS), has been delegated authority for conducting these security risk assessments. The regulations provide that, unless exempted, entities must register with CDC or APHIS if they possess, use, or transfer select agents or toxins. The current list of select agents and toxins is available on the CDC and APHIS Web sites (see below). The regulations set out a procedure for excluding an attenuated strain of a select agent or toxin and exemptions for certain products and for select agents or toxins identified in specimens presented for diagnosis, verification, or proficiency testing. The regulations also contain requirements to ensure that the select agents and toxins are handled safely and secured against unauthorized access, theft, loss, or release. For example, entities and their personnel must undergo a security risk assessment by CJIS as part of their registration; entities must limit access to select agents and toxins and develop and implement biosafety, security, and incident response plans. In addition, all select agents or toxins must be transferred in accordance with the regulations and any theft, loss, or release of a select agent or toxin must be reported to CDC or APHIS.

HHS and USDA Select Agents and Toxins
7CFR Part 331, 9 CFR Part 121, and 42 CFR Part 73

HHS SELECT AGENTS AND TOXINS

Abrin
Botulinum neurotoxins*
Botulinum neurotoxin producing species of *Clostridium**
Conotoxins (Short, paralytic alpha conotoxins containing the following amino acid sequence $X_1CCX_2PACGX_3X_4X_5X_6CX_7$)[1]
Coxiella burnetii
Crimean-Congo haemorrhagic fever virus
Diacetoxyscirpenol
Eastern Equine Encephalitis virus[3]
Ebola virus*
*Francisella tularensis**
Lassa fever virus
Lujo virus
Marburg virus*
Monkeypox virus[3]
Reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments (Reconstructed 1918 Influenza virus)
Ricin
Rickettsia prowazekii
SARS-associated coronavirus (SARS-CoV)
Saxitoxin
South American Haemorrhagic Fever viruses:
Chapare
Guanarito
Junin
Machupo
Sabia
Staphylococcal enterotoxins A,B,C,D,E subtypes
T-2 toxin
Tetrodotoxin
Tick-borne encephalitis complex (flavi) viruses:
Far Eastern subtype
Siberian subtype
Kyasanur Forest disease virus
Omsk hemorrhagic fever virus
Variola major virus (Smallpox virus)*
Variola minor virus (Alastrim)*
*Yersinia pestis**

OVERLAP SELECT AGENTS AND TOXINS

*Bacillus anthracis**
Bacillus anthracis Pasteur strain
Brucella abortus
Brucella melitensis
Brucella suis
*Burkholderia mallei**
*Burkholderia pseudomallei**
Hendra virus
Nipah virus
Rift Valley fever virus
Venezuelan equine encephalitis virus[3]

USDA SELECT AGENTS AND TOXINS

African horse sickness virus
African swine fever virus
Avian influenza virus[3]
Classical swine fever virus
Foot-and-mouth disease virus*
Goat pox virus
Lumpy skin disease virus
Mycoplasma capricolum[3]
Mycoplasma mycoides[3]
Newcastle disease virus[2,3]
Peste des petits ruminants virus
Rinderpest virus*
Sheep pox virus
Swine vesicular disease virus

USDA PLANT PROTECTION AND QUARANTINE (PPQ) SELECT AGENTS AND TOXINS

Peronosclerospora philippinensis (Peronosclerospora sacchari)
Phoma glycinicola (formerly Pyrenochaeta glycines)
Ralstonia solanacearum
Rathayibacter toxicus
Sclerophthora rayssiae
Synchytrium endobioticum
Xanthomonas oryzae

*Denotes Tier 1 Agent

[1] C = Cysteine residues are all present as disulfides, with the 1st and 3rd Cysteine, and the 2nd and 4th Cysteine forming specific disulfide bridges; The consensus sequence includes known toxins α-MI and α-GI (shown above) as well as α-GIA, Ac1.1a, α-CnIA, α-CnIB; X1 = any amino acid(s) or Des-X; X2 = Asparagine or Histidine; P = Proline; A = Alanine; G = Glycine; X3 = Arginine or Lysine; X4 = Asparagine, Histidine, Lysine, Arginine, Tyrosine, Phenylalanine or Tryptophan; X5 = Tyrosine, Phenylalanine, or Tryptophan; X6 = Serine, Threonine, Glutamate, Aspartate, Glutamine, or Asparagine; X7 = Any amino acid(s) or Des X and; "Des X" = "an amino acid does not have to be present at this position." For example, if a peptide sequence were XCCHPA then the related peptide CCHPA would be designated as Des-X.

[2] A virulent Newcastle disease virus (avian paramyxovirus serotype 1) has an intracerebral pathogenicity index in day-old chicks (Gallus gallus) of 0.7 or greater or has an amino acid sequence at the fusion (F) protein cleavage site that is consistent with virulent strains of Newcastle disease virus. A failure to detect a cleavage site that is consistent with virulent strains does not confirm the absence of a virulent virus.

[3] Select agents that meet any of the following criteria are excluded from the requirements of this part: Any low pathogenic strains of avian influenza virus, South American genotype of eastern equine encephalitis virus , west African clade of Monkeypox viruses, any strain of Newcastle disease virus which does not meet the criteria for virulent Newcastle disease virus, all subspecies Mycoplasma capricolum except subspecies capripneumoniae (contagious caprine pleuropneumonia), all subspecies Mycoplasma mycoides except subspecies mycoides small colony (Mmm SC) (contagious bovine pleuropneumonia), and any subtypes of Venezuelan equine encephalitis virus except for Subtypes IAB or IC, provided that the individual or entity can verify that the agent is within the exclusion category. 9/10/13.

The BSO and EHS Specialist must ensure that appropriate permits and controls are in place, and on file, prior to allowing acquiring select agents.

NIH Guidelines/Exemptions

The NIH Guidelines are applicable to all recombinant or synthetic nucleic acid research within the United States (U.S.) or its territories that is within the category of research involving:

- Research that is conducted at or sponsored by an institution that receives any support for recombinant or synthetic nucleic acid research from NIH, including research performed directly by NIH. An individual who receives support for research involving recombinant or synthetic nucleic acids must be associated with or sponsored by an institution that assumes the responsibilities assigned in the NIH Guidelines
- Research that involves testing in humans of materials containing recombinant or synthetic nucleic acids developed with NIH funds, if the institution that developed those materials sponsors or participates in those projects. Participation includes research collaboration or contractual agreements, not mere provision of research materials
- Research supported by NIH funds
- Research that involves testing in humans of materials containing recombinant or synthetic nucleic acids developed with NIH funds, if the institution that developed those materials sponsors or participates in those projects. Participation includes research collaboration or contractual agreements, not mere provision of research materials

The lease at the Danforth Center contractually binds STLCC to follow NIH Guidelines.

Provided that the experiment does not:

- Contain DNA from Risk Group 3, 4, or restricted organisms or cells known to be infected with these agents
- Involve whole plants regenerated from plant cells and tissues cultures that do not remain axenic cultures
- Are not large-scale experiments (more than 10 liters of volume in a single culture vessel)
- Deliberately introduce gene coding for the biosynthesis of molecules that are toxic for vertebrates with an LD50 greater than 100 nanograms/kg but less than or equal to 100 micrograms/kg

The following molecules are exempt from NIH Guidelines:

- For synthetic nucleic acids, those that: (1) can neither replicate nor generate nucleic acids that can replicate in any living cell (e.g., oligonucleotides or other synthetic nucleic acids that do not contain an origin of replication or contain elements known to interact with either DNA or RNA polymerase), and (2) are not designed to integrate into DNA and (3) do not produce a toxin that is lethal for vertebrates at an LD50 of less than 100 nanograms per kilogram body weight. If a synthetic nucleic acid is deliberately transferred into one or more human research participants it is not exempt
- Molecules that are not in organisms, cells, or viruses and that have not been modified or manipulated (e.g., encapsulated into synthetic or natural vehicles) to render them capable of penetrating cellular membranes
- Molecules that consist solely of the exact recombinant or synthetic nucleic acid sequence from a single source that exists contemporaneously in nature
- Molecules that consist entirely of nucleic acids from a prokaryotic host, including its indigenous plasmids or viruses when propagated only in that host (or a closely related strain of the same species), or when transferred to another host by well-established physiological means
- Molecules that consist entirely of nucleic acids from a eukaryotic host including its chloroplasts, mitochondria, or plasmids (but excluding viruses) when propagated only in that host (or a closely related strain of the same species).
- Molecules that consist entirely of DNA segments from different species that exchange DNA by known physiological processes, though one or more of the segments may be a synthetic equivalent
- Genomic DNA molecules that have acquired a transposable element, provided the transposable element does not contain any recombinant and/or synthetic DNA
- Molecules that do not present a significant risk to health or the environment as determined by the NIH Director, with advice from the RAC and public comment

Blood borne Pathogens

Blood borne pathogens are microorganisms such as viruses and bacteria that may be present in human blood and other human-derived materials such as, but not limited to, human cell lines, blood components, body fluids, tissues and organs. All work with human materials is covered by the Occupational Safety and Health Administration (OSHA) Blood borne Pathogen Standard and College Blood Born Exposure Plan. The requirements of the plan address items such as: universal precautions, engineering and work practice controls, personal protective equipment, housekeeping, hepatitis B vaccination, post-exposure follow-up, hazard communication and training, and recordkeeping.

All employees who work with human materials will be offered the Hepatitis B vaccination free of charge. They may accept or decline, and if they initially decline they may change their mind at a later time and receive the vaccination free of charge.

All employees and students that work with human materials in a laboratory setting or have the potential for occupational exposure through job duties must receive initial training and annual retraining. Contact the EHS Specialist for training.

Risk Assessment

Risk assessment is a process used to identify the hazardous characteristics of a known biological agent or materials, the activities that can result in a person's exposure to the agent or material, the likelihood that such exposure will cause a laboratory acquired infection, and the probable consequences of such an infection. The information identified by the risk assessment will provide a guide for the selection of appropriate biosafety levels and microbiological practices, safety equipment, and facility safeguards that can prevent laboratory acquired infection. The risk assessment process is the responsibility of the laboratory investigators and laboratory supervisors, with assistance from the Biosafety Officer and Institutional Biosafety Committee.

Faculty, researchers, and laboratory supervisors should use risk assessment to alert their students and employees to the hazards of working with infectious agents and to the need for developing proficiency in the use of selected safe practices and containment equipment. Successful control of hazards in the laboratory also protects persons not directly associated with the laboratory, such as other occupants of the same building, and the public. The primary factors to consider in risk assessment and selection of precautions fall into two broad categories: agent hazards and laboratory procedure hazards. In addition, the capability of the laboratory staff to control hazards must be considered. This capability will depend on the training, technical proficiency, and good habits of all members of the laboratory, and the operational integrity of containment equipment and facility safeguards.

Registration and Approval Process

Faculty and researchers planning to carry out research using recombinant or synthetic nucleic acid molecules and/or biologically hazardous/infectious materials that pose a potential risk to the health of humans or animals, either directly through infection or indirectly through damage to the environment, must submit proposals for review and approval by the IBC prior to starting work.

New Protocol

A new protocol form shall be submitted to the biological safety officer. IBC approval is good for 3 years. All proposed deviations from the protocol as initially approved; changes in

laboratory location; changes in laboratory staff working on the project; and any project titles to be added must be included on the renewal form.

If there are significant deviations from the protocol, especially deviations that affect the containment level (i.e., new study organisms, a new host-vector-donor system, or any other modifications that may affect the containment level), the IBC may ask to seek an additional approval to cover the additional experiments.

Protocol Amendments

All changes should be detailed on the amendment form, for review and approval. Lab space additions approval applies only to work performed in registered lab space. For personnel changes, individuals must be trained in lab techniques and have completed necessary trainings.

If technical changes are extensive, the IBC may require a completely new application. A change in staff also requires full committee review. The new staff must attach his or her CV (two-page NIH format) to the amendment.

Biosafety Levels and Risk Groups

The World Health Organization (WHO) and CDC have recommended an agent risk group classification for laboratory use that describes four general risk groups based on principal characteristics and the route of transmission of the natural disease. The four groups address the risk to both the laboratory worker and the community. The *NIH Guidelines* established a comparable classification and assigned human etiological agents into four risk groups on the basis of hazard. The descriptions of the WHO/CDC and NIH risk group classifications are presented below in Table 1. They correlate with but do not necessarily equate to biosafety levels. The risk assessment will determine the degree of correlation between an agent's risk group classification and biosafety level.

Biological Agent Classification

Biological agent classification is possible through risk assessment. Features of microorganisms as well as host and environmental factors that influence the potential for individuals to have a biohazard exposure are identified to evaluate risk. The following factors are considered when evaluating the risk of a particular agent and/or operation:

- Pathogenicity: The more severe the potentially acquired disease, the higher the risk
- Route of transmission: Agents transmitted by aerosol route have been known to cause the most laboratory- acquired infections. The greater the aerosol potential, the higher the risk of infection
- Agent stability: The greater the potential for an agent to survive in the environment, the higher the risk of infection

- Infectious dose: The amount of an infectious agent needed to cause infection varies among individuals and can range from one to hundreds of organisms. The infectious dose is also influenced by the individual's immune status. The lower the infectious dose, the higher the risk
- Concentration: In most cases, the risk increases as the concentration of microorganisms increases
- Origin: In some cases, the geographic location or nature of the source can increase the risk of infection
- Availability of data from animal studies: If human data is not available, information on the pathogenicity, infectivity, and route of exposure from animal's studies may be valuable. Caution must be used when translating infectivity data from one species to another
- Availability of an effective prophylaxis or therapeutic intervention: Effective vaccines, if available, should be offered to laboratory personnel in advance of their handling of infectious material. However, immunization does not replace engineering controls, proper practices and procedures and the use of PPE. The availability of post-exposure prophylaxis should also be considered

The National Institute of Health (NIH) has utilized the above mentioned risk analysis approach and defined four Risk Group categories as presented in Table 11. In the cases where the hazard is unknown, a higher risk level is assigned.

The requirements for these biosafety levels are summarized in Table 2.

Table 1: Risk Group Classifications for Biological Agents

Risk Group Classification	NIH Guidelines for Research Involving Recombinant DNA Molecules	World Health Organization (WHO) /CDC
Risk Group 1 (e.g. E. coli K12)	Agents not associated with disease in healthy adult humans.	No or low individual and community risk. A microorganism unlikely to cause human or animal disease.
Risk Group 2 (e.g.*Streptococcus pyogenes*)	Agents associated with human disease that is rarely serious and for which preventive or therapeutic interventions are *often* available.	Moderate individual risk and low community risk. A pathogen that can cause human or animal disease but is unlikely to be a serious hazard to laboratory workers, the community, livestock or the environment. Laboratory exposures may cause serious infection, but effective treatment and preventive measures are available and the risk of spread of infection is limited.
Risk Group 3 (e.g. *Francisella tularensis*)	Agents associated with human disease that is rarely serious and for which preventive or therapeutic interventions are *often* available.	High individual risk and low community risk. A pathogen that usually causes serious human or animal disease but does not ordinarily spread from one infected individual to another. Effective treatment and preventive measures are available.
Risk Group 4 (e.g. Ebola Virus)	Agents likely to cause serious or lethal human disease for which preventive or therapeutic interventions are not usually available.	High individual and community risk. A pathogen that usually causes serious human or animal disease and can be readily transmitted from one individual to another, directly or indirectly. Effective treatment and preventive measures are not usually available.

A fundamental objective of any biosafety program is the containment of potentially harmful biological agents. The term “containment” is used in describing safe methods, facilities and equipment for managing infectious materials in the laboratory environment where they are being handled or maintained. The purpose of containment is to reduce or eliminate exposure of laboratory workers, other persons, and the outside environment to potentially hazardous agents. The use of vaccines may provide an increased level of personal protection. The risk assessment of the work to be done with a specific agent will determine the appropriate combination of these elements.

Labels and Signs

The Universal Biohazard Symbol is utilized on door signage, as well as stickers found on laboratory equipment, to denote a biological hazard. All rooms that contain biohazardous agents must be posted with the Universal Biohazard Symbol, the biosafety level, lab contact number, and agents contained in the lab. The background must be red/orange in color with a black universal biohazard symbol and black lettering.

The form below can be used as a template.

Biological Safety Signage Template

Biosafety Level: _____

Biological Agents Present: _____

Contact Phone Number: _____

After Hours Phone Number: _____

All equipment (centrifuges, water baths, refrigerators/freezers, incubators, etc.) that comes in contact with biohazardous materials must be labeled with the universal biohazard symbol.

Biosafety Level Requirements

CDC and NIH have established four levels of biosafety, based on the degree of hazard associated with a microbial agent, to describe the combination of laboratory practices and techniques, safety equipment, and facilities needed to protect against exposure. These four different biological safety levels are appropriate for the operations performed in a laboratory, the documented or suspected routes of transmission of the biological agent, and the laboratory function or activity. These four biosafety levels (BSL) require successively more stringent practices and facilities as work moves from the least restrictive, BSL-1, to work with the highest hazard level of BSL-4 (Contact the EHS Specialist for BSL-4 work). Exposure to biohazards may be prevented or limited by establishing and following the appropriate biosafety level practices and conditions. The requirements for each laboratory biosafety level are outlined in the tables below:

Table 2- Biological Safety Level Requirements Summary

Biosafety levels (BSL)	BSL–1	BSL–2	BSL–3
1. Access to the laboratory	Access does not have to be restricted – however, doors cannot be propped open (in violation of fire code).	Doors to the laboratory are closed when BSL-2 work is being conducted to prevent public access.	Doors to the laboratory are closed and locked to prevent untrained personnel access.
2. Biohazard signage	No biohazard sign is required.	Biohazard sign must be posted.	Biohazard sign must be posted.
3. Class II Biological safety cabinet (with annual certification)	Not required.	Required for all aerosol generating processes	Required for all work. Room itself should be under negative pressure.
4. Sealed rotors or safety cups for centrifuging	Not required.	Required for high concentrations or large volumes of infectious agents. Exception: Centrifuges without secondary containment can be operated inside a certified biosafety cabinet.	Required for all work.
5. Laboratory coats	Required.	Required.	Required (solid front disposable gown). Don and doff in separate gowning room.
6. Gloves (alternatives to latex gloves should be available)	Required.	Required.	Required. Don and doff in separate gowning room.

Biosafety levels (BSL)	BSL–1	BSL–2	BSL–3
7. Eye protection (safety glasses, goggles)	Required. This includes work in the biosafety cabinet.	Required. This includes work in the biosafety cabinet.	Required. This includes work in the biosafety cabinet.
8. Sleeve protectors	Not required.	Recommended.	Required
9. Eating, drinking, application of cosmetics or contact lenses	Permitted only in designated clean areas.	Permitted only in designated clean areas. Not permitted if Aerosol Transmissible Disease Pathogens are used.	Not permitted at any time.
10. Contaminated sharps (e.g., needles, blades, glass)	Safe handling practices must be developed and implemented. Substitute plastic ware for glassware whenever possible.		
11. Decontamination of work surfaces	Daily, after finishing work and following spills.		
12. Pipetting	Mechanical device – no mouth pipetting.		
13. Storage of biohazardous waste material	Double red bags held in rigid, leak-proof containers with biohazard labels on the top and side. Biohazardous waste must be under direct control of the responsible laboratory until it is placed in the storage area.		
14. Handwashing	Required after working with potentially hazardous materials and before leaving the laboratory. BSL 3 should have elbow or foot operated sink.		

Biosafety levels (BSL)	BSL–1	BSL–2	BSL–3
15. Training	The laboratory supervisor must ensure that laboratory personnel receive appropriate training regarding their duties, the necessary precautions to prevent exposures, and exposure evaluation procedures.		
16. Medical surveillance	Recommended where personal health status may result in increased susceptibility to infection or inability to receive vaccinations or prophylactic interventions.	Required. Laboratory personnel must be provided with medical surveillance and offered appropriate immunizations.	
17. Equipment decontamination	Equipment must be cleaned of residues before repair, maintenance, or removal from laboratory.	Equipment must be decontaminated before repair, maintenance, or removal from laboratory. No rugs or cloth backed chairs.	
18. Animals and plants (Including cells) not associated with the work	Allowed if approved by IBC.	Not allowed in the laboratory.	

Audits and Inspections

Periodic internal audits and inspections of work areas including laboratories are conducted by the Environmental Health and Safety Specialist. They may be prearranged or unannounced. The purpose of these internal activities is to identify areas of non-compliance and remediate them quickly. In addition, local, state and federal regulatory agencies with jurisdiction over the college may make prearranged or unannounced inspections. Therefore, it is important that anyone who observes a potential non-compliance situation or unsafe condition reports the information to the Environmental Health and Safety Specialist.

Training

Biosafety training is required by a number of biosafety regulations and guidelines. All employees and students who work with human materials must have Blood borne Pathogens Training. To schedule training, contact the Environmental Health and Safety Specialist.

Medical Surveillance

Research with certain biological agents may require medical surveillance. Medical surveillance is the term use to describe the program that has been implemented to help assure the health of employees and students who have potential workplace exposures to hazards including, but not limited to, animal allergens, biohazardous materials, and high noise levels. All projects involving work with biological agents must be reviewed by the Biosafety Officer, prior to beginning work. A project registration and approval by the Institutional Biosafety Committee may also be necessary.

The medical surveillance program is coordinated Environmental Health and Safety Specialist. Participants typically complete a health history questionnaire and may also receive a medical examination by a licensed physician. These screenings are used to establish a baseline of the participant's health. Periodic future assessments are compared to the baseline to monitor potential occupational exposures. In some cases, vaccinations may be recommended. For example, the Hepatitis B vaccination is recommended for all employees who have potential occupational exposures to human blood or other potentially infectious materials.

Injury Involving Biological Material

All injuries and illnesses that result from, or may lead to, exposure to biological materials must be reported to campus police. Suspected exposures and "Near Misses" must also be reported. Near Misses are defined as unplanned occurrences that did not lead to an injury

or exposure but could have. For example, if a researcher is splashed with a culture of an infectious organism, but is wearing sufficient personal protective equipment that no skin or mucous membrane contact was made, this event would be considered a “Near Miss.”

For injuries involving sharps, such as needles and razor blades, in a laboratory or health clinic setting, a log known as the Sharps Log is completed. The Sharps Log is used for recording percutaneous injuries from contaminated sharps. The Sharps Log must contain, at a minimum, information about the injury, the type and brand of device involved in the injury (if known), the department or work area where the exposure occurred, and an explanation of how the incident occurred. The log must be recorded and maintained in such a manner so as to protect the confidentiality of the injured employee (e.g., removal of personal identifiers). The EHS Specialist keeps and maintains the sharp log.

The IBC will meet and explore opportunities to enhance biological safety after each near miss or injury.

UV Lights

Ultraviolet (UV) lights are used in a variety of laboratory applications. UV lights may be found as an accessory within a biological safety cabinet (BSC). UV lights may also be used to visualize gels or to induce DNA damage. UV light is hazardous to humans and can cause burns to skin and eyes with as little as a few seconds of exposure.

Prior to purchasing a new BSC, it is important to review the need for a UV light with the Biological Safety Officer and to purchase a BSC that has a sash interlock. Older models of BSC’s that may not have a sash interlock to disconnect the UV light when the sash is opened should be reported to the Biological Safety Officer for review. A UV light in a BSC is never a substitute for thorough cleaning and disinfection with a chemical disinfectant such as 70% ethanol or a freshly prepared solution of sodium hypochlorite (bleach).

Use of UV lights for other laboratory applications must be conducted with the appropriate personal protective equipment to shield skin and eyes from UV exposure. At a minimum, a lab coat, gloves, and a UV-rated face shield should be worn.

Autoclave Use

An autoclave is a piece of laboratory equipment that uses high pressure and high temperature steam to sterilize materials such as microbiological media and glassware. It may also be used to sterilize biohazardous waste.

The use of an autoclave to sterilize biohazardous and sharps waste is regulated by the State of Massachusetts. All autoclaves used for this purpose must be periodically validated through the use of biological indicators. Biological indicators use thermophilic bacteria,

typically *Geobacillus stearothermophilus*, to verify that cycle time and temperature are adequate to kill microorganisms that may be present in the waste.

When using an autoclave, it is important to remember that interior and exterior surfaces may be very hot. Therefore, wear appropriate heat-resistant protective equipment and allow the contents to cool prior to removing them from the autoclave.

Disinfection and Decontamination

There is no such thing as a “Universal Disinfectant”. All chemical disinfectants have pros and cons. For example, 70% ethanol is an effective disinfectant for some biological agents, does not leave a residue, but is flammable.

Disinfection is the process of applying a product directly to a surface or object to destroy or irreversibly inactivate most pathogenic microorganisms, but not usually bacterial or fungal spores. Disinfection reduces the level of microbial contamination to an acceptably safe level. Decontamination renders an area, device, item or material safe to handle, and may be accomplished through the process of cleaning with soap and water, disinfection or sterilization.

All work areas and equipment where biological materials have been used should be wiped down with an effective disinfectant after use and after any spills or contamination incidents. The tables below should be used for selecting the appropriate disinfectant:

DISCINFECTANT ACTIVITY											
Disinfectants		**Practical Requirements**					**Inactivates**				
Type	Category	Use Dilution	Contact Time (min) Lipovirus	Contact Time (min) Broad Spectrum	Temperature (C^{o})	Relative Humidity (%)	Vegetative Bacteria	Lipoviruses	Nonlipid Viruses	Mycobacteria	Bacterial Spores
Liquid	Quaternary Ammonia Compounds	0.1%-2.0%	10	NE			+	+			
	Phenolic Compounds	1.0%-5.0%	10	NE			+	+	B		
	Chlorine Compounds	500 ppm*	10	30			+	+	+	+	+
	Iodophor	25-1600 ppm*	10	30			+	+	+		
	Alcohol, Ethyl	70%-85%	10	30			+	+	B		
	Alcohol, Isopropyl	70%-85%	10	30			+	+	B		
	Formaldehyde	0.2%-8.0%	10	30			+	+	+	+	+
	Glutaraldehyde	2%	10	30			+	+	+	+	+
Gas	Ethylene Oxide	8-23g/ft^3	60	60	37	30	+	+	+	+	+
	Paraformaldehyde	0.3 g/ft^3	60	60	>23	60	+	+	+	+	+

NE=not effective
B=Variable results dependent on virus
*=Available halogen (1:100)

DISINFECTANT CHARACTERISTICS												
Disinfectants		**Important Characteristics**										
Type	Category	Effective Shelf Life >1 week (A)	Corrosive	Flammable	Explosion Potential	Residue	Inactivated by Organic Matter	Compatible for Optics (D)	Skin Irritant	Eye Irritant	Respiratory Irritant	Toxic (E)
Liquid	Quaternary Ammonia Compounds	+					+	+	+	+		+
	Phenolic Compounds	+	+			+			+	+		+
	Chlorine Compounds		+			+	+		+	+	+	+
	Iodophor	+	+			+	+		+	+		+
	Alcohol, Ethyl	+		+						+		+
	Alcohol, Isopropyl	+		+						+		+
	Formaldehyde	+				+			+	+	+	+
	Glutaraldehyde	+				+		+	+	+	+	+
Gas	Ethylene Oxide	N/A		+(B)	+(B)			+	+	+	+	+
	Paraformaldehyde	N/A		+(C)	+(C)			+	+	+	+	+

N/A=not applicable (A)=Protected from light and air (B)=Neither flammable nor explosive in 90% CO_2 or fluorinated hydrocarbon, the usual form (C)=At concentrations of 7%-73% by volume in air, solid exposure to open flame (D)=Usually compatible but consider interferences from residues and effects on associated materials such as mounting (E)=By skin or mouth, or both. Refer to manufacturer's literature and the MSDS.

DISINFECTANT APPLICATIONS												
Disinfectants		**Important Characteristics**										
Type	Category	Work Surface	Dirty Glassware	Large Area	Air Handling	Portable Equip. Surface Decon	Portable Equip. Penetrating Decon	Fixed Equip. Surface Decon	Fixed Equip. Penetrating Decon	Optical & Electronic Inst.	Liquid & Discard	Book, Paper
Liquid	Quaternary Ammonia Compounds	+	+			+		+				
	Phenolic Compounds	+	+			+		+				
	Chlorine Compounds	+	+			+		+			+	
	Iodophor	+	+			+		+				
	Alcohol, Ethyl	+	+			+		+				
	Alcohol, Isopropyl	+	+			+		+				
	Formaldehyde	+	+			+		+				
	Glutaraldehyde	+	+			+		+				
Gas	Ethylene Oxide					+	+			+		+
	Paraformaldehyde			+	+	+	+		+	+		

Spill Management

Spill kits should be readily available in all areas where biohazardous materials are used. Contact the Environmental Health and Safety Specialist for instructions on what items to obtain for the spill kit.

BSL 1 Cleanup:

1. Notify and evacuate others in the area, to prevent contamination of additional personnel and the environment
2. Wearing: gloves, shoe covers, lab coat, and face protection cover spill with paper towels/absorbent pads
3. Pour concentrated disinfectant (Bleach) around the spill allowing it to mix with spilled material
4. Allow suitable contact time (15-30 minutes).
5. Pick up any pieces of broken glass with forceps and place in a sharps container.
6. Discard all disposable materials used to clean up the spill into a biohazard bag.
7. Remove any contaminated clothing and wash exposed skin with disinfectant

BSL 2 Cleanup:

1. Notify and evacuate others in the area, to prevent contamination of additional personnel and the environment. If spill is on an individual remove their contaminated clothing, turn it inward, and place the clothing into a biohazard bag. Get medical attention for exposed individuals
2. Close the lab area, post a warning sign, and wait 30 minutes for aerosols to dissipate. Gather and prepare spill cleanup materials
3. Wearing: gloves, shoe covers, lab coat, and appropriate respirator/surgical mask
4. Pour concentrated disinfectant (Bleach) on pads/towels and place on spill area. Pour additional disinfectant around the spill allowing it to mix with the spilled material
5. Allow at least 30 minutes of contact time with the disinfectant
6. Pick up any pieces of broken glass with forceps and place in a sharps container. Using a disinfectant decontaminate the lab area where it may have splashed by wiping all surfaces. Discard all disposable materials used to clean up the spill into a biohazard bag.
7. Spray area with 10% bleach solution and allow it to air dry
8. Remove any contaminated PPE and wash exposed skin with disinfectant

BSL 3 and 4 Cleanup:

1. Notify others and evacuate from the area, to prevent contamination of additional personnel and the environment. If spill is on an individual remove their contaminated clothing, turn it inward, and place the clothing into a biohazard bag. Get medical treatment for exposed individuals

2. Close the lab
3. Set up area directly outside of the lab to decontaminate individuals
4. Wearing: A fully encapsulated suite and appropriate respirator remove contaminated clothing from affected persons.
5. Have campus police contact 911. Do not allow individuals who were contaminated to leave the scene until the authorities clear indicate they can leave
6. Remove PPE at zone in front of lab and wash/shower in the decontamination zone
7. Contact the EHS specialist for decontamination procedures. The lab is to remain closed until decontaminated.

If a spill involved non NIH exempt materials the Biological Safety Officer will work with the Principal Investigator to collectively complete the NIH OBA Template for Reporting Incidents Involving Recombinant DNA at http://oba.od.nih.gov/rdna_ibc/ibc_faq.html if the recombinant DNA/biohazardous spill resulted in:

- overt personnel exposure at Biosafety Level 2 and/or Animal Biosafety Level 2 ,
- overt or potential exposure in the Biosafety Level 3 and/or Animal Biosafety Level 3 laboratories outside of a biosafety cabinet,
- a violation of the NIH Guidelines containment or biosafety practices, or significant problems leading to a breach of containment (including escape or improper disposal of a transgenic animal) and/or
- a significant-research-related accident or illness.

In conjunction with the IBC Chairperson and the Biological Safety Officer will submit the final incident report to the EHS Specialist and after review by chief legal counsel will file the report with the respective federal agency on behalf of the college. The final incident report will be reviewed by the IBC and corrective actions recommended and instituted as necessary.

Emergency Eyewash and Drench Shower

Emergency eyewash and drench showers are located in areas where hazardous materials are used or stored. They must be kept accessible at all times. Do not store materials under or around the eyewash and drench shower as they may block access during an emergency situation. The emergency eyewash and drench showers are checked periodically (Weekly/monthly) by facilities staff or the Biological Safety Officer. Promptly report any malfunctions to facilities.

In the event that an exposure occurs to a hazardous material such as but not limited to a biohazardous material, quickly move to the eyewash or shower area. Inform others of the situation and ask for assistance and have someone report the event to campus police. If there is an exposure to the eye, activate the eyewash and rinse for 15 minutes. If there is an exposure to the body, activate the shower and rinse for 15 minutes, removing clothing as necessary.

Waste Management

The facility is a conditionally exempt small quantity generator under RCRA. The requirements for chemical waste are:

Must perform and document waste determinations

- Must manage accumulated waste so that they do not exceed the 100 kg limit non-acute/1 kg acutely hazardous waste limit
- Must label waste
- Must use a licensed transporter to haul waste to a licensed waste disposal facility
- Must keep LDR documents or equivalent records

The BRDGPRK facility produces biological, pathological, or medical waste. Protocols outlined in the College Blood borne Pathogen Exposure Control Plan must be followed to safely dispose of biological or blood borne pathogens and sharps. The following procedures will be followed for packaging biological, pathological and medical waste disposal:

Sharps

- All sharps, including but not limited to needles, syringe, lancets and blades, shall be disposed of in one time use sharps containers
- When a sharps container is full it shall be placed in the MedAssure Package

Medical Waste

- All medical waste shall be placed in red biohazard bags
- All biohazard bags shall be placed in the MedAssure Package

These wastes are regulated by the Department of Transportation as UN3291 Regulated Medical Waste. This waste is picked up through Med Assure. Follow the package instructions for filling the Med Assure tub. If DOT certified, for function specific Regulated Medical Waste, you may sign for the pick-up of these materials. Access to the electronic manifest system will be requested after completion of DOT training.

Appendix I- IBC Protocol Approval Form

Institutional Biosafety Committee
Biological Agent/Toxin Protocol Form

Complete this application to register and obtain approval for use of a biological agent/toxin in research or teaching projects. This information can be submitted at any time. Application must beresubmitted when there is a change made to the proposed work. Please do not hesitate to contact the Biosafety Officer or members of the IBC concerning any policy or procedure.

New Submission ☐ Teaching Purposes ☐ Previous IBC # ☐____

Principal Investigator_____Phone_____

Laboratory/rooms where work will be performed_____E-mail _____

Project Title_____

Dates of Project: From_____To _____

1. Attach a concise scientific summary and rationale of the proposed study.
2. Name(s) of biological agent/toxin that will be used in this project:
   _____
3. Name of strains or isolates: _____
4. Where will the agent/toxin(s) be stored? (Bldg, Room) _____
5. Is the agent pathogenic to humans? Yes No
6. Will the project utilize human blood, body fluids or tissue? Yes No
7. Describe the sources of human tissue, blood or body fluids to be used in your project: _____
8. Human Risk Group_____*(Laboratories using Risk Group 3 agents must submit a laboratory safety and procedures manual and have it approved by the IBC prior to work with that agent).*
9. Is the agent pathogenic to animals? Yes No
10. Is the agent pathogenic to plants? Yes No
11. Is the agent antibiotic resistant? Yes No
12. Does the project involve or does the microorganism synthesize a toxic molecule lethal for vertebrates?
    Yes___ No ___ Not Known ___

    If yes, what toxin?
13. Is a USDA or CDC permit required for use of this agent? Yes No
14. Does the project generate > 10 liters of culture? Yes___ No___

15. What Biosafety Level (BL1, BL2 or BL3) will be used during this project? _____

16. **Provide laboratory protocols specific to this research**. Be sure to include the following information:

    a. Identification of potential exposure hazards during sample preparation and experimental manipulations. (e.g. aerosol generation when transferring, mixing or centrifuging, use of sharps, excretion by animals, etc.)

    b. Safety procedures that will be used to minimize risk and prevent release of infectious agents. (e.g. protective clothing, use of biological safety cabinet, sharps disposal procedures, waste disposal procedures, etc.)

    c. Methods to inactivate/decontaminate agent.

    d. Accidental spill/exposure procedures.

17. Identify personnel conducting the experiments (including students and temporary staff). Specify applicable training and experience including duration (e.g. 2 years), and project responsibilities. * New PIs must attach CV.

NAME	TRAINING/EXPERIENCE	PROJECT RESPONSIBILITIES

By signing below you are agreeing that all work on this project will be conducted using biosafety practices described in the CDC/NIH Publication entitled *Biosafety in Medical and Biomedical Laboratories (BMBL)* and following college policy and procedures. Work must not be conducted before IBC approval is granted.

As Principal Investigator, I hereby certify that prior to initiation of this project, all laboratory staff will be given the protocols that describe potential biohazards and precautions to be taken while working with this material. Laboratory staff involved in this project will be trained in laboratory practices and techniques to ensure safety of personnel and the environment. Personnel will be informed of procedures involving accidents and if medical surveillance is necessary. All laboratory staff will attend compliance training in applicable government rules and regulations.

Principal Investigator's Signature _____ Date: _____

Biological Safety Officer Signature _____ Date: _____

IBC Chairperson Signature: _____ Date: _____