GEORGIA INSTITUTE OF TECHNOLOGY BIOSAFETY MANUAL

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Laboratory-Specific Information:

Laboratory PI:
Lab Room #'s:
Infectious Materials in Use:
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Signature Page for Laboratory Personnel

Each lab member must sign below

By signing below I certify that:

- I have received lab-specific safety training on the biological materials listed on pg. 5
- I have read and understand the Georgia Tech Biosafety Manual and will abide by the policies set forth in that document.

Name	Signature	Date
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INTRODUCTION

Biosafety is an essential element of any institution that engages in biological laboratory work. The fundamental purpose of any biosafety program is to ensure "containment" of biological materials. The field of biosafety aims to ensure containment by assessing biological hazards and then mitigating that risk to laboratory personnel and to the overall community.

At the Georgia Institute of Technology (Georgia Tech, GT) safety is a team effort and a shared responsibility. Employees at all levels of the agency receive appropriate safety training and are actively engaged in ensuring a safe working environment, identifying potential hazards, conducting and reviewing risk assessments, and encouraging the reporting of incidents and near misses without any fear of reprisals. By reporting incidents and analyzing the root causes, response, and lessons learned, the practice of safety becomes a learning opportunity for the agency and other institutions.

This manual describes basic principles of biosafety that are applicable to biological laboratory work at Georgia Tech; it contains general information on biohazards and biosafety levels, the risk assessment process, outlines processes and procedures for conducting biological activities, and details emergency response actions. This manual is reviewed annually by the Biosafety Office to ensure that the information is accurate and timely.

The most current version of the GT Biosafety Manual can be found at the Environmental Health & Safety website.

Safe work practices and procedures must be adhered to at all times by all parties. Neither efficiency nor convenience shall be an excuse for deviating from safe work practices. Performing a task safely shall always take precedence over doing a task quickly. Anyone who endangers the health of a colleague or our community is subject to disciplinary action.

Biological Definitions

- 1. Biological Material microorganisms, cell lines, or any other biological samples known to be free of hazards to humans, animals, or the environment.
- 2. Biohazard infectious agents, or parts thereof, presenting a real or potential risk to the well-being of humans, other mammals, or plants hazardous to environmental safety directly through infection or indirectly through disruption of the environment; and venomous vertebrate or invertebrate animals, or toxins thereof, presenting a real or potential risk to humans.
- 3. Containment Reducing or eliminating exposure of laboratory workers and the community to harmful biological materials by implementing safe practices, facilities, and equipment
- 4. Restricted Mammalian Pathogens nonindigenous pathogens of domestic livestock and poultry that may require special containment strategies and facilities.
- 5. Infectious Biological Agents- include biological agents and biologically derived materials that present a risk or potential risk to the health of humans or mammals, either directly through infection or indirectly through damage to the environment. Categories of potentially infectious biological materials include the following:
 - a. Human, mammalian, and plant pathogens (bacteria, parasites, fungi, viruses)
 - b. All human blood, blood products, tissues, and certain body fluids (excluding routine use of human blood and body fluid for clinical purposes);
 - c. Cultured human or mammalian cells
 - d. Clinical specimens and waste
 - e. Infected mammals and mammalian tissues.

RESPONSIBILITIES

Georgia Institute of Technology

The Institute and its administrative officers are responsible for:

- 1. Endorsing appropriate policies, including this manual, regarding the conduct of potentially biohazardous research, education, and service activities.
- 2. Developing mechanisms for ensuring faculty and staff adherence to biosafety policies.
- 3. Providing the resources necessary for the construction of safe research and teaching facilities.
- 4. Provide the resources for the implementation of a comprehensive biosafety program.
- 5. Providing adequate resources for the dissemination of information on biohazards and biosafety procedures, including training programs and workshops.
- 6. Providing resources for appropriate medical surveillance measures to protect the health and safety of employees.

Environmental Health & Safety

The Environmental Health & Safety (EHS) office is responsible for:

- 1. Developing and implementing safety policies and practices on Georgia Tech's campus
- 2. Providing guidance and oversight for laboratory safety programs including biosafety, chemical safety, laser, and radiological safety.
- 3. Providing fire safety and general safety services
- 4. Processing and managing hazardous materials for proper disposal
- 5. Providing emergency assistance for hazardous materials incidents / accidents (spills)
- 6. Providing safety training

For EHS Contacts, Training information, GT Committee information, and more please visit the EHS website: www.ehs.gatech.edu

Biosafety Officer/Assistant Biosafety Officer

The Institute's Biosafety Officer has responsibility for the daily administration of biosafety standards set by the BMSC, IBC, and OHSC. Other responsibilities include:

1. Review of grant applications, ensuring research is properly approved by the appropriate committee and that the laboratory is compliant with biosafety policies.

- 2. Suspension of any experiment if there is an immediate threat to human health and safety from the experiment or other conditions in the laboratory by following the procedure described in Section II of this manual
- 3. Conducting initial and annual inspections of laboratories used in biohazardous research to ensure that standards set by the BMSC, IBC, and OHSC are followed
- 4. Providing technical advice to Principal Investigators and to the BMSC, IBC, and OHSC committees on research safety procedures
- 5. Developing and conducting trainings on biological materials for the Institute community
- 6. Providing technical advice to the Institute regarding biohazard safety needs and requirements for projects involving the renovation or construction of laboratory or other facilities in which biohazards will be used
- 7. Participating in committees involving biological safety

Biological Materials Safeguards Committee

- 1. Reviews for appropriateness and adequacy the containment levels and safety measures proposed and/or used in biohazardous research and teaching.
- 2. Assesses the adequacy of containment facilities for biohazards of select agents, pathogens, etiological agents, certain human samples, and other biological materials as required by regulatory agencies.
- 3. Develops, with the Biosafety Officer, training seminars and workshops on biohazards for the Institute community.
- 4. Periodically reviews biological research being conducted at the Institute to ensure that the requirements of the Institute, funding sources, and regulatory agencies are being fulfilled.
- 5. Recommends to the Institute Administration appropriate sanctions for non- compliance with biosafety standards, guidelines, or regulations.
- 6. Develops with the Biosafety Officer emergency plans covering accidental exposure and personnel contamination resulting from biohazardous research.

The chairman of the committee is selected by the Provost and the Executive Vice President for Administration and Finance. The chairman then selects committee members from Institute professors with bacterial, viral, and cell line expertise. The Biosafety Officer, Assistant Biosafety Officer and Assistant Vice President of EHS also serve on the committee for regulatory expertise for biosafety and select agents.

Institute Biosafety Committee

1. Reviews for appropriateness and adequacy the containment levels and safety measures proposed and/or used in rDNA research and teaching.

- 2. Periodically reviews rDNA research being conducted at the Institute to ensure that the requirements of the Institute, funding sources, and regulatory agencies are being fulfilled.
- 3. Reviews allegations of non-compliance with rDNA standards, guidelines, or regulations.
- 4. Develops, with the Biosafety Officer, emergency plans covering accidental exposure and personnel contamination resulting from rDNA research.

The minimum composition of the Institutional Biosafety Committee (IBC) is specified in the NIH "Guidelines for Research Involving Recombinant DNA Molecules". The IBC shall have at least 5 members selected to have expertise and experience in recombinant DNA technology and capable of assessing the safety of rDNA research experiments and any potential risks to public health and the environment. The IBC shall include at least 2 members who are not affiliated with the Institute by other than their committee membership. In addition, when experiments using mammals or plants require prior IBC approval, there shall be at least one (1) scientist with expertise in plant pathogens or plant pest containment and one (1) scientist with mammalian containment expertise on the IBC. The members of the IBC are appointed by the Vice Provost of Research and Innovation

Occupational Health and Safety Committee

- 1. Advises EHS on the development and administration of an Occupational Health Program (OHP).
- 2. Periodically reviews the OHP for effectiveness and compliance with safety regulations.
- 3. Reviews and develops other Institute occupational health policies for implementation of best management practices.
- 4. Reviews Institute incidents for areas of improvement to policy.

The committee is composed of members with expertise in occupational health, faculty, EHS staff members, healthcare professionals, and research compliance. The committee is appointed by the Executive Vice President of Business and Finance and the Provost.

Department/Unit Heads

Department/Unit Heads have the following responsibilities:

- 1. To ensure that, prior to initiation of work, each investigator or laboratory director using a biological agent files the appropriate committee applications and receives approval prior to initiation of research activities on campus.
- 2. To ensure that staff and students have had instruction in safety procedures in teaching laboratories or field situations where biohazardous agents are used.

- 3. To ensure that appropriate facilities and safety equipment are available for proposed research or instruction involving biohazardous agents.
- 4. To ensure that all faculty, staff, and students are following EHS policies, guidelines, and enrolls in the appropriate EHS programs.
- 5. To provide leadership in laboratory safety at the management level in the department.

Faculty and Professional Staff (Principal Investigators/Project Directors)

Developing and maintaining a healthy and safe work environment depends on the day-to-day supervision of research practices by personnel with a positive safety attitude. The Principal Investigator is ultimately responsible for setting the safety culture of their laboratories. The principal investigator (PI), laboratory director, project director, or teaching supervisor is responsible for knowing and complying fully with Georgia Institute of Technology Biosafety Manual and the General Laboratory Safety Manual. The principal investigator and/or laboratory supervisor shall:

- 1. Provide those personnel under his/her supervision with knowledge of biological materials to which they may be exposed and safety procedures to be followed. This is to be accomplished by:
 - a. The PI being knowledgeable of good laboratory safety practice and setting a positive safety attitude and culture for the lab.
 - b. Advising all laboratory members of the potential hazards they will encounter in the lab
 - c. Posting or making readily available to the laboratory staff copies of the protocols that describe potential biohazards and the precautions to be taken. These protocols, as well as biosafety concerns, should first be in the form of a well written proposal application and then translated into standard operating procures for each task in the laboratory.
 - d. Providing laboratory staff with formal and informal instruction and training in the practices and techniques required to ensure safety. This should include procedures for dealing with accidental spills, personnel contamination, and other laboratory accidents.
 - e. Supervising the performance of the staff to ensure that required safety practices and techniques are observed.
- 2. Report, via the <u>EHS Supervisor's Accident Reporting Form</u>, any accident, exposure, or suspected illness of laboratory personnel.

- 3. Report in writing to the Biosafety Officer any release from containment of biohazardous materials or significant problems pertaining to operations and implementation of containment practices and procedures.
- 4. Ensure that all laboratory members under their direction are following all EHS polices and guidelines as well as participate in the appropriate EHS trainings.
- 5. Adhere to the IBC and BMSC approved emergency plan for handling spills and personnel containment.
- 6. Ensure the integrity of the physical containment of the laboratory.
- 7. Notifying EHS prior to buying a BSC, so that the appropriate equipment is selected as well as notifying EHS once the BSC has been installed to allow for certification. Pl's are also required to have all cabinets decontaminated prior to movement from one area to another. This must also be brought to EHS attention for coordination of decontamination and recertification in the new location.
- 8. Adhere to the requirements of federal and state agencies, DOT, FAA, and Georgia Tech for interstate and international shipment of biological agents and rDNA.
- 9. The Principal Investigator is responsible for keeping the laboratory secure from unauthorized persons by developing laboratory security policies. For research areas requiring high security, the PI/PD should seek assistance from the Director of Emergency Preparedness at 404-894-8392.
- 10. The Principal Investigator is responsible for appointing a designee to act as substitute PI if at any point he/she will be away from campus for more than 90 days or is he/she leaves an operating laboratory when leaving Georgia Tech permanently.

Research Staff and Students

Research Staff and Students are the day-to-day practitioners of biosafety. Each member of a laboratory should be well versed in general biosafety as well as specific Georgia Tech Biosafety requirements. Research staff and students shall:

- 1. Read and understand the information contained in the Georgia Tech Biosafety Manual.
- 2. Complete the Signature page on pg. 6 of this manual.
- 3. Enroll in the Biological Occupational Health Program (BOHP).
- 4. Attend EHS training based on research activities and as determined by your BOHP personal risk assessment/exposure questionnaire.
- 5. Follow all safety and security guidelines established by EHS via the Georgia Tech Biosafety Manual, the Georgia Tech Laboratory Safety Manual and your PI.
- 6. Report all accidents and spills immediately to the PI and EHS or Georgia Tech Police.

PRINICPALS OF BIOSAFETY

Risk Assessment

Prior to working with an organism in the laboratory, its risk must first be assessed. Risk assessment primarily focuses on the prevention of laboratory-acquired infections (LAI). The risk assessment process involves identifying hazards associated with a material and the planned activities and then determining which mitigations will reduce the risk to the lowest practical and acceptable level

Risk assessment requires thorough and considerate judgment. Negative consequences are more likely to occur if risk is underestimated. However, implementation of safeguards more rigorous than necessary may result in additional burden for the laboratory, with little or no safety benefit.

Some factors to consider when determining hazards include:

- Hazardous Characteristics of the Agent
 - a. Risk Group classification
 - b. Routes of transmission
 - c. History of LAI
 - d. Origin of the agent
- Planned Laboratory Activities
 - a. Potential for generating aerosols
 - b. Potential for spills
 - c. Use of sharps
 - d. Use of animals

Once the hazards have been carefully identified and considered, risk mitigation can be implemented. Risk mitigation should include:

- Determination of appropriate biosafety level
- Determination of PPE
- Implementation of safety equipment
- Implementation of Occupational Health assessment

A Risk Assessment form must be completed by the Principal Investigator prior to starting new projects involving biohazardous material. The Risk Assessment will then be submitted to the Biosafety Office (biosafety@ehs.gatech.edu) for review. This form should be included with any applications to the Biological Materials Safeguard Committee (BMSC), Institutional Biosafety Committee (IBC), or Institute Animal Care and Use Committee (IACUC).

The Georgia Institute of Technology Biological Risk Assessment Form can be found <u>here</u>.

Hierarchy of Controls

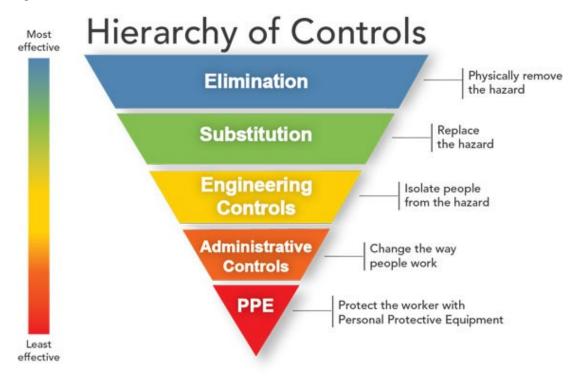
The hierarchy of controls is a tool used in biological risk assessment to determine how best to achieve safety within the laboratory. Each step must be properly considered in order of most effective to least effective.

Elimination and substitution are the most effective controls, however, can also be challenging to implement in an existing study. These steps call for eliminating a potentially hazardous material or substituting it for a less hazardous material. An example of this would be using a less virulent but genetically similar strain of a bacteria or virus or even an inactivated virus.

Engineering controls remove the hazard at its source before it can come into contact with the laboratorian. Common engineering controls in laboratories can include directional airflow, HEPA filtration, biosafety cabinets, safety needles, and vacuum line filtration.

Administrative controls limit the exposure to hazards by changing the way people work with them. Examples of administrative controls include proper training for laboratorians, clear standard operating procedures, detailed laboratory procedures, posting hazard signage, and placing limits on hours/times worked in the lab

Personal Protective Equipment (PPE) is the last line of control to be used when the risk of exposure cannot be eliminated. PPE merely provides a barrier between the hazard and the individual instead or reducing the risk or hazard.



Risk Groups

The World Health Organization (WHO) and the National Institutes of Health (NIH) establish risk groups to classify human infectious agents based on the potential hazard to both the individual and to the community.

RISK GROUP	DESCRIPTION	PORTAL OF ENTRY/TRANSMISSION		RISK LEVEL
Risk Group 1 (RG1)	Defined and well-characterized strains of viable microorganisms not known to consistently cause disease in healthy adult humans or animals.	Laboratory personnel may become infected through high doses or unusual routes of exposure that are not commonly encountered in a natural setting.	Opportunistic RG1 pathogens may cause serious disease in elderly persons, infants, and persons with compromised immune systems.	- No or Low individual risk - No or Low community risk
Risk Group 2 (RG2)	Associated with a human or animal disease which is rarely serious. Preventive or therapeutic interventions are often available.	RG2 organisms have the capability to cause serious disease based on dose, route of exposure, and immune status.	Laboratory exposures may cause serious infection, but the risk of spread of infection is limited.	- Moderate individual risk - Low community risk
Risk Group 3 (RG3)	Associated with a serious or lethal human or animal disease and have potential for respiratory transmission. Preventive or therapeutic interventions may be available.			- High individual risk - Low community risk
Risk Group 4 (RG4)	Agents are associated with serious or lethal human or animal disease, and for which there is no available vaccine or therapy	RG4 agents may be transmitted via the aerosol route, can be readily transmitted from one individual to another, directly or indirectly.		- High individual risk - High community risk

Biosafety Levels

Biosafety levels are a combination of laboratory practices, safety equipment, and laboratory facilities used to achieve biosafety and biocontainment. This chart is a summary, detailed information can be found under "Containment of Biological Research":

BIOSAFET' LEVEL	Y DESCRIPTION	FACILITY REQUIREMENTS	SPECIAL PRACTICES
BSL-1	Used to study infectious agents not known to consistently cause disease in healthy adults. Example: noninfectious materials, K12 E.coli	 Sink for hand washing Doors for access control Surfaces are easily cleaned, non-fabric chairs Screens on windows that open to the exterior Eyewash must be available 	Standard Microbiological Practices (SEE BELOW)
BSL-2	Used to study moderate-risk infectious agents that pose a risk via inhalation, ingestion, or injection Examples: human blood, cell lines, rDNA, RG2 viruses and bacteria	BSL-1 Requirements, Plus: - BSC or other physical containment for manipulations that cause splash or aerosols - Doors should self-close and lock - Vacuum lines protected - Autoclave is available - Labs should be under negative pressure	BSL-1 Practices, Plus: - Limited access - Biohazard signs - Sharps precautions - Lab-specific Biosafety manual - Lab training must be documented - Medical surveillance is offered
BSL-3	Used to study infectious agents that may be transmitted through the air and can cause potentially lethal infection.	BSL-1 & 2 Requirements, Plus: - Double door entry - Negative air flow - Sink is hands free - Lab must be sealable	BSL-1 & 2 Requirements, Plus: - Controlled access - BSC or other physical containment for all manipulations of infectious materials

BSL-4

BSL4 work is not conducted at Georgia Tech

CONTAINMENT OF BIOLOGICAL RESEARCH

Containment of potentially hazardous biological materials is a primary objective for biological safety programs. Containment includes primary and secondary barriers in place as well as practices and procedures used within the space.

Biosafety Levels

Biosafety Level 1 (BSL-1)

Standard Microbiological Practices:

- 1. The laboratory supervisor enforces the institutional policies that control safety in and access to the laboratory.
- 2. The laboratory supervisor ensures that laboratory personnel receive appropriate training regarding their duties, potential hazards, manipulations of infectious agents, necessary precautions to minimize exposures, and hazard/exposure evaluation procedures (e.g., physical hazards, splashes, aerosolization) and that appropriate records are maintained. Personnel receive annual updates and additional training when equipment, procedures, or policies change. All persons entering the facility are advised of the potential hazards, are instructed on the appropriate safeguards, and read and follow instructions on practices and procedures. An institutional policy regarding visitor training, occupational health requirements, and safety communication is considered.
- 3. Personal health status may affect an individual's susceptibility to infection and ability to receive available immunizations or prophylactic interventions. Therefore, all personnel, and particularly those of reproductive age and/or those having conditions that may predispose them to increased risk for infection (e.g., organ transplant, medical immunosuppressive agents), are provided information regarding immune competence and susceptibility to infectious agents. Individuals having such conditions are encouraged to self-identify to the institution's healthcare provider for appropriate counseling and guidance.
- 4. A safety manual specific to the facility is prepared or adopted in consultation with the facility director and appropriate safety professionals. The safety manual is available, accessible, and periodically reviewed and updated, as necessary.
 - a. The safety manual contains sufficient information to describe the biosafety and containment procedures for the organisms and biological materials in use, appropriate agent-specific decontamination methods, and the work performed.
 - b. The safety manual contains or references protocols for emergency situations, including exposures, medical emergencies, facility malfunctions, and other potential emergencies. Training in emergency response procedures is provided to emergency response personnel and other responsible staff according to institutional policies.
- 5. A sign incorporating the universal biohazard symbol is posted at the entrance to the laboratory when infectious materials are present. Posted information includes: the laboratory's Biosafety Level, the supervisor's or other responsible personnel's name and telephone number, PPE

requirements, general occupational health requirements (e.g., immunizations, respiratory protection), and required procedures for entering and exiting the laboratory. Agent information is posted in accordance with the institutional policy.

- 6. Long hair is restrained so that it cannot contact hands, specimens, containers, or equipment.
- 7. Gloves are worn to protect hands from exposure to hazardous materials.
 - a. Glove selection is based on an appropriate risk assessment.
 - b. Gloves are not worn outside the laboratory.
 - c. Change gloves when contaminated, glove integrity is compromised, or when otherwise necessary.
 - d. Do not wash or reuse disposable gloves and dispose of used gloves with other contaminated laboratory waste.
- 8. Gloves and other PPE are removed in a manner that minimizes personal contamination and transfer of infectious materials outside of the areas where infectious materials and/or animals are housed or manipulated.
- 9. Persons wash their hands after working with potentially hazardous materials and before leaving the laboratory.
- 10. Eating, drinking, smoking, handling contact lenses, applying cosmetics, and storing food for human consumption are not permitted in laboratory areas. Food is stored outside the laboratory area.
- 11. Mouth pipetting is prohibited. Mechanical pipetting devices are used.
- 12. Policies for the safe handling of sharps, such as needles, scalpels, pipettes, and broken glassware are developed, implemented, and followed; policies are consistent with applicable state, federal, and local requirements. Whenever practical, laboratory supervisors adopt improved engineering and work practice controls that reduce risk of sharps injuries. Precautions are always taken with sharp items. These include:
 - a. Plasticware is substituted for glassware whenever possible.
 - b. Use of needles and syringes or other sharp instruments is limited in the laboratory and is restricted to situations where there is no alternative (e.g., parenteral injection, blood collection, or aspiration of fluids from laboratory animals or diaphragm bottles). Active or passive needle-based safety devices are to be used whenever possible.
 - i. Uncapping of needles is performed in such a manner to reduce the potential for recoil causing an accidental needlestick.
 - ii. Needles are not bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal.
 - iii. If absolutely necessary to remove a needle from a syringe (e.g., to prevent lysing blood cells) or recap a needle (e.g., loading syringes in one room and injecting animals in another), a hands-free device or comparable safety procedure must be used (e.g., a needle remover on a sharps container, the use of forceps to hold the cap when recapping a needle).

- iv. Used, disposable needles and syringes are carefully placed in puncture-resistant containers used for sharps disposal immediately after use. The sharps disposal container is located as close to the point of use as possible.
- c. Non-disposable sharps are placed in a hard-walled container for transport to a processing area for decontamination, preferably by autoclaving.
- d. Broken glassware is not handled directly. Instead, it is removed using a brush and dustpan, tongs, or forceps.
- 13. Perform all procedures to minimize the creation of splashes and/or aerosols.
- 14. Decontaminate work surfaces after completion of work and after any spill or splash of potentially infectious material with appropriate disinfectant. Spills involving infectious materials are contained, decontaminated, and cleaned up by staff who are properly trained and equipped to work with infectious material. A spill procedure is developed and posted within the laboratory.
- 15. Decontaminate all cultures, stocks, and other potentially infectious materials before disposal using an effective method, consistent with applicable institutional, local, and state requirements. Depending on where the decontamination will be performed, the following methods are used prior to transport:
 - a. Materials to be transported outside of the immediate laboratory are placed in a durable, leak-proof container and secured for transport. For infectious materials, the outer surface of the container is disinfected prior to moving materials and the transport container has a universal biohazard label.
 - b. Materials to be removed from the facility for decontamination are packed in accordance with applicable local, state, and federal regulations.
- 16. An effective integrated pest management program is implemented.
- 17. Animals and plants not associated with the work being performed are not permitted in the laboratory

Special Practices:

None required.

Safety Equipment (Primary Barriers and Personal Protective Equipment):

- 1. Special containment devices or equipment, such as BSCs, are not generally required.
- 2. Protective laboratory coats, gowns, or uniforms are worn to prevent contamination of personal clothing.
- 3. Protective eyewear is worn by personnel when conducting procedures that have the potential to create splashes and sprays of microorganisms or other hazardous materials. Eye protection and face protection are disposed of with other contaminated laboratory waste or decontaminated after use.
- 4. In circumstances where research animals are present in the laboratory, the risk assessment considers appropriate eye, face, and respiratory protection, as well as potential animal allergens.

<u>Laboratory Facilities</u> (Secondary Barriers):

- 1. Laboratories have doors for access control.
- 2. Laboratories have a sink for hand washing.
- 3. An eyewash station is readily available in the laboratory.
- 4. The laboratory is designed so that it can be easily cleaned.
 - a. Carpets and rugs in laboratories are not appropriate.
 - b. Spaces between benches, cabinets, and equipment should be accessible for cleaning.
- 5. Laboratory furniture is capable of supporting anticipated loads and uses.
 - a. Benchtops must be impervious to water and resistant to heat, organic solvents, acids, alkalis, and other chemicals.
 - b. Chairs used in laboratory work are covered with a non- porous material that can be easily cleaned and decontaminated with appropriate disinfectant.
- 6. Laboratories windows that open to the exterior are fitted with screens.
- 7. Illumination is adequate for all activities and avoids reflections and glare that could impede vision.

Biosafety Level 2 (BSL-2)

In addition to the <u>Standard Microbiological Practices</u> outlined under Biosafety Level 1, the following special practices, safety equipment, and facility requirements apply to BSL-2.

Special Practices

- 1. Access to the laboratory is controlled when work is being conducted.
- 2. The laboratory supervisor must ensure that laboratory personnel demonstrate proficiency in standard and special microbiological practices before working with agents requiring BSL-2 containment.
- 3. Laboratory personnel must be enrolled in the Biological Occupational Health Program and offered available immunizations for agents handled or potentially present in the laboratory.
- 4. Properly maintained BSCs or other physical containment devices are used, when possible, whenever:
 - a. Procedures with a potential for creating infectious aerosols or splashes are conducted. These 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. High concentrations or large volumes of infectious agents are used. Such materials may be centrifuged in the open laboratory using sealed rotors or centrifuge safety cups with loading and unloading of the rotors and centrifuge safety cups in the BSC or another containment device.

- c. If it is not possible to perform a procedure within a BSC or other physical containment device, a combination of appropriate personal protective equipment and administrative controls are used, based on a risk assessment
- 5. Laboratory equipment is routinely decontaminated; after spills, splashes, or other potential contamination; and before repair, maintenance, or removal from the laboratory.
- 6. A method for decontaminating all laboratory waste is available (e.g., autoclave, chemical disinfection, incineration, or other validated decontamination method).
- 7. Incidents that may result in exposure to infectious materials are immediately evaluated per institutional policies. All such incidents are reported to the laboratory supervisor and any other personnel designated by the institution. Appropriate records are maintained.

Safety Equipment (Primary Barriers and Personal Protective Equipment):

- 1. Protective laboratory coats, gowns, or uniforms designated for laboratory use are worn while working with hazardous materials and removed before leaving for non-laboratory areas (e.g., cafeteria, library, and administrative offices). Protective clothing is disposed of appropriately or deposited for laundering by the institution. Laboratory clothing is not taken home.
- 2. Eye protection and face protection (e.g., safety glasses, goggles, mask, face shield or other splatter guard) are used for manipulations or activities that may result in splashes or sprays of infectious or other hazardous materials. Eye protection and face protection are disposed of with other contaminated laboratory waste or decontaminated after use.
- 3. The risk assessment considers whether respiratory protection is needed for the work with hazardous materials. If needed, relevant staff are enrolled in a properly constituted respiratory protection program.
- 4. In circumstances where research animals are present in the laboratory, the risk assessment considers appropriate eye, face, and respiratory protection, as well as potential animal allergens.

<u>Laboratory Facilities</u> (Secondary Barriers)

- 1. Laboratory doors are self-closing and have locks in accordance with the institutional policies.
- 2. Laboratories have a sink for hand washing. It should be located near the exit door.
- 3. The laboratory is designed so that it can be easily cleaned and decontaminated. Carpets and rugs in laboratories are not permitted.
- 4. Laboratory furniture must be capable of supporting anticipated loads and uses. Spaces between benches, cabinets, and equipment should be accessible for cleaning.
 - a. Bench tops must be impervious to water and resistant to heat, organic solvents, acids, alkalis, and other chemicals.
 - b. Chairs used in laboratory work must be covered with a non- porous material that can be easily cleaned and decontaminated with appropriate disinfectant.
- 5. 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.

- 6. BSCs must be installed so that fluctuations of the room air supply and exhaust do not interfere with proper operations. BSCs should be located away from doors, windows that can be opened, heavily traveled laboratory areas, and other possible airflow disruptions.
- 7. Vacuum lines in use are protected with liquid disinfectant traps and in-line HEPA filters or their equivalent. Filters are replaced, as needed, or are on a replacement schedule determined by a risk assessment.
- 8. There are no specific requirements for 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.
- 9. HEPA filtered exhaust air from a Class II BSC can be safely recirculation 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. Provisions to assure proper safety cabinet performance and air system operation must be verified.
- 10. Illumination is adequate for all activities and avoids reflections and glare that could impede vision.

Biosafety Level 3 (BSL-3)

Biosafety Level 3 is applicable to clinical, diagnostic, teaching, research, or production facilities where work is performed with indigenous or exotic agents that may cause serious or potentially lethal disease through the inhalation route of exposure. Laboratory personnel must receive specific training in handling pathogenic and potentially lethal agents and must be supervised by scientists competent in handling infectious agents and associated procedures. All procedures involving the manipulation of infectious materials must be conducted within BSCs or other physical containment devices.

A BSL-3 laboratory has special engineering and design features. In addition to the Standard Microbiological Practices outlined under Biosafety Level 1, the following special practices, safety equipment, and facility requirements apply to BSL-2.

Special Practices

- 1. All persons entering the laboratory must be advised of the potential hazards and meet specific entry/exit requirements. Only persons whose presence in the facility or laboratory areas is required for scientific or support purposes are authorized to enter.
- 2. All persons who enter operational laboratory areas are provided information on signs and symptoms of disease and receive occupational medical services including medical evaluation, surveillance, and treatment, as appropriate, and offered available immunizations for agents handled or potentially present in the laboratory

- 3. The laboratory supervisor is responsible for ensuring that laboratory personnel demonstrate proficiency in standard microbiological practices and techniques for working with agents requiring BSL-3 containment.
- 4. A system is established for reporting and documenting near misses, laboratory accidents, exposures, unanticipated absences due to potential laboratory-associated infection, and for the medical surveillance of potential laboratory-associated illnesses.
- 5. Incidents that result in exposure to infectious materials must be immediately evaluated and treated according to procedures described in the laboratory biosafety manual. All such incidents are reported to the laboratory supervisor, institutional management, and institutional biosafety office. Appropriate records are maintained.
- 6. Biological materials that require BSL-3 containment are placed in a durable leak-proof sealed primary container and then enclosed in a non-breakable, sealed secondary container prior to removal from the laboratory. Once removed, the primary container is opened within a BSC in BSL-3 containment unless a validated inactivation method is used. All inactivation methods are documented in-house with viability testing data to support the method.
- 7. All procedures involving the manipulation of infectious materials are conducted within a BSC or other physical containment device, when possible. No work with open vessels is conducted on the bench. If it is not possible to perform a procedure within a BSC or other physical containment device, a combination of personal protective equipment and other administrative and/or engineering controls, such as centrifuge safety cups or sealed rotors, are used, based on a risk assessment. Loading and unloading of the rotors and centrifuge safety cups take place in the BSC or another containment device.
- 8. Laboratory equipment is routinely decontaminated after spills, splashes, or other potential contamination, and before repair, maintenance, or removal from the laboratory.
 - a. Spills involving infectious materials must be contained, decontaminated, and cleaned up by staff properly trained and equipped to work with infectious material.
 - b. Equipment must be decontaminated before repair, maintenance, or removal from the laboratory.
- 9. A method for decontaminating all laboratory waste is available in the facility, preferably within the laboratory (e.g., autoclave, chemical disinfection, or other validated decontamination method).
- 10. Decontamination of the entire laboratory is considered when there has been gross contamination of the space, significant changes in laboratory usage, major renovations, or maintenance shutdowns. Selection of the appropriate materials and methods used to decontaminate the laboratory is based on a risk assessment.
- 11. Decontamination processes are verified on a routine basis

<u>Safety Equipment</u> (Primary Barriers and Personal Protective Equipment)

- 1. Laboratory workers wear protective clothing with a solid-front, such as tie-back or wrap-around gowns, scrub suits, or coveralls. Protective clothing is not worn outside of the laboratory. Reusable clothing is decontaminated before being laundered. Clothing is changed when contaminated.
- 2. Based on work being performed, additional PPE may be required.
 - a. Eye protection and face protection (e.g., safety glasses, goggles, mask, face shield or other splash guard) are used for manipulations or activities that may result in splashes or sprays of infectious or other hazardous materials. Eye protection and face protection are disposed of with other contaminated laboratory waste or decontaminated after use.
 - b. Two pairs of gloves are worn when appropriate.
 - c. Respiratory protection is considered. Staff wearing respiratory protection are enrolled in a properly constituted respiratory protection program.
 - d. Shoe covers are considered.
- 3. In circumstances where research animals are present in the laboratory, the risk assessment considers appropriate eye, face, and respiratory protection, as well as potential animal allergens.

<u>Laboratory Facilities</u> (Secondary Barriers)

- 1. The laboratory is separated from areas that are open to unrestricted traffic flow within the building.
 - a. Laboratory access is restricted. Laboratory doors are lockable in accordance with institutional policies. Access to the laboratory is through two consecutive self-closing doors. A clothing change room and/or an anteroom may be included in the passageway between the two self-closing doors.
- 2. Laboratories have a sink for handwashing. The sink is hands-free or automatically operated and should be located near the exit door. If a laboratory suite is segregated into different zones, a sink is also available for handwashing in each zone.
- 3. An eyewash station is readily available in the laboratory.
- 4. The laboratory is designed, constructed, and maintained to facilitate cleaning, decontamination, and housekeeping.
 - a. Carpets and rugs are not permitted.
 - b. Spaces between benches, cabinets, and equipment are accessible for cleaning.
 - c. Seams, floors, walls, and ceiling surfaces are sealed. Spaces around doors and ventilation openings are capable of being sealed to facilitate space decontamination.
 - d. Floors are slip-resistant, impervious to liquids, and resistant to chemicals. Flooring is seamless, sealed, or poured with integral cove bases.

- e. Walls and ceilings are constructed to produce a sealed smooth finish that can be easily cleaned and decontaminated.
- 5. Laboratory furniture can support anticipated loads and uses.
 - a. Benchtops are impervious to water and resistant to heat, organic solvents, acids, alkalis, and other chemicals.
 - b. Chairs used in laboratory work are covered with a non-porous material that can be easily cleaned and decontaminated with an appropriate disinfectant.
- 6. All windows in the laboratory are sealed.
- 7. Illumination is adequate for all activities and avoids reflections and glare that could impede vision.
- 8. Vacuum lines in use are protected with liquid disinfectant traps and in-line HEPA filters or their equivalent. Filters are replaced, as needed, or are on a replacement schedule determined by a risk assessment. Vacuum lines not protected as described are capped. The placement of an additional HEPA filter immediately prior to a central vacuum pump is considered.
- 9. A ducted mechanical air ventilation system is required. This system provides sustained directional airflow by drawing air into the laboratory from "clean" areas toward "potentially contaminated" areas. The laboratory is designed such that under failure conditions the airflow will not be reversed at the containment barrier.
 - a. A visual monitoring device that confirms directional airflow is provided at the laboratory entry. Audible alarms to notify personnel of airflow disruption are considered.
 - b. The laboratory exhaust air is not re-circulated to any other area in the building.
 - c. The laboratory exhaust air is dispersed away from occupied areas and from building air intake locations or the exhaust air is HEPA filtered.
- 10. BSCs and other primary containment barrier systems are installed and operated in a manner to ensure their effectiveness.
 - a. BSCs are installed so that fluctuations of the room air supply and exhaust do not interfere with proper operations. BSCs are located away from doors, heavily traveled laboratory areas, and other possible airflow disruptions.
 - b. BSCs can be connected to the laboratory exhaust system by either a canopy connection (Class IIA only) or directly exhausted to the outside through a hard connection (Class IIB, IIC, or III). Class IIA or IIC BSC exhaust can be safely recirculated back into the laboratory environment if no volatile toxic chemicals are used in the cabinet.
 - c. BSCs are certified at least annually to ensure correct performance, or as specified in Appendix A, Part 7.
 - d. Class III BSCs are provided supply air in such a manner that prevents positive pressurization of the cabinet or the room.

- 11. Equipment that may produce infectious aerosols is used within primary barrier devices that exhaust air through HEPA filtration or other equivalent technology before being discharged into the laboratory. These HEPA filters are tested annually and replaced as needed.
- 12. Facility is constructed to allow decontamination of the entire laboratory when there has been gross contamination of the space, significant changes in usage, major renovations, or maintenance shutdowns. Selection of the appropriate materials and methods used to decontaminate the laboratory is based on the risk assessment.
 - a. Facility design consideration is given to means of decontaminating large pieces of equipment before removal from the laboratory.
- 13. Enhanced environmental and personal protection may be necessary based on risk assessment and applicable local, state, or federal regulations. These laboratory enhancements may include one or more of the following: an anteroom for clean storage of equipment and supplies with dress-in, shower-out capabilities; gas-tight dampers to facilitate laboratory isolation; final HEPA filtration of the laboratory exhaust air; laboratory effluent decontamination; containment of other piped services; or advanced access control devices, such as biometrics.
- 14. When present, HEPA filter housings have gas-tight isolation dampers, decontamination ports, and/or bag-in/bag-out (with appropriate decontamination procedures) capability. All HEPA filters are located as near as practicable to the laboratory to minimize the length of potentially contaminated ductwork. The HEPA filter housings allow for leak testing of each filter and assembly. The filters and housings are certified at least annually.
- 15. The BSL-3 facility design, operational parameters, and procedures are verified and documented prior to operation. Facilities are tested annually or after significant modification to ensure operational parameters are met. Verification criteria are modified as necessary by operational experience.
- 16. Appropriate communication systems are provided between the laboratory and the outside (e.g., voice, fax, and computer). Provisions for emergency communication and emergency access or egress are developed and implemented.

Further information can be found in the Biosafety in Microbiological and Biomedical Laboratories (BMBL) guidelines. The most current version of the BMBL can be found at the following link:

https://www.cdc.gov/labs/BMBL.html

INFECTIOUS MATERIALS

Human and Primate-Source Material

All human and primate-source materials must be handled as if they are infected with Bloodborne Pathogens. This practice is known as following Universal Precautions.

Bloodborne Pathogens

Bloodborne Pathogens are pathogenic microorganisms that could be present in human blood. Typically, these pathogens are Hepatitis B, Hepatitis C, and HIV but could include any infectious disease. Other Potentially Infectious Material (OPIM) must also be treated as if they are infectious: semen, vaginal secretions, breast milk, amniotic fluid, and other body fluids.

The following are the key elements which must be used at Georgia Institute of Technology to control occupational exposures to bloodborne pathogens when working with human and/or mammalian blood or bodily fluids. All blood and body fluids must be considered as potentially infectious, and personnel are to use appropriate protective measures to prevent exposure.

Universal Precautions

Universal Precautions is an approach to infection control whereby all human source material is treated as if they are infectious and includes the following practices:

- Hand Hygiene (Washing hands)
 - When hands become contaminated with blood or body fluids
 - When gloves are removed after working with biologicals
 - Before going to lunch, breaks, or home
 - When leaving the lab at any time
- PPE
 - Wearing gloves, safety glasses, and lab coats whenever working with or near human/primate-source material
 - Don/Doff PPE properly to avoid self-contamination
 - Remove gloves by "beaking"
- Safe Sharps Handling
 - DO NOT recap, bend, or break used needles
 - Discard needles & sharps in appropriate "Sharps" containers
 - Transport reusable sharps in leak-proof puncture-resistant container
 - Use mechanical device (forceps) to place contaminated broken glass into appropriate containers for autoclaving

Cell Line & Primary Cell Research

Cell line and primary cell research accounts for a large portion of biological research activities at Georgia Tech. All human and primate cell lines must be worked with under BSL2 containment and practices. While many human cell lines have been tested and certified to be free from bloodborne pathogens, these cells must still be handled with caution. Many cell lines have also been constructed with viral genes or are known carriers of viral diseases. These well-characterized cell lines must be handled at the supplier's suggested biosafety level. Researchers must follow the following precautions while working with any cell line or primary cell, even those certified as disease-free. Care should be taken when handling cells obtained from foreign sources as the screening process for pathogens may be different. Researchers should also be aware of possible human trafficking violations involved in accepting cells from foreign countries and should be sure to initiate an incoming Material Transfer Agreement before receiving foreign cells.

General Definitions:

- 1. Cell culture/line The growth of cells grown outside of the natural environment within controlled conditions.
- 2. Primary Cell A cell culture that is harvested from a living organism that contains a variety of cell types and have a limited lifespan.

Procedures:

- 1. Work with cell lines and primary cells must only be conducted with the knowledge and approval of the BMSC or IBC.
- 2. Untested cell lines and primary cells must be treated as if hazardous to human health, thus, all work with these cell types must be performed using Biosafety Level 2 practices and containment.
- 3. Cell line or primary cell waste must be disposed of properly in biohazard waste boxes.
- 4. Gloves, lab coats, and safety glasses must be worn whenever cell lines or primary cells are being handled.
- 5. All researchers and workers handling cell line or primary tissue from a human or primate source are encouraged to be immunized against Hepatitis B. (This vaccine can be provided via the Biological Occupational Health Program, see section IX for more details.)
- 6. Special Primate Cell Line Requirements:
 - a. All tissue origins should be clearly defined in writing so that researchers having the ability to review that information at any time and provided to EHS upon request.
 - b. All accidental exposures to primate tissues must be reported to EHS immediately with copies of the tissue origin information.

<u>Viral Vectors</u>

Biological research at Georgia Tech increasingly uses viral vectors to conduct important rDNA research. A viral vector is a viral particle used to deliver genetic material into cells for the purpose of transfection or transduction of the cell These rDNA segments are generally carried by viruses that normally produce disease in humans. These viruses have been engineered to have only the necessary envelope, polymerase, and capsule genes with all disease and replication causing genes removed. This allows for safety to be maintained while using a highly stable transfection system to insert new DNA. There are several candidates for use in a viral vector including Retroviruses, Lentiviruses, Adenoviruses, and Adeno- associated viruses. Some viruses have been selected for usage as viral vectors due to the specificity the virus has for infecting a limited cell type to deliver targeting of insertion.

Viral Vector Safety

<u>Adenovirus</u> – most commonly causes respiratory illness via ingestion or inhalation exposure. Adenovirus viral vectors must be worked with using BSL2 containment and practices. For animal work, ABSL2 containment for the first 48 hours post-injection and then ABSL-1 containment is acceptable.

Adeno-Associated Virus (AAV/rAAV) – infectious human virus with no known disease association. AAV or rAAVs in which the transgene does *not* encode either an oncogenic protein or toxin, is generated *without* adenovirus or any other helper virus, AND is propagated in insect cells can be worked with under BSL1 and ABSL1 conditions. If *any* of the following are true, then BSL2/ABSL2 containment is required: Transgenes express an oncogenic protein or toxin, helper virus of human origin is used to generate AAV/rAAV, AAV/rAAV is propagated in human cell lines without further purification before use.

<u>Lentivirus</u> – non-oncogenic retroviruses that produce multi-organ diseases characterized by long incubation periods and persistent infection. Most lentiviral vectors presently in use are HIV-derived vectors. Lentiviruses persist lifelong due to their ability to integrate into the host chromosome and evade host immunity. Lentiviral vectors must be used under BSL-2 containment. Animal work is conducted under ABSL-2 containment for the first 48 hours post-injection and then ABSL-1 containment is acceptable.

Recombinant DNA and Synthetic Nucleic Acids

At Georgia Tech, the IBC oversees all research involving recombinant DNA and/or synthetic nucleic acids.

In the context of the NIH Guidelines, recombinant and synthetic nucleic acids are defined as:

- (i) molecules that a) are constructed by joining nucleic acid molecules and b) that can replicate in a living cell, i.e., recombinant nucleic acids;
- (ii) nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, i.e., synthetic nucleic acids, or
- (iii) molecules that result from the replication of those described in (i) or (ii) above.

Any research involving these materials must be approved by the IBC prior to ordering or using them.

Other Infectious Materials

Additional safety resources for specific viruses, bacteria, and other infectious materials:

Pathogen Safety Data Sheets

Biosafety in Microbiological and Biomedical Laboratories

ABSA's Risk Group Database

PERSONAL PROTECTIVE EQUIPMENT (PPE)

PPE is specialized equipment that is worn to minimize exposure to hazards that can cause workplace injuries or illness. PPE can include safety glasses, goggles, face shields, gloves, lab coats, aprons, ear plugs, and respirators. PPE should only be used if the potential exposures cannot be eliminated with properly-designed engineering controls. PPE is carefully selected based on Risk Assessment to ensure that it is compatible with the materials and the process used. PPE must be provided to laboratory visitors and required PPE must be posted on the door to the lab.

<u>The minimum PPE for Biological Labs at GT is closed-toe shoes, gloves, lab coat, and eye</u> protection. Additional PPE may be necessary based on risk assessment.

1. Gloves:

- a. Gloves must be comfortable and of sufficient length to go over the lab coat cuff
- b. Gloves should be properly sized to avoid hand strain or compromised dexterity
- c. Gloves must be changed when soiled or integrity is compromised
- d. Disposable gloves may NOT be reused
- e. Gloves must be disposed of in biohazardous waste containers
- f. Do not touch door handles, cell phones, computers, or other "clean" items with gloved hands
 - i. Equipment in the lab such as keyboards should be labeled "gloves only" or "no gloves" in order to ensure common practices between users
- g. Gloves are not to be worn in hallways or non-laboratory spaces

Glove material should be chosen based on risk assessment. Nitrile and Latex gloves are suitable for most work with biological materials. Options for cut resistance, cold protection, and heat protection are readily available.

2. Eye Protection:

- a. Safety glasses or chemical goggles must be donned upon initiation of work with any hazardous material or when adjacent lab members are working with hazardous materials. This applies to lab visitors, GT maintenance and custodial workers, as well as staff and students
- b. Safety glasses must meet the ANSI Z87.1 standard for impact resistance and have side shields for splash protection.
- c. Chemical goggles may be required for certain processes where safety glasses are deemed inadequate: Safety Glasses do not provide protection from chemical vapors, liquids, or caustic dust hazards which may bypass safety glasses.
- d. Individuals who wear prescription lenses must either wear eye protection over their prescriptive lenses or wear prescription safety glasses.

3. Lab coats:

- a. Lab coats must be donned upon initiation of work with any hazardous material or when adjacent lab members are working with hazardous materials. This applies to lab visitors, GT maintenance and custodial workers, as well as staff and students
- b. Shall not be worn outside of the laboratory and shall not be taken home
- c. Lab coats must be laundered when soiled or at least every 30 days. Lab coats must not be taken home to launder.
- d. Shall cover the wearer to the knees
- e. Lab coats of 100% cotton are required in all undergraduate labs where chemicals, biologicals, or radiological are used including labs for Chemistry, Biology, Materials Science Engineering, Chemical and Biomolecular Engineering, and Biomedical Engineering. Lab coats must be made of 100% cotton or flame resistant materials in labs where open flames are used (such as alcohol burners)
- f. Lab coats made of polyester-cotton blends (no less than 35% cotton) are acceptable in labs where no open flames are present
- g. Lab coats which meet the Georgia Tech specifications can be purchased at the VWR store located in room L2320 of the ES&T building. (hours of operation are Monday-Friday 8 am to 4:30 pm).

RESEARCH APPROVAL REQUIREMENTS

Prior to beginning a new project or starting up a new laboratory, there are several steps to ensure a smooth process. Committee approvals, initial laboratory inspection, and personnel training are some of the considerations you will need to take into account when getting started. It is recommended that you meet with a member of EHS to discuss your plans and learn about the services and processes available to your lab.

Committee Approvals

Biological Materials Safeguards Committee

For approval of all biological research

An approved BMSC permit must be in place for research involving biological materials. BMSC applications are managed via EHSA, which can be accessed via the EHS website: www.ehs.gatech.edu

Permits must be amended any time a new material or lab member is added or removed to/from the project. Approvals are valid for 3 <u>years</u> and must be renewed if the project is still active.

All individuals working with biological materials must also enroll in the Biological Occupational Health Program.

Institutional Biosafety Committee

For approval of all rDNA research

The IBC is responsible for reviewing and approving all research pertaining to recombinant or synthetic DNA or nucleic acids.

Information on IBC processes can be found at: https://oria.gatech.edu/ibc

The approval process can take up to 3 months and materials should be prepared and submitted well in advance of the expected project start date in order to allow sufficient review time.

IBC registrations must be amended any time a new material or lab member is added or removed to/from the project. Approvals are valid for 3 <u>years</u> and must be renewed if the project is still active.

Additional information on the requirements and regulations for work with these materials, please review the NIH Guidelines found here.

All individuals working with biological materials must also enroll in the Biological Occupational Health Program

IACUC

For approval of all research involving animals

The IACUC reviews all research and teaching activities that involve vertebrate animal subjects. IACUC approval is required prior to the start of any activity conducted by faculty, staff, or students regardless of location or funding source.

Information on the submission and review process can be found at: https://oria.gatech.edu/iacuc

The approval process can take up to 3 months and materials should be prepared and submitted well in advance of the expected project start date in order to allow sufficient review time.

IACUC protocols must be amended if there are any changes to the approved protocol and protocols must be renewed every 3 years if the study will continue.

All associated research must also be approved by the BMSC or IBC and all individuals on an IACUC must also be enrolled in the BOHP.

Biological Occupational Health Program (BOHP)

For enrollment into the Occupational Health Program

Instructions on how to enroll in the BOHP can be found at:

https://ehs.gatech.edu/biosafety/bohp.

Any individual working with infectious materials or conducting animal research must enroll in the BOHP. Enrollment is valid for 3 years and must be renewed every 3 years.

The BOHP process involves submission of a Risk Assessment to the Biosafety office, submission of health history information to a 3rd party reviewer, and then recommendations and training requirements are provided back to the enrollee. Individuals are able to decline vaccines and physical exams. Training recommendations are required.

Biological Laboratory Inspection

Laboratory inspections are a vital part of any quality biosafety program. GT Biosafety aims to conduct an initial and then an annual biosafety inspection for all biological laboratories on campus. These inspections focus on a variety of areas including biological materials handling, sharps, equipment signage and certification, personal protective equipment, and more. Biosafety also conducts inspections following incidents that involve biological materials. Annual inspection forms can be found on the EHS website. The goal of the inspection is to ensure that the researchers working in GT

laboratories are well educated and trained on the materials they are working with and the proper procedures for working with them safely.

GT Biosafety also requires self-inspections of laboratories by researchers or principal investigators at least every other month. These inspections are to ensure that laboratories are conscience of ongoing or potential issues in the laboratory prior to the annual inspection. This is also a tool to help new members of laboratories to understand the basics of biosafety inspections. The self-inspection form can be found online at the www.ehs.gatech.edu website under the Biosafety section.

Annual Inspections are conducted building-wide on a monthly basis. You will be informed when your building is due for their inspections and will be provided with at least 30-days notice. You will receive an invitation to choose a time frame that works best for your lab based on the week that your floor will be inspected. You will also receive your inspection packet, which will include the Biological Risk Assessment Form and Inspection Checklist. These materials will be provided back to the Biosafety office no less than 14 days prior to your inspection so that we can better understand your research prior to inspection.

Biosafety Training

EH&S provides training to users of biological materials based on the nature and risk of the materials being handled. These trainings seek to cover important safety practices as well as to instill basic knowledge of research materials. This knowledge is important for all researchers to obtain prior to initiation of research so that the Georgia Tech research community maintains safety in the laboratory.

The following classes are currently being offered through EH&S Biosafety and can be registered for <u>here</u>:

General Biosafety - This course discusses all the guidelines, regulations, and safety practices for maintaining a safe biological laboratory environment. Topics covered include review of research by biosafety committees, basic biosafety information, waste disposal, sharps handling, GT shipping rules, and much more. New researchers and students are required to attend this training upon starting research and an annual refresher. Required every 3 years.

Bloodborne Pathogens for Researchers — Bloodborne pathogens are of great concern to researchers dealing with human tissues, bone, teeth, organs, cell lines, blood, or other bodily fluids. The course teaches students universal precautions as well as the causes of bloodborne diseases, proper personal protective equipment, and the regulatory basis for a bloodborne pathogens program. Required annually

Understanding Biosafety Cabinets – Many Georgia Tech researchers conduct activities inside of a Biological Safety Cabinet (BSC). The BSC is an important piece of laboratory safety but can

be misused. This class will teach the basic types of BSC, proper usage techniques, and maintenance.

Recombinant DNA - This class focuses on the history, regulation, and proper handling of rDNA. Students will learn about the various categories of research covered, the committee structure approving rDNA research, and responsibilities of principal investigators and other researchers. Required every 3 years

Shipment of Dangerous Goods (Online Tutorial) - Shipments of dangerous goods requires extensive training and practice to ensure that shipments are packaged properly for shipment. This tutorial covers the basic information required by the Department of Transportation (DOT) and the Federal Aviation Administration for preparing and offering hazardous materials for shipment to EHS. The training also covers the procedure for initiating a shipment with EHS as required for dangerous goods.

BIOLOGICAL DECONTAMINATION

Biohazardous Waste Handling

It is expected that investigators using biohazardous agents and/or producing biomedical wastes as defined below will comply with the rules promulgated by the Georgia Environmental Protection Division in Chapter 391-3-4 section .01 "Solid Waste Management" and Georgia Tech policy. The waste streams generated by biological laboratories should be separated into non-hazardous waste (trash), biohazardous waste, chemical waste, and radioactive waste.

Procedures for Handling Biological Waste on Campus

- 1. Biological waste shall be segregated from other waste at the point of generation. This waste, except for sharps, is to be placed in red plastic bags clearly identified with the universal biohazard symbol or clearly marked with the word "BIOHAZARD".
- 2. Bags of non-infectious biological waste are housed inside a biohazardous waste box provided by Environmental Health & Safety. Once boxes are 2/3 full, the bags are closed, boxes are taped closed, boxes are individually labeled with a waste ticket, and pickup is requested from FHS.
- 3. Broken glass may or may not be considered biohazardous waste glassware that has been contaminated with biological agents should be disposed of in a sharps container.
- 4. Mammalian carcasses should be collected in leak-proof, closed containers or refrigerators before being placed in biohazardous waste boxes. Clearly mark the biohazardous waste box with the appropriate classification of "animal carcass".
- 5. Human tissue can be disposed of two ways. If the human tissue is unrecognizable as an organ or body part, the tissue can be disposed of in a biohazardous waste bag and box. If the human tissue is an identifiable body part or organ, the PI must clearly mark on the box "human tissue". This segregates the waste for proper disposal by cremation or burial.
- 6. No bag that contains biohazard waste shall be disposed of in outdoor dumpsters.
- 7. Liquid biological materials are to be properly inactivated or sterilized prior to disposal in the community sewage treatment system. Methods for inactivation may be specific to the biohazardous agent contaminating the liquid. Typically, a freshly made solution of 1:10 bleach for 30 min is adequate.

Handling and Disposal of Sharps

OSHA has promulgated a regulation on Bloodborne Pathogens (29 CFR 1910.1030) that contains sharps guidelines as well as the United States House of Representatives passed Public Law 106-430 that added to these regulations. The public law established that employers must create and maintain an exposure control plan that contains effective engineering and work practice controls for workers using sharps in everyday activities. Since Georgia Tech is a part of the State of Georgia government,

the federal regulations do not have to be followed but Georgia state law is. Thus, Georgia Tech must follow House Bill 1448 that essentially mimics Public Law 106-430.

General Definitions:

1. Sharps – this term means any discarded article that may cause punctures or cuts and has been exposed to infectious or potentially infectious agents, including humans and mammals. This waste includes, but is not limited to, items such as needles, IV tubing and syringes with needles attached, and scalpel blades.

Procedures:

- 1. Contaminated Sharps (needles and syringes, Pasteur pipettes, etc.) must be placed in puncture proof and leak proof containers which are closed, labeled, and picked up by EHS
- 2. Sharps should never be re-sheathed prior to disposal unless the sharp comes equipped with a safety device designed to be engaged after usage.
- 3. Use sharps with safety devices whenever possible or use needleless systems to conduct research.
- 4. All sharps containers should be labeled with the PI's name and the date the box was placed in the work area. This is to ensure that sharps boxes remain in the originating laboratory and can be identified during the disposal process if required.
- 5. Sharps should be disposed of as biohazardous waste. The outer box must be labeled to indicate that the box contains sharps to allow for proper disposal since most sharps are classified as medical waste.

Approved Surface Disinfectants

Laboratory personnel should be familiar with the various disinfectants that will effectively kill the biohazardous agents being used. The following information is provided to assist in your selection of appropriate disinfectants. Contact times are dependent upon what you are trying to kill.

<u>Alcohols</u> – Ethyl and Isopropyl are good disinfectants for the vegetative forms of bacteria and lipoviruses.

Ethyl Alcohol:

Use Dilution: 70-95%

Inactivates: vegetative bacteria and lipoviruses, has variable results with non-lipoviruses and is ineffective with bacterial spores.

Other Characteristics: flammable, eye irritant, and an upper respiratory tract irritant

Isopropyl Alcohol

Use Dilution: 70%

Inactivates: bacteria, enveloped viruses, and fungi; does convey residual effects

Other Characteristics: Flammable, CNS depressant, and irritating to mucous membranes

<u>Chlorine Compounds</u> – The germicidal effect of chlorine compounds is dependent upon the release of hypochlorous acid and is therefore dependent upon the available chlorine.

Inactivates: vegetative bacteria of the non-spore forming groups, biofilms, polysaccharide webs, and lipid and non-lipid viruses

Use Dilution: Typical dilution is 1:10 of household bleach.

Other Characteristics: Chlorine compounds are corrosive to metals; leave a residue; irritate the skin, eyes, and respiratory tract; and are toxic. Chlorine compounds are also rapidly inactivated by organic matter.

<u>Quaternary Ammonium Compounds:</u> Quats are effective in destroying ordinary vegetative bacteria and lipid containing virus but are not effective against pseudomonas, proteus, and other gram-negative bacilli. Also, Quats are not effective against spores at the usual use concentrations of 1:750.

Use Dilutions: 0.1 to 2.0%

Other Characteristics: Quats are surface-active compounds which possess the useful property of lowering the surface tension of the solution. Other advantages include being nontoxic, odorless, non-staining, non-corrosive to metals and stable. If used at recommended concentrations, Quats are nonirritating.

Calculations:

In order to determine the volume of solution required, apply the following formula:

$$Vf = Vi(Ci/Cf)$$
, Where:

Vi = volume of original solution needed

Ci = initial concentration of original solution

Vf = final volume of solution

Cf = final concentration of solution

EMERGENCY RESPONSE

The most important component of emergency response is understanding what you are working with in the laboratory. It is critical that you understand the true risks of what you are working with and what the consequences are of exposure. You need to know how the material can infect you, what the symptoms are, and what the implications of an exposure are. If a vial of your research material falls off the bench and splashes you in the eye, can it infect you? What would the symptoms be? How sick would it make you?

You must be able to communicate these risks to emergency responders as well. If someone in your lab has an unrelated medical episode and needs assistance, you will need to communicate to emergency responders about the risks of entering your lab space. Often, the perceived risk of the lab is much greater than the actual risk, so it is critical to able to communicate this information clearly and simply in terms of exposure routes and risks.

Implementing emergency response plans is another critical component. Thinking through how to handle emergencies, writing lab-specific emergency plans, and practicing these plans are all part of implementing emergency response plans in your laboratory. All lab members should read these plans so that they understand how to respond to an emergency before it happens. Part of this plan should include knowing the phone number for GTPD, your building name, and lab number.

Preventing incidents and emergencies is not always possible, but many times, hindsight shows us that there are things we could have done differently which would have led to a better outcome. Accidents are much more likely to happen when we are stressed, upset, sick, or otherwise distracted. When deadlines mount, we rush and then mistakes compound. When we don't feel well, we are also more likely to rush and even worse, we could have a medical event in the lab and require medical attention in a contained environment.

As a laboratorian it is imperative to prepare for emergencies by educating yourself on what you are working with, prepare yourself by implementing emergency preparedness plans, and to check in with yourself to ensure that you aren't over-stressed or unwell when working in the lab.

Spills of Biological Material

Primary responsibility for preventing and cleaning up laboratory spills remains with the principal investigator or laboratory supervisor. Laboratory protocols should be carefully designed to prevent hazardous spills.

When accidents occur that involve mishandling or spills of biohazardous materials, the principal investigator or laboratory supervisor is to be notified immediately. Spills of high-risk organisms (RG 2) should be reported to the EHS Emergency Phone: 404-216-5237. All employees and/or students have an obligation to themselves and their colleagues to report accidents immediately in order to minimize potential hazards to the lab and the community.

When a biohazardous spill also involves radioactivity, cleanup procedures may have to be modified. The extent of the modification will depend on the level of radiation and the nature of the isotope involved. The Radiation Safety Officer should be called during normal working hours at 404/894-3605, or Georgia Tech police should be called after working hours at 404/894-2500.

The following guidelines must be followed by the principal investigator, laboratory supervisor, and other responsible individuals who may be involved in the cleanup of biological spills.

Biohazard Spills inside Biological Safety Cabinets (BSC)

The occurrence of a spill in the biological safety cabinet poses less of a risk than a spill in an open laboratory as long as the spilled materials are contained in the biological safety cabinet.

- Keep the BSC on, if it is not yet on, turn it on
- Wearing appropriate PPE, spray the spill with an appropriate disinfectant
- Allow to sit for appropriate contact time. If using Ethanol, ensure enough is sprayed to stay wet for the appropriate time.
- Wipe up spill
- Spray area, including walls and items that may have been splashed, with disinfectant again
- Wipe and discard paper towels in biohazard waste bin

Biohazard Spills Outside of a Biological Safety Cabinet

The protocol to be used in cleaning up of spills involving microorganisms will depend on the amount of material spilled and the degree of laboratory containment required.

Minor Spills (less than 10 ml with no splashing):

a. Alert personnel in the laboratory to the spill and to stay clear of the contaminated area.

- b. Remove any contaminated PPE, turning soiled areas inward, and place in a biohazard bag for disposal or laundering.
- c. Thoroughly wash hands and other apparently contaminated areas with soap and water. Put on a pair of clean gloves.
- d. Cover the spill area with paper towels and pour an appropriate disinfectant on the towels and around the spill. Allow a contact time of at least 20 minutes or more if recommended for your material and disinfectant.
- e. During the contact time, spray down the general area including cabinets, nearby floor, containers, etc. to ensure nothing splashed on them.
- f. After 20 minutes, or the appropriate time, place soiled paper towels in a biohazard bin. Spray and wipe down the spill area to ensure the entire area has been cleaned. Remove gloves and wash hands

Major Spills (more than 10 ml, or with considerable splashing):

- a. Step away from the spill and alert all others in the laboratory of the spill. All lab members not associated with the spill should leave the laboratory quickly and safely. Ensure lab doors leading to outward areas are closed.
- b. Remove any contaminated PPE, turning soiled areas inward, and place in a biohazard bag for disposal or laundering.
- c. Wash hands and any other potentially contaminated areas with soap and water.
- d. Exit the laboratory, and post "Do Not Enter" signs on lab doors. Do not re-enter the lab for 30 minutes.
- e. Report the accident to the supervisor and to the EHS Emergency Phone at 404-216-5237. If additional spill guidance is needed, ask for assistance.
- f. After reporting the spill and after 30 minutes has passed you may re-enter the lab to clean up.
- g. Don lab coat, gloves, safety glasses.
- h. Cover the spill with paper towels and carefully pour an appropriate decontamination solution on the towels and around the spill. Allow the solution to sit for a minimum of 20 minutes, or longer if appropriate for the specific material and disinfectant.
- i. During the contact time, spray down the general area including cabinets, nearby floor, containers, etc. to ensure nothing splashed on them.
- j. After 20 minutes, or the appropriate time, place soiled paper towels in a biohazard bin. Spray and wipe down the spill area to ensure the entire area has been cleaned. Remove gloves and wash hands

Accidental Exposure to Biohazardous Material

If an individual is injured or contaminated with a hazardous substance, addressing the injury or personnel contamination takes priority over implementing spill control measures. The closest laboratory should be the destination if the injured or contaminated person must be moved. It is important to obtain medical attention as soon as possible by calling GTPD at 404-894-2500.

Absorption (Skin or Eye contact):

- 1. Flush eyes or skin immediately with clean water, saline, or a sterile wash
- 2. Report the exposure to your supervisor and to the EHS emergency phone 404-216-5237
- 3. Seek medical attention if necessary

Needlestick/Animal Bite:

- 1. Wash injury with soap and water
- 2. Report the exposure to your supervisor and to the EHS emergency phone 404-216-5237
- 3. Seek medical attention if necessary

Injury/Illness

Illness

The following guidelines can help you if a laboratorian becomes ill or injured in the lab:

- Individuals who are feeling unwell should not perform work in the lab. Supervisors and other lab members should support this guideline.
 - Individuals who have underlying medical conditions should consider disclosing this information to a supervisor, lab manager, or lab member. In the event of a medical emergency, information about these conditions can be critical.

Minor Injury

- If an individual becomes injured (not related to a biological material) in the lab:
 - Remove PPF
 - Leave the lab and get to a safe area, outside the lab
 - Call the EHS Emergency Phone at 404-216-5237
 - Seek medical attention if necessary

Major Injury

• If an individual sustains a major injury in the lab: Call 911 or GTPD 404-894-2500

TRANSPORT OF BIOLOGICAL MATERIALS

Moving Biological Materials Around Campus

These guidelines apply on campus at any time biological material will be transferred from one laboratory to another or from one building to another. These guidelines are to prevent contamination of hallways, the environment, and persons not involved with transport of biological materials.

- 1. Biological material must be contained inside a closed or sealed primary container (such as a sample tube, flask, or other sealed laboratory container) and decontaminated.
- 2. The primary container should be placed inside a sealable secondary container (sealable bag, box, etc) along with sufficient absorbent material.
- 3. The secondary container is then placed inside of a durable transport container for transport (cooler, box, etc).
- 4. The transport container must be labeled with a biohazard sticker, and contact information for the laboratory.
- 5. A cart must be used to transport heavy, multiple, or large items.
- 6. The primary container must be decontaminated prior to packing in secondary containment.
- 7. The transport container must be decontaminated prior to departing the laboratory
- 8. PPE must be donned prior to unpacking the transported material.

Shipment of Biological Materials

Due to the numerous regulations involved with shipping hazardous materials, the staff at EHS conduct these shipments for GT. Individuals wishing to ship biological, chemical, or radiological materials should see the website for specific requirements including training and paperwork: https://ehs.gatech.edu/shipping

A summary of specific requirements follows, along with links to additional information, contacts and forms.

Export Limitations

Some materials and information cannot be shipped to certain countries. In addition, foreign nationals from certain countries are prohibited from receiving such materials even if they are residing in the United States. All international shipments require an export review. You can initiate this review by completing the MTA and International Shipping Export Review Form at http://industry.gatech.edu/researchers/forms/ When you have completed the form, send the form via email to export@gtrc.gatech.edu. The appropriate person will be notified to review your request.

This process can take several days or weeks to complete. Most chemicals and biological materials do not need an export license, but there are exceptions. If an export license is needed, the process takes an average of 60-90 days - but can take up to a year to complete.

Material Transfer Agreement

A Material Transfer Agreement (MTA) is a legal contract between two entities which specifies that materials are to be used for scientific work only and not for commercial use. MTAs are executed between a company and GTRC, not between individuals. You will not need an MTA if you are sending samples for analysis, you are returning material to a supplier, or you are providing product(s) to a project sponsor.

If you need an MTA, or are unsure, visit <u>mta.gatech.edu</u> for additional information on the process.

Material Safety Data Sheet (MSDS)

All shipments of hazardous materials require an MSDS. This is true for even "small" amounts and newly created products/samples. If there is no commercial MSDS, you must create one. EHS can teach you how to do this. Contact Debbie Wolfe- Lopez at deborah.wolfe-lopez@ehs.gatech.edu or 404-385-2964 to learn how to create an MSDS.

Training for Individuals

Due to Federal Aviation Administration (FAA) regulations, all individuals involved in the shipping process must complete shipping training every 2 years. This includes the person filling the materials container, the person that packages the shipment to bring to EHS, and the person actually bringing the shipment to EHS. This training involves viewing a PowerPoint presentation on shipping and being tested over the material. The training can be found at https://ehs.gatech.edu/shipping.

Materials for Off-Site Research

If you are ordering chemicals (or any other regulated materials) from a vendor to be used off the premises of Georgia Tech or Georgia Tech Research Institute, you are required to have the materials shipped to the institution where the research is to be conducted in the interest of time and monetary efficiency. If you are finding difficulties expediting this, please contact EHS and we will assist in any way we can to ensure that your materials are shipped to the proper location and handled appropriately.

Shipping Hazardous Materials

Domestic and international regulations govern the commercial shipment of hazardous materials/dangerous goods. Hazardous materials/dangerous goods can only be offered legally for

transport by trained and certified individuals. If you suspect that your material may be controlled or regulated in any way, please contact the appropriate EHS Specialist.

Procedure for Shipment

All shipments must be scheduled in advanced by completing the online webform. The webform must be complete and accurate and must be submitted at least 24 hours in advance for domestic shipments or 48 hours in advance for international shipments. All shipments must be brought to the ES&T loading dock for drop-off or must be scheduled for drop off at the EHS building.

All samples must be appropriately sealed and then packaged in a secondary, sealed outer container for drop off. If dry ice is necessary, it must be brought with the shipment.

Detailed information on packaging and necessary forms can be found at: https://www.ehs.gatech.edu/shipping

Shipment of DNA, Plasmids, and Protein

EHS has developed a basic shipping awareness course that has been constructed to allow for basic transport of dangerous goods, on campus. This training does not allow for researchers to ship dangerous goods outside of Georgia Tech. To assist lab groups in efficiency in research, EHS has determined that all biological shippers will be trained in basic knowledge of dangerous goods and be allowed to ship select non-hazardous items from their laboratories.

Procedures:

- 1. Biological shippers shipping out DNA sequences, plasmids and proteins for testing and sequencing are able to ship these items out of their individual labs as long as the shipment meets the following four conditions:
 - a. The material is not in a cell of any type
 - b. The shipment can be sent at ambient temperature or on ice packs
 - c. The shipment is being sent for analysis only
 - d. The destination is in the continental United States only
- 2. Items not allowed to be shipped from labs under this new process include international shipments, shipments on dry ice as it is a regulated dangerous good, shipments of microorganisms of any type, shipments that require a Material Transfer Agreement (MTA) or notification statement, and any other shipments deemed to require handling by EHS.
- 3. All biological shippers sending out these items must complete the On-line Shipping of Hazardous Materials Training—available at:

- 4. www.trainsweb.gatech.edu
- 5. Hands-on Function Specific Training by EHS Biosafety Staff, call or email the Biosafety Officer or the Assistant Biosafety Officer (see contacts below) to schedule this hands on training for all the shippers in your laboratory.
- 6. Fed Ex or UPS paperwork must now indicate the type of material shipped from the laboratory. This can be done in the additional references section with a simple statement about the nature of the samples.
- If the shipping papers are developed online a shipment notification email can be sent to shipping@ehs.gatech.edu from the Fed Ex or UPS website. This will allow for real time knowledge of shipments and to verify that all shipments are being handled appropriately.
- All labs are required to keep a file of shipping papers to be audited by EHS as well as Federal Regulators. This is a requirement of the FAA and DOT so that information can be reviewed immediately about a particular shipment in the presence of the shipper.
- Researchers can request that other materials be considered for this program on a case-bycase basis.

WORKPLACE OCCUPATIONAL HEALTH POLICY

Workplace Occupational Health is an important issue for Georgia Tech and its employees. Scientific research and other work activities involving the use of chemical, biological, and/or radiological materials has the potential to expose employees to health hazards. These hazards can create both short-term and long- term health issues. Georgia Tech is strongly committed to protecting the health of all its employees through awareness, training, medical evaluations, engineering controls and appropriate workplace protective measures.

Assessing Workplace Occupational Health Risks:

Occupational health risks in the workplace can be very difficult to quantify or predict with certainty, and can vary significantly based on several different factors including:

- Type of hazard
- Dosage or intensity of its exposure
- Duration of the exposure
- Route of exposure
- Susceptibility of the individual
- Combined effects of multiple hazards

Georgia Tech Environmental Health and Safety (EHS) is responsible for working with departmental supervisors and employees to assess occupational exposure risks and recommend appropriate control measures.

All employees are responsible for following recommended work practices, using appropriate personal protective equipment (PPE), attending safety training programs and reporting any exposure incidents to their supervisor.

Types of Exposures:

The exposures covered by this program are chemical, biological, radiological (both non-ionizing and ionizing) and other potential physical stressors that may impact occupational health. Within each exposure group, there are several identified potential health risks. Protective measures should be taken to avoid/minimize exposures.

Common Chemical Exposures:

- Heavy metals
- Pesticides
- Organic solvents
- Chemotherapeutic agents
- Anesthetic gases

<u>Common Biological Exposures:</u>

- Bacteria
- Viruses
- Toxins
- Mold
- Animals

Common Ionizing Radiation Exposures:

- Radioactive Source Materials (C-14, H-3, P-32, Th-229, Ni-63, etc.)
- X-ray Units
- Analytical Instruments (electron microscopes, spectroscopy, etc.)
- Neutron Generators

Common Non-Ionizing Radiation Exposures:

- Lasers
- High Power Magnets
- Radio Frequency (RF) Radiation
- Microwave Radiation
- Ultra-Violet Light (including from electric arcs or plasma generation)

Common Other Physical Stressors:

- Extreme Heat or Cold
- Noise
- Vibration
- Repetitive Motion

Departmental Supervisors are responsible for ensuring that workplace health protective measures are in place, including ensuring that:

- Employees complete all appropriate safety training including the proper use of fume hoods, biosafety cabinets, and emergency equipment.
- Appropriate personal protective equipment (PPE) is worn. Safety glasses must always be
 worn in laboratories or other work areas where eye exposure risks are present. All persons
 handling chemicals, biologicals, and radiologicals must wear lab coats and protective
 gloves. Other forms of PPE may be necessary based on the exposure (e.g. hearing
 protection for noise exposures, lead aprons for radiation exposures, etc.)
- Individuals understand how to read the Material Safety Data Sheet (MSDS) for all chemicals used in the laboratory to
- determine appropriate handling procedures and to determine if a chemical is a potential health hazard.

- Employees exposed to potential workplace health hazards are enrolled in the Georgia Tech Occupational Health Program (OHP) to receive an overall risk assessment, medical evaluation, and any appropriate vaccinations or medical tests.
- All employees attend Chemical Right-to-Know, Laboratory Safety, Biosafety, Radiological Material, X-ray Safety, and other training courses as applicable offered by EHS to learn more about potential workplace health risks associated with the materials or equipment they are working with.

Procedures:

Georgia Tech EHS performs workplace occupational hazard/risk assessments on an ongoing basis and will work closely with faculty, staff or students who have any concerns or wish to discuss potential health risks associated with their work activities.

EHS will collect and evaluate information on exposures of concern to provide appropriate safety recommendations to protect Georgia Tech employee's health in the workplace. These recommendations will be reviewed with the employees as well as the departmental supervisor, the Georgia Tech OHP medical provider, and/or the Principal Investigator (PI) as needed. EHS will work with the department and the employee to implement the appropriate safety, exposure control and health monitoring measures.

To have a job hazard analysis conducted or for additional information on enrollment in the Georgia Tech OHP, EHS should be contacted at (404)894-4635 or www.ehs.gatech.edu

LABORATORY EQUIPMENT

Georgia Tech personnel should not operate equipment on which they have not been specifically trained and authorized to use. Operating manuals or detailed operating instructions must be available and consulted as necessary.

Equipment known or suspected of being faulty should be labeled as "out of service" and should not be operated. Equipment that is broken or no longer needed should be properly removed from the lab after consultation with the PI and building manager.

Many common manipulations of biological materials in the laboratory can generate aerosols of viable organisms. This principle must be considered when evaluating the risk of a procedure. The information below addresses several the risks that can be associated with common laboratory equipment:

Autoclaves

Autoclaves produce superheated steam under high pressure and are used for two processes: decontamination and sterilization. Moist heat, in the form of steam under pressure, is the most dependable medium for the destruction of microbial life. Autoclaves are ideal for sterilizing many common items associated with biological research including stainless steel tools, media, glass, and certain plastics. Biohazardous waste should NOT be autoclaved at Georgia Tech.

Pre-programmed cycles on the autoclaves should not be altered. Preset cycles help to ensure appropriate function of the autoclave. While most loads require cycle times of 15 to 30 minutes at 121°C, longer times may be needed to meet the thermodynamic needs of special loads. The needs for sterilizing liquids differ from the needs of sterilizing solids.

- Liquids require the use of slow exhaust to prevent boiling over of media as the boiling point returns to 100°C.
- Liquid cycles are recommended for loads consisting primarily of liquid media
- Glass containers are recommended for the liquid cycle type as long as closures are vented and the containers are no more than 2/3 full.
- Solid cycles can otherwise accommodate loads that don't require the aforementioned considerations.

The duties of maintaining autoclaves are varied and require participation by all who regularly interact with the units.

• Ensure that the autoclave is doing its intended job is a daily process. Any researcher using an autoclave is expected to participate in the quality assurance of this work by maintaining autoclave logs.

- The specific information needed at minimum shall include the date and time of use, contact information, which cycle is in use, and a record kept of the temperature, pressure, and length of time the load was sterilized. This information can be viewed on the autoclave printout that accompanies each individual cycle.
- If you find an autoclave is failing to meet sterilization standards, is leaking, or is broken report it to your building manager immediately.
- The preventive maintenance contractor is required to perform quarterly preventive maintenance on all large research autoclaves and attached boilers, as well as provide repairs for units as needed.
- The contractor responds to all reported autoclave performance issues as soon as possible.

The pressure and temperatures of an autoclave do not neutralize chemicals, and in many cases can cause chemical vapors. Radioactive materials, chemicals, and non-heat and non-water-resistant materials should not be placed inside the autoclave. An autoclave will turn any residual bleach in waste into a cloud of chlorine gas and cause corrosion to the autoclave. Other chemicals, such as flammable materials and acids and bases also present risks after undergoing chemical changes under autoclave conditions, some with potentially fatal consequences.

The EHS provided biohazard bags are NOT to be used inside the autoclave. Generally, thicker plastic materials are autoclavable, but if you're not sure, review product information to determine if the plastic you have is safe to be autoclaved. Plastics that are safe to autoclave include:

- polypropylene (PP)
- polycarbonate (PC)
- polymethylpentene (PMP)
- PTFE Resin
- polymethyl methacrylate (PMMA or Acrylic)

Plastics that aren't safe to autoclave include:

- polyethylene (PE)
- polyvinyl chloride (PVC or Vinyl)
- polyethylene terephthalate copolymer (PET)
- polystyrene (PS)

While loading the autoclave, keep these essential tips in mind.

- Be sure to arrange items to allow steam to effectively penetrate all items. Closed bags and containers prevent steam from entering and thus reduce sterilizing capacities.
- Be aware that overfilling the chamber can reduce the effectiveness of the autoclave. The
 more densely loaded an autoclave, the longer it will take to reach the desired pressure and
 temperature.
- Spill clean-up procedures should be posted in every autoclave room and followed when a spill occurs.

- As you close the autoclave door, make sure items and fingers will not be trapped in the door to avoid severe pinches.
- Be sure the door on the autoclave is firmly locked before starting a cycle.

After the cycle has completed, there are several safety considerations to remember while unloading.

- Using effective personal protective equipment is absolutely essential to a researcher unloading an autoclave. A lab coat, closed-toed shoes, and gloves that are both heat and liquid resistant will ensure safety is maintained should an accident happen.
- The heat and pressure involved with sterilization is high, so be mindful of hot surfaces and steam releases.
- The pressure within the device should be zero before you attempt to open it.
- The door should be opened slowly to allow steam to gradually leave the unit, preventing steam burns and exploding glass.
- Give the contents time to cool before handling.
- Liquids can potentially be superheated, meaning they've reached a temperature above their boiling point without boiling. Disturbing such liquids can cause them to boil over!

Biosafety Cabinets

Biological safety cabinets (BSCs) come in a variety of types and configurations. The main purpose of a BSC is to protect workers, the product, and/or the environment. Not all biosafety cabinets protect all three but may protect one or two of them.

BSC should be selected based on the biological materials being used, the type of protection needed for the research, and the air handling system already provided in the building. All BSC contain a HEPA filter that separates the BSC from a fume hood. BSCs are classified into categories depending on the type of protection rendered. Nearly all BSC's in use at Ga Tech are Class II A2. These cabinets provide protection to the personnel, the environment, and the product. Laminar Flow hoods/clean benches do provide product protection but do not offer personnel protection and must never be used with infectious or toxic materials.

Working Safely in a BSC

- Turn on the Cabinet and allow to run for at least 4 minutes prior to starting work
- Collect all materials prior to work and place inside at the same time
- Move arms in and out of the cabinet slowly, perpendicular to the grill
- Do not store items on the front grill
- Perform operations at least four inches from the grill
- Clean with an appropriate disinfectant such as 70% ethanol after use
- 1:10 dilution of bleach can damage the stainless steel in the BSC

- o Wipe the cabinet with sterile water after the bleach is applied to remove residual chlorine that can corrode stainless steel
- Open flames in a BSC create turbulence; try alternatives like electric furnaces or touch-plate micro burners
- Wipe down all surfaces of materials prior to removing the item from the cabinet
- Always work from clean to dirty

Maintenance

- BSCs should be placed away from high traffic areas, doors, windows, air supply registers, and chemical fume hoods.
- All these areas can alter the airflow into the cabinet and cause a lapse in function and containment
- HEPA filters should be replaced on a regular basis or when airflow is no longer being maintained
- UV lamps in the units are not recommended for usage

Certification

- Must be performed on newly purchased units and anytime that a cabinet moves to a new location
- Must be performed annually
- Georgia Tech EHS uses a contractor that inspects and certifies BSCs and covers the costs of BSC certification
- EHS must be notified prior to purchase of a BSC and then when the unit is installed to ensure timely certification prior to usage of new BSCs
- EHS should also be notified prior to a BSC being moved to a new location to coordinate the
 decontamination of the cabinet prior to the move and recertification once the BSC is in the
 new location

Centrifuges

Individuals operating a centrifuge must be trained on the proper loading, operation, and unloading of the centrifuge. Severe damage and injury can occur if a centrifuge is not properly balanced. High-speed centrifugal force can generate significant amounts of aerosol if a tube breaks or leaks and an improperly balanced centrifuge can result in a centrifuge bucket being thrown through laboratory walls. The following procedures are recommended when centrifuging hazardous materials:

- Centrifuge tubes should never be filled more than ¾ full. Tube exteriors should be wiped prior to placing in the centrifuge cup or rotor
- Load infectious materials into the cup or rotor inside the biosafety cabinet. If working with RG2 materials, you are required to seal the rotor inside safety cup with a gasketed lid.

- Ensure the centrifuge is properly balanced prior to starting the run
- Allow samples to rest for a minute prior to unloading the cup or rotor inside the BSC
- Decontaminate the cup or rotor

Cryogenic Liquids

Cryogenic liquids are gases that have been transformed into extremely cold refrigerated liquids and are maintained at temperatures below -90°C. They are normally stored at low pressures in multi-walled, vacuum-insulated containers. The hazard potential presented by cryogenic liquids results from the extreme cold and pressure, which can result from rapid vaporization, and asphyxiation due to the displacement of air. Cryogenic liquids can produce effects similar to thermal burns and prolonged exposure can cause frostbite. When cryogenic liquids form a gas, it displaces air and if there isn't enough oxygen, asphyxiation can occur. Oxygen monitors are recommended in areas where liquid nitrogen dewers are stored.

Appropriate personal protective equipment (heavy leather gloves/gloves for extreme cold, safety shoes, aprons, and eye protection) must be worn when handling cryogenic liquids or materials preserved in cryogenic liquids.

Lasers

Laser use at Georgia Tech is subject to the regulations of the Georgia Department of Community Health. All laser users must take appropriate training and all lasers must be properly registered. Information on laser safety can be found here: https://www.ehs.gatech.edu/radiation/laser

Microwave Ovens

Microwave ovens used in the laboratory for research may not be used to heat food.

When melting agar the following precautions must be taken to prevent explosions: caps on screw-cap bottles must be loosened prior heating the bottles in the microwave, and the operator must wear appropriate personal protective equipment including laboratory coat or apron, heat resistant gloves, and face shield.

<u>Ultraviolet Light</u>

Under certain conditions of radiation intensity and exposure time UV radiation may kill certain types of microorganisms. The NIH, CDC, NSF, and ABSA agree that UV lamps are not recommended or necessary for decontamination of biosafety cabinets. The age of the UV lamp, dust accumulations on the bulb, and other factors that impede direct contact of the UV on the microorganisms contribute to decreased efficacy. Direct exposure to skin or eyes from UV light should be avoided.

Vacuum Lines

When a laboratory vacuum is used to manipulate biohazard materials, suitable filters and traps must be used to prevent contamination of the vacuum lines and pumps. Vacuum lines may need a HEPA filter depending on the specific material and laboratory setting.

Water Baths

All water baths should contain a disinfectant that is appropriate for use in a water bath. All water baths must be turned off overnight and monitored regularly for water levels. Immersion water baths must be used with metal containers, not plastic.

GUIDELINES FOR LABORATORY MOVES

It is expected that new construction and renovation projects involving biological laboratories are to be reviewed in the planning stages by the Environmental Health & Safety department in cooperation with Facilities Management, Campus Planning and Space Management, and other campus support groups. The Biosafety in Microbial and Biomedical Laboratories Guidelines (BMBL) and the Board of Regents Yellow Book should be followed when designing new construction and renovation projects.

Moving Laboratory Equipment

Potentially contaminated equipment is not to be removed from biological laboratories for repair, servicing, cleaning, surplus, or other purposes until decontamination and removal of biohazard labels has been performed. The investigator or laboratory supervisor is to certify such equipment as being free of biohazard agents. Service personnel may ask laboratory personnel to sign a certification statement that the decontamination procedure was performed.

Decontamination

Whenever moving equipment or materials from one location to another or surplus equipment in a biological laboratory, the Biosafety Officer must be notified at the EH&S office (404-894-6120).

After notifying the Biosafety Officer, all equipment used to manipulate or store biological agents or located in a biological laboratory (ex. Freezers, incubators, centrifuges, etc.) must be decontaminated with a disinfectant according to the following guidelines.

- Put on appropriate personal protective equipment
- Freezers should be emptied, thawed, and decontaminated prior to removal
- Run clean cycle on incubators or thoroughly disinfect interior chamber
- Spray laboratory equipment and items thoroughly with appropriate disinfectant
- Allow disinfectant to remain on the equipment and/or work surfaces for the appropriate contact time
- Completely remove (by wiping with a disposable towel) the disinfectant from the equipment or work surface if needed
- After decontamination, equipment can be sent to surplus or moved

Biosafety cabinets (BSCs) are not to be decontaminated by laboratory staff.

Disposing and Relocation of Biological Materials

Dispose of any waste materials (partially full sharps containers, used pipette tips, unwanted plastic/glassware) prior to moving by properly labeling and requesting pickup from EHS.

Assess all your biological materials and determine which materials will be transferred to your new laboratory. If you wish to dispose of any stock cultures to discontinue research with a particular material, dispose of it in the same way as you would have during your normal experimentation. If you are disposing of large quantities or are unsure of the proper procedure, contact the biosafety office.

Biological materials and potentially biohazardous materials (including all etiologic agents, microbial agents, toxins, human and animal tissues, blood and body fluids, etc.) to be moved must be inventoried and packed by responsible, trained staff. The materials must be properly labeled and packed to prevent spills or damage during transport. The packed boxes must also be labeled. Materials must be moved by trained staff or movers.

Materials (packaged or not) to be moved must not be abandoned or placed in hallways or other public areas.

As you prepare your samples for transport, consider creating a computerized inventory of your lab's biological materials.

Upon Arrival in Your New Lab

- If you have committee approvals with the IBC, IACUC, BMSC, or other Institute committee, you must notify the appropriate committee of your new building/room numbers.
- Your old lab must be decommissioned and the registration documents amended before work begins and your laboratory must be certified at the appropriate biosafety level by the Biosafety Officer.
- Transfer your chemical inventory to your new lab in EHSA

INSTITUTE RESPONSE TO UNSAFE ACTIONS/CONDITIONS IN LABORATORIES

The following information provides guidance as to how laboratory hazard levels are identified and responded to by EHS. However, this list is not all-inclusive; individual circumstances will vary, and the most appropriate action will be taken:

Level 1: Imminent Hazard with Potentially Severe Consequences

Imminent hazard caused by unsafe conditions or unsafe actions, which, in the judgment of the EHS representative on site, have the potential for severe consequences and may result in:

- Loss of life
- Serious injury with possibility of permanent damage to health or permanent disability
- Injury (including those by chemical exposures) likely to result in hospitalization
- May affect people outside of the lab
- May involve multiple victims
- May involve significant property damage, and/or building-wide business disruption and/or business disruption affecting the Institute.

Examples of imminent hazards with potentially severe consequences that may result from unsafe conditions or unsafe acts include, but are not limited to:

- Fires
- Floods
- Toxic or flammable gas releases or explosions
- Releases of highly toxic materials
- Releases of highly toxic materials to the environment
- Detonation of potentially explosive materials
- Run away reactions with the potential to cause any of the above
- Failure to use personal protective equipment or follow lab safety procedures while working with highly–hazardous substances such as pyrophorics or highly-energetic materials

Level 1 Response:

- Safely shut down process.
- If necessary, close lab to protect personnel, contain hazard, or to prevent re-entry by unauthorized personnel.
- Change locks if necessary.
- Situation report to PI, Chair, Dean, Director, Provost, EVP of Finance and Administration, and AVP of EHS.
- For unsafe conditions: lab may open as soon as conditions are rectified to EHS satisfaction/approval

• For unsafe acts by individuals or unsafe practices by lab groups: lab re- opening and /or disciplinary actions to be determined by Chair, Dean or Director and in accordance with Institute procedures.

Level 2: Imminent Hazard with Potentially Serious Consequences

Imminent hazard caused by unsafe conditions or unsafe actions which, in the judgment of the EHS representative on site, have the potential for serious consequences, and may result in:

- Temporary illness or minor injury
- May involve victim(s) receiving outside medical attention such as from an Emergency Room or Occupational Medicine Clinic, but is not likely to require hospitalization.
- May involve property damage and/or building-wide business disruption

Examples of serious events that may result from unsafe conditions or unsafe acts include but are not limited to:

- Exposures to one or more individuals to chemical, biological, or radiological materials
- Extremely poor housekeeping, improper segregation or storage of hazardous chemicals. Poor chemical hygiene
- Failure to use protective equipment or follow lab safety procedures while working with hazardous substances.
- Spills of chemical, biological, or radiological materials in a lab or in common areas
- Odor releases of known or unknown substances

Level 2 Response:

- Safely shut down process.
- If necessary, close lab to protect personnel, contain hazard, or to prevent re-entry by unauthorized personnel.
- Change locks if necessary.
- Situation report to PI, AVP of EHS
- For unsafe conditions: lab may open as soon as conditions are rectified to EHS approval
- For unsafe acts by individuals or unsafe practices by lab groups: additional situation reports to Chair, Dean, Provost, and EVP of Finance and Administration.
- For unsafe acts by individuals or unsafe practices by lab groups: lab re- opening and/ or disciplinary actions to be determined by Chair or Dean

Level 3: Not Imminent Hazard but Potentially Serious Consequences

Hazard caused by unsafe conditions or unsafe actions which, in the judgment of the EHS representative on site, have the potential for serious consequences.

Examples of Not Imminent Hazard but potentially Serious Consequences are generally the same as described in Levels 1 and 2.

Level 3 Response:

- Situation report to PI, AVP of EHS
- Follow up in 24 hours
- If no response, additional situation reports to Chair and Dean

Level 4: Not Imminent but Potential for Undesirable Consequences

Hazard caused by unsafe conditions or unsafe actions, which, in the judgment of the EHS representative on site, have the potential for undesirable consequences and may result in:

- Minor or minimally dangerous chemical spills
- Non- life threatening unplanned chemical reactions
- Increased risk of fire
- Increased risk of slips, trips, and falls

Examples of undesirable events that may result from unsafe conditions or unsafe acts include but are not limited to:

- Spills caused by poor housekeeping or clutter
- Unplanned reactions resulting from inappropriately stored chemicals or inadequately labeled waste
- Slips, trips, or falls caused by clutter, or by wires or tubing across walkways
- Adverse impact to indoor environmental quality in the lab and/or the building.

Level 4 Response:

Situation report or Lab Inspection report to PI within 3 days. If no response or situation still uncorrected after 1 month – situation report to Chair and Dean.

Level 5: Repeat Violations/ Failure to Correct

Hazard caused by unsafe conditions or unsafe actions which, in the judgment of the EHS representative on site, have the potential for Level 1-4 consequences.

- For unsafe conditions- would include multiple deficiencies which have not been corrected by the lab group in the specified time period
- For unsafe acts by individuals or unsafe practices by groups would include repeated violation of basic safety rules including housekeeping, attire, and personal protective equipment

Level 5 Response:

Situation Report to Dean/ Request for 1 week lab closure

- Close lab, change locks
- Meet with PI and Chair
- PI to present Chair and EHS with a written plan for correcting unsafe conditions and keeping the lab in the "corrected" condition.
- Lab to reopen at a time mutually agreed upon by EHS, Chair, Dean, and PI, not to exceed 1 week (assuming that all unsafe conditions have been corrected).

Other Circumstances:

For certain situations such as repeated and willful disregard and/or failure to use personal protective equipment (PPE), or grossly inadequate housekeeping, EHS is authorized to take appropriate action up to and including closing the laboratory until EHS, the Department and School Chair, Dean (or appropriate next level of supervision) authorizes re-opening. The PI, Chair and Dean will be notified promptly when this action is deemed necessary.

Disciplinary Actions

Any Georgia Tech student, faculty or staff member who fails to meet their responsibilities for safe conduct of work in laboratories or who knowingly and willfully disregards safety procedures will be held accountable and will be subject to disciplinary action in accordance with Institute procedures. In addition, any visitors using Georgia Tech laboratories who fail to meet their responsibilities for safe conduct of work, knowingly and willfully disregard safety procedures, or fail to comply with direct safety instructions from their Georgia Tech faculty sponsor, EHS, or emergency response personnel regarding emergencies or evacuations will be held accountable and subject to loss of privileges to use Georgia Tech laboratory facilities. (NOTE: "visitors" may include contractors, visiting scholars and other non-Georgia Tech personnel.