GEORGIA INSTITUTE OF TECHNOLOGY BIOSAFETY MANUAL POLICIES AND PROCEDURES April 2014

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Signature Page for Laboratory Personnel

l certify that:

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

Biological Materials I am trained to work with:

Signature

Date

PURPOSE

This document provides informational and policy resources for all Biosafety Level 1 (BSL-1) and Biosafety Level 2 (BSL-2) laboratory facilities and classrooms located at Georgia Institute of Technology and areas located off-campus under the supervision of Principal Investigators associated with Georgia Institute of Technology. Specifically, it details the approval process of all biological activities and details the standard operating procedures to be used to ensure a safe working environment while conducting research with recombinant DNA materials, toxins, infectious microorganisms, human cell cultures, body fluids, and other biological materials. The manual also addresses the movement of equipment and materials on and off campus to ensure the safety of those outside of Georgia Tech laboratories. This manual will be reviewed annually by the Biosafety Officer for changes or corrections to ensure that it is timely and accurate.

ENVIRONMENTAL HEALTH & SAFETY

The Environmental Health & Safety (EHS) office is responsible for biosafety on Georgia Tech's campus. EHS also provides guidance and oversight for laboratory safety programs including biosafety, chemical safety, laser, and radiological safety, provides fire safety and general safety services, processes and manages hazardous materials for proper disposal, provides emergency response for hazardous materials incidents / accidents (spills), and provides safety training.

For EHS Contacts, please check the EHS website: www.ehs.gatech.edu

Members of the Biological Materials Safeguards Committee Georgia Institute of Technology

Chair: Alfred Merrill, Ph.D. Professor and Smithhgall Chair in Molecular Cell Biology School of Biology 404 / 385-2842		
Thomas Barker Ph.D. Associate Professor Department of Biomedical Engineering 404 / 385-5044	Jim Spain, Ph.D. Professor School of Civil and Environmental Engineering 404 / 894-0628	Mary Beran Compliance Officer, Office of Research Compliance 404 / 385-2083
Mark Demyanek Environmental Health and Safety Assistant Vice President 404 / 894-1244	Meagan Fitzpatrick Biosafety Officer and Responsible Official Environmental Health and Safety 404 / 894-6120	Shane Gillooly Assistant Biosafety Officer and Responsible Official Environmental health and Safety 404 / 894-6119

The Biological Materials Safeguards Committee (BMSC) has the important mission of reviewing all applications for research, teaching, and training that involve the use of select agents, pathogenic organisms other than select agents, etiological agents, certain human samples, and other biological materials at Georgia Tech and ensuring that the proposed activities comply with the federal regulations governing them. The BMSC works closely with Georgia Tech's Institutional Biosafety Committee (IBC), the Institute Animal Care and Use Committee (IACUC), the Office of Research Integrity Assurance (ORIA), and the EHS Biosafety Officer.

The BMSC holds meetings as needed to review applications proposing the use of biological materials including pathogenic organisms, select agents, etiological agents, and human samples.

Members of the Institutional Biosafety Committee Georgia Institute of Technology

Chair: Andres Garcia, Ph.D. Associate Professor School of Mechanical EngineeringImage: Constraint of Mechanical EngineeringVoice 404-385-9384 Fax 404/894-0519Image: Constraint of Mechanical Engineering				
Kirill Lobachev Ph.D. Associate Professor School of Biology 404 / 385-6197	Meagan Fitzpatrick Biosafety Officer Environmental Health & Safety 404 / 894-6120		Todd McDevitt, Ph.D. Associate Professor School of Mechanical Engineering 404/ 385-6647	
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Barbara S. Henry Executive Director, Office of Research Integrity Assurance 404 / 894-6949				

The Institutional Biosafety Committee (IBC) has the important mission of reviewing all applications for research, teaching, and training that involve the use

of recombinant DNA and ensuring that the proposed activities comply with the federal regulations governing them. The IBC is responsible for maintaining Georgia Tech's registration with the National Institutes of Health's Office of Biotechnology Activities (OBA). IBC works closely with the EHS Biosafety Officer.

The IBC holds meetings on a quarterly basis or as needed to review applications proposing use of recombinant DNA.

General guidelines for covered rDNA projects can be found at: http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html

Members of the Occupational Health Committee Georgia Institute of Technology

Chair: Dennis Folds, Ph.D. Principal Research Scientist GRTI-ELSYS 404/407-7262				
Dr. Laura O'Farrell Attending Veterinarian GTRC 404/853-6233	Scott Morrison Chief HR Officer Human Resources 404/894-2499	Director of Facilities Operations and Maintenance 404/894-1631		
Barbara S. Henry Executive Director Office of Research Integrity Assurance 404 / 894-6949	Meagan Fitzpatrick Biosafety Officer Environmental Health & Safety 404 / 894-6120	Shane Gillooly Assistant Biosafety Officer Environmental Health and Safety 404/894/6119		
Debbie Wolfe-Lopez Chemical Safety Manager Office of Environmental Health and Safety 404/385-2964	Aleece Foxx General Safety Manager Office of Environmental Health and Safety 404/385-0263	Marueen Olsen Medical Director of Student Health Services		
	Ex Officia	404/385-3256		
Ex Officio				
Mark Demyanek Assistant Vice President Environmental Health and Safety/Facilities Management 404 / 894-1244				

The Occupational Health and Safety Committee (OHSC) has the mission of ensuring employee and student workplace health and safety. The committee is responsible for developing and advising EHS on the administration of the Occupational Health Program for workers engaged in research using animal models, human tissues and blood, pathogenic organisms, select agents, and other biological materials. OHSC works closely with Georgia Tech's Responsible Official and Biosafety Officer in the Office of Environmental Health and Safety.

SECTION I- RESPONSIBILITIES

A. Georgia Institute of Technology

The Institute and its administrative officers are responsible for the following:

- 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.

B. 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 grant applications and determine if the research is properly approved by the Biological Materials Safeguards Committee as well as to ensure that the laboratory is in compliance with all biosafety policies.
- 2) May suspend or interrupt 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) Review BMSC applications and assign applications to the BMSC for review as appropriate.
- Arranging for initial and periodic inspections of laboratories used in biohazardous research to ensure that standards set by the BMSC, IBC, and OHSC are followed.

- 5) Providing technical advice to Principal Investigators and to the BMSC, IBC, and OHSC committees on research safety procedures.
- 6) Develop and conducting trainings on biological materials for the Institute community.
- 7) 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.
- 8) Participate in committee meetings involving biological safety.

C. Responsible Official/Alternate Responsible Official for Select Agents

The Responsible Official has the following responsibilities:

- Submits applications regarding select agents to United States Department for Health and Human Services via the Center for Disease Control (CDC) or United States Department of Agriculture via the Animal Plant Health Inspection Services (APHIS) for Georgia Tech.
- 2) Works with Emergency Preparedness to determine security needs for select agent or toxin laboratories.
- 3) Develop a biosafety plan for select agent laboratories.
- 4) Regularly inspect laboratories containing select agents.
- 5) Develop an emergency response plan for laboratories housing select agents.
- 6) Provide training for all individuals that work with the select agent/toxin.
- 7) Keep thorough records of individuals, inventories, and areas where agents/toxins are used.
- 8) Provide technical advice to the BMSC on select agent proposals.
- 9) Notify DHHS to report thefts, losses, or releases of select agent/toxin.
- 10) Advise PI on destruction of materials and notify DHHS before destroying a select agent/toxin.
- D. Biological Materials Safeguards Committee

The Biological Materials Safeguards Committee (BMSC) serves to advise the Institute's administration on policies pertaining to biological research. The committee recommends standards under which biohazardous activities should be conducted and reviews projects for compliance with appropriate federal, state, and Institutional guidelines and regulations. Other specific responsibilities include:

- 1) Review for appropriateness and adequacy the containment levels and safety measures proposed and/or used in biohazardous research and teaching.
- 2) Assess 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) Develop, with the Biosafety Officer, training seminars and workshops on biohazards for the Institute community.
- 4) Periodically review biological research being conducted at the Institute to insure that the requirements of the Institute, funding sources, and regulatory agencies are being fulfilled.
- 5) Recommend to the Institute Administration appropriate sanctions for noncompliance with biosafety standards, guidelines, or regulations.
- 6) Develop with the Biosafety Officer emergency plans covering accidental spills 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.

E. Institute Biosafety Committee

The Institutional Biosafety Committee (IBC) strives to ensure the safe conduct of activities involving recombinant DNA (rDNA). The committee also advises the Institute's administration on policies pertaining to rDNA research. The committee establishes standards under which rDNA activities should be conducted and reviews projects for compliance with appropriate federal, state, and Institutional guidelines and regulations. Other specific responsibilities include:

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

- 2) Assess the adequacy of containment facilities for rDNA molecules as required by NIH or other funding or regulatory agencies.
- 3) Periodically review rDNA research being conducted at the Institute to insure that the requirements of the Institute, funding sources, and regulatory agencies are being fulfilled.
- 4) Reviews allegations of non-compliance with rDNA standards, guidelines, or regulations.
- 5) Develop, with the Biosafety Officer, emergency plans covering accidental spills 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

F. Occupational Health and Safety Committee

The Occupational Health and Safety committee serves to advise the Institute's administration on policies pertaining to the creation and maintenance of a safe research environment. Other specific responsibilities include:

- 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.

G. 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.

H. 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 (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 a positive safety attitude.
 - b. Posting or making readily available to the laboratory staff copies of the protocols that describe potential biohazards/rDNA issues 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.
 - c. 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.

- d. Supervising the performance of the staff to ensure that required safety practices and techniques are employed.
- 2) Report, via an EHS Injury and Illness Report Form, any accident, exposure, or suspected illness of laboratory personnel.
- 3) Report in writing to the Biosafety Officer any release from containment of biohazardous/rDNA agents 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) Insure 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.

I. 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 a Signature page for Laboratory Personnel and return the form to EHS.
- 3) Enroll in the Occupational Health Program by completing the Occupational Health Program Confidential Risk Assessment/Exposure Questionnaire.
- 4) Attend EHS training based on research activities and as determined by your 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 if after hours.

SECTION II – INSTITUTE RESPONSE TO UNSAFE ACTIONS AND/OR UNSAFE CONDITIONS IN LABORATORIES

Taken from the Georgia Tech Laboratory Safety Manual (May, 2013) pages 15-18

The following table 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 reopening 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 reopening 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 walk ways
- 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.

SECTION III – PERSONAL PROTECTIVE EQUIPMENT (PPE)

The following is an excerpt on appropriate PPE in Georgia Tech laboratories. The entire Laboratory Personal Protective Equipment and Appropriate Attire Policy can be found at: <u>http://www.ehs.gatech.edu/chemical/ppePolicy.pdf</u>

PPE includes, but is not limited to, safety glasses, goggles, face shields, gloves, lab coats, aprons, ear plugs, and respirators. Additional PPE such as ear plugs and respirators should only be used as a "last resort" if the potential exposures cannot be eliminated with properly-designed engineering controls. PPE is carefully selected to ensure that it is compatible with the chemicals and the process used.

7.1 Eye Protection:

7.1.1. Safety glasses or chemical goggles must be donned before entering any wet bench lab, including cell culture labs. This applies to lab visitors, GT maintenance and custodial workers as well as staff and students

7.1.2. Safety glasses must meet the ANSI Z87.1 standard for impact resistance and have side shields for splash protection.

7.1.3. Safety glasses should be chosen to conform to the wearers face and minimize gaps around the glasses.

7.1.4. 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. When exposure to these hazards cannot be avoided by use of engineering controls, chemical goggles shall be worn.

7.1.5. Safety glasses or goggles must be worn over prescription glasses and must be of a type intended to be worn over prescription glasses.

7.1.6. Prescription safety glasses are acceptable as long as they have side shields for splash protection and conform to the wearer's face.

7.1.7 Safety glasses or goggles are required in all labs where soldering or machine/grinding occur.

7.2 Contact Lenses

7.2.1 Do not provide protection against chemicals or particulates and are allowed in laboratories only with appropriate eye protection

7.2.2 Per the National Institutes of Occupational Safety and Health, wearing contact lenses does not appear to require enhanced eye and face protection.
7.2.3 OSHA recommends against the use of contact lenses when working with the following chemicals: acrylonitrile, methylene chloride, 1,2 dibromo-3-chlorppropane, ethylene oxide, and methylene dianiline.

7.2.3.2 OSHA has not published documentation supporting this recommendation.

7.2.3.2 GT EHS recommends working with these materials only inside a fume hood and has no objections to contact lens use in laboratories where these chemicals are present.

7.3 Lab coats

7.3.1 Shall be donned before handling chemicals, biologicals, or radiological.

7.3.2 Must be in good condition and reasonably clean so as to not create a hazard.

7.3.3 Shall cover the wearer to the knees

7.3.4 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.

7.3.5 Lab coats made of polyester-cotton blends (no less than 35% cotton) are acceptable in labs where no open flames are present

7.3.6 Lab coats must be made of 100% cotton or flame resistant materials in labs where open flames are used (such as alcohol burners)

7.3.7 Lab coats of flame resistant (FR) material are required in labs where pyrophoric materials are handled. Persons working with pyrophoric liquids are also required to wear 100% cotton clothing underneath the FR lab coat on days that they handle these materials in the lab.

7.3.8 Flame Resistant lab coats must meet the following criteria for the purpose of minimizing injury in the event of a splash of pyrophoric liquid:

7.3.8.1 9oz fabric weight7.3.8.2 Arc Rating: 12.4 ATPV7.3.8.3 Meets NFPA 70E Hazard Risk Category (HRC) 8

7.4 Laundering Lab Coats

7.4.1 Laboratories are expected to keep lab coats in good condition and reasonably clean so as to not create a safety hazard.

7.4.2 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).

7.4.3 As of August 2010, there were no identified laundry services in Atlanta that would accept lab coats from chemistry labs, however: some labs at GT use a uniform service to both supply and launder their lab coats (including pickup and delivery). If you would like more information about this service (which was found

to be very cost effective) please contact EHS Chemical and Laboratory Safety at 404-894-4635 or (www,ehs,gatech.edu)

7.5 Face Protection

7.5.1 Face Shields worn over safety glasses may be required for certain processes as determined by the Principal Investigator (PI) and/or GT EHS. These include but are not limited to cryogenic operations and soldering.

7.5.2 Face Shields must always be worn over safety glasses or goggles, not instead of safety glasses or goggles.

7.5.3 The use of face shields over safety glasses are required with processes involving high pressure reactors (>30 PSI), machining operations.

7.6 Hand Protection

7.6.1 Chemically-Resistant Gloves

7.6.1.1 Appropriately resistant gloves must be worn when handling chemicals, biologicals, or radiologicals.

7.6.1.2 Gloves shall be chosen to be appropriately chemically resistant but also to be appropriate for the process, e.g. gloves shall not put the wearer at risk by causing:

7.6.1.2.1 Loss of dexterity

7.6.1.2.2 Risk of ergonomic injury (s/a increased muscle strain from gloves that are too heavy or stiff for pipetting, handling small objects, etc.)

7.6.1.2.3 Increased risk of being caught in rotating equipment (from gloves that are too loose on the user's hands)

7.6.1.3 Nitrile exam gloves shall be used in all general purpose chemistry labs as the "general purpose Glove".

7.6.2 Other Types of Gloves

7.6.2.1 Protective gloves must be selected as appropriate for their processes to protect from physical trauma including but not limited to:

7.6.2.1.1 Thermally protective gloves for hot or cold processes. Lineman rubber gloves for electrical hazards.

7.6.2.1.2 Appropriate gloves for protection against abrasions and cuts 7.6.2.1.3 Gloves must be chosen so as to not create a hazard around moving machinery.

SECTION IV- 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 man, 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 man.
- Risk Group 1 Agents are those agents which are unlikely to cause disease in humans. Class 1 Agents can be handled in Biosafety Level 1 or greater containment facilities. Most commonly found in general undergraduate microbiology laboratory classes.
- 4) Risk Group 2 Agents are those agents which may produce disease of varying degrees of severity from exposure by injection, ingestion, adsorption, and inhalation, but which are contained by good laboratory techniques are included in this level. There are generally effective prophylaxis and treatments for these agents. Class 2 Agents must be handled using Biosafety Level 2 or greater containment facilities and practices.
- 5) Risk Group 3 Agents are indigenous or exotic agents or exotic strains of indigenous agents which may cause serious or potentially lethal disease. Most have an effective prophylaxis or treatment yet these agents are still a serous risk to researchers and the community at large. Class 3 agents should be handled using Biosafety Level 3 or greater containment facilities and practices.
- 6) Risk Group 4 Agents are indigenous or exotic agents or exotic strains of indigenous agents which cause serous or lethal disease. These agents do not have effective prophylaxis or treatments and pose a very serious risk to researcher health and the community at large. Class 4 Agents should be handled using Biosafety Level 4 or greater containment facilities or practices.
- 7) Restricted Mammalian Pathogens nonindigenous pathogens of domestic livestock and poultry that may require special containment strategies and facilities not discussed in this manual.
- 8) 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:

- i. Human, mammalian, and plant pathogens (bacteria, parasites, fungi, viruses);
- ii. All human blood, blood products, tissues, and certain body fluids (excluding routine use of human blood and body fluid for clinical purposes);
- iii. Cultured human or mammalian cells and potentially infectious agents these cells may contain;
- iv. Clinical specimens and waste
- v. Infected mammals and mammalian tissues.

SECTION V- BIOSAFETY LEVEL DEFINITIONS

There are four biosafety levels for biocontainment that are used to isolate biological materials and protect workers:

- a) <u>Biosafety Level 1 (BSL 1)</u> suitable for work involving agents of no known or of minimal potential hazard to laboratory personnel and the environment.
- b) <u>Biosafety Level 2 (BSL 2)</u> suitable for work involving agents of moderate potential hazard to personnel and the environment. Agents which may produce disease of varying degrees of severity from exposure by injection, ingestion, adsorption, and inhalation, but which are contained by good laboratory techniques are included in this level. Any agents from outside of Georgia which may require a state or federal permit for importation are to be contained at BSL-2 or greater.
- c) <u>Biosafety Level 3 (BSL 3)</u>– applicable to clinical, diagnostic, teaching, and research or production facilities involving indigenous or exotic agents or exotic strains of indigenous agents which may cause serious or potentially lethal disease as a result of exposure by inhalation. Autoinoculation and ingestion also represent major hazards to personnel working with agents in this classification. A greater level of attention to microbiological practices, laboratory containment and safety equipment, and facilities is required. There are currently no BSL 3 laboratories on the Georgia Tech campus.
- d) <u>Biosafety Level 4 (BSL 4)</u> required for work with dangerous and exotic agents which pose a high individual risk of life-threatening disease. There are currently no BSL-4 approved facilities at Georgia Institute of Technology at this time.

SECTION VI – STANDARD OPERATING PROCEDURES AND CONTAINMENT OF BIOLOGICAL RESEARCH

Physical Containment of Experiments

Within each type of biohazard there are different degrees of risk which require different levels of containment. The term "containment" is used to describing safe methods for managing biohazardous agents in the laboratory environment where they are being handled or maintained. Primary containment, the protection of personnel and the immediate laboratory environment from exposure, is provided by good technique and the use of appropriate safety equipment that has been properly designed, located, installed, and maintained. Secondary containment, the protection of the environment external to the laboratory from exposure to biohazardous agents, is provided by a combination of facility design and operational practices.

Definitions:

- a. Primary Containment—the usage of safety equipment including but not limited to biological safety cabinets as well as the usage of personal protective equipment.
- b. Secondary Containment—the control of release of microorganisms into the environment by appropriate building design, air handling standards, and operational practices.

Biosafety Level 1

Biosafety Level 1 is suitable for work involving well-characterized agents not known to consistently cause disease in immunocompetent adult humans, and present minimal potential hazard to laboratory personnel and the environment. BSL-1 laboratories are not necessarily separated from the general traffic patterns in the building. Work is typically conducted on open bench tops using standard microbiological practices. Special containment equipment or facility design is not required, but may be used as determined by appropriate risk assessment. Laboratory personnel must have specific training in the procedures conducted in the laboratory and must be supervised by a scientist with training in microbiology or a related science.

The following standard practices, safety equipment, and facility requirements apply to BSL-1.

A. Standard Microbiological Practices

1. The laboratory supervisor must enforce the institutional policies that control access to the laboratory.

- 2. Persons must wash their hands after working with potentially hazardous materials and before leaving the laboratory.
- 3. Eating, drinking, smoking, handling contact lenses, applying cosmetics, and storing food for human consumption must not be permitted in laboratory areas. Food must be stored outside the laboratory area in cabinets or refrigerators designated and used for this purpose.
- 4. Mouth pipetting is prohibited; mechanical pipetting devices must be used.
- 5. Policies for the safe handling of sharps, such as needles, scalpels, pipettes, and broken glassware must be developed and implemented. Whenever practical, laboratory supervisors should adopt improved engineering and work practice controls that reduce risk of sharps injuries. Precautions, including those listed below, must always be taken with sharp items. These include:
 - a. Careful management of needles and other sharps are of primary importance. Needles must not be bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal.
 - Used disposable needles and syringes must be carefully placed in conveniently located puncture-resistant containers used for sharps disposal.
 - c.Non-disposable sharps must be placed in a hard walled container for transport to a processing area for decontamination, preferably by autoclaving.
 - d. Broken glassware must not be handled directly. Instead, it must be removed using a brush and dustpan, tongs, or forceps. Plastic ware should be substituted for glassware whenever possible.
- 6. Perform all procedures to minimize the creation of splashes and/or aerosols.
- 7. Decontaminate work surfaces after completion of work and after any spill or splash of potentially infectious material with appropriate disinfectant.
- 8. Decontaminate all cultures, stocks, and other potentially infectious materials before disposal using an effective method. Depending on where the decontamination will be performed, the following methods should be used prior to transport.
 - a. Materials to be decontaminated outside of the immediate laboratory must be placed in a durable, leak proof container and secured for transport.

- b. Materials to be removed from the facility for decontamination must be packed in accordance with applicable local, state, and federal regulations.
- 9. A sign incorporating the universal biohazard symbol must be posted at the entrance to the laboratory. A sign with the name and phone number of the laboratory supervisor or other responsible personnel must also be posted. Georgia Tech does not require specific agent information except in the case of viral vectors. This sign can be found in the appendix section of this manual.
- 10. An effective integrated pest management program is required.
- 11. The laboratory supervisor must ensure that laboratory personnel receive appropriate training regarding their duties, the necessary precautions to prevent exposures, and exposure evaluation procedures. Personnel must receive annual updates or additional training when procedural or policy changes occur. Personal health status may impact an individual's susceptibility to infection, ability to receive immunizations or prophylactic interventions. Therefore, all laboratory personnel and particularly women of childbearing age should be provided with information regarding immune competence and conditions that may predispose them to infection. Individuals having these conditions should be encouraged to self-identify to the institution's healthcare provider for appropriate counseling and guidance.

B. Special Practices

None required.

C. 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 required to prevent contamination of personal clothing.
- 3. Wearing of protective eyewear is required. Persons who wear contact lenses and glasses in laboratories must also wear eye protection.
- 4. Gloves must be worn to protect hands from exposure to biological materials. Glove selection should be based on an appropriate risk assessment. Alternatives to latex gloves should be available. Wash hands prior to leaving the laboratory. In addition, BSL-1 workers should:
 - a. Change gloves when contaminated, glove integrity is compromised, or when otherwise necessary.

- b. Remove gloves and wash hands when work with hazardous materials has been completed and before leaving the laboratory.
- c. Do not wash or reuse disposable gloves. Dispose of used gloves with other contaminated laboratory waste. Hand washing protocols must be rigorously followed.

D. Laboratory Facilities (Secondary Barriers)

- 1. Laboratories should have doors for access control.
- 2. Laboratories must have a sink for hand washing.
- 3. The laboratory should be designed so that it can be easily cleaned. Carpets and rugs in laboratories are not appropriate.
- 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 nonporous material that can be easily cleaned and decontaminated with appropriate disinfectant.
- 5. Laboratories windows that open to the exterior should be fitted with screens.

Biosafety Level 2

Biosafety Level 2 builds upon BSL-1. BSL-2 is suitable for work involving agents that pose moderate hazards to personnel and the environment. It differs from BSL-1 in that: 1) laboratory personnel have specific training in handling pathogenic agents and are supervised by scientists competent in handling infectious agents and associated procedures; 2) access to the laboratory is restricted when work is being conducted; and 3) all procedures in which infectious aerosols or splashes may be created are conducted in BSCs or other physical containment equipment.

The following standard and special practices, safety equipment, and facility requirements apply to BSL-2.

A. Standard Microbiological Practices

- 1. The laboratory supervisor must enforce the institutional policies that control access to the laboratory.
- 2. Persons must wash their hands after working with potentially hazardous materials and before leaving the laboratory.
- 3. Eating, drinking, smoking, handling contact lenses, applying cosmetics, and storing food for human consumption must not be permitted in laboratory areas. Food must be stored outside the laboratory area in cabinets or refrigerators designated and used for this purpose.34 Biosafety in Microbiological and Biomedical Laboratories
- 4. Mouth pipetting is prohibited; mechanical pipetting devices must be used.
- 5. Policies for the safe handling of sharps, such as needles, scalpels, pipettes, and broken glassware must be developed and implemented. Whenever practical, laboratory supervisors should adopt improved engineering and work practice controls that reduce risk of sharps injuries. Precautions, including those listed below, must always be taken with sharp items. These include:
 - a. Careful management of needles and other sharps are of primary importance. Needles must not be bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal.
 - b. Used disposable needles and syringes must be carefully placed in conveniently located puncture-resistant containers used for sharps disposal.
 - c.Non-disposable sharps must be placed in a hard walled container for transport to a processing area for decontamination, preferably by autoclaving.
 - d. Broken glassware must not be handled directly. Instead, it must be removed using a brush and dustpan, tongs, or forceps. Plastic ware should be substituted for glassware whenever possible.
- 6. Perform all procedures to minimize the creation of splashes and/or aerosols.
- 7. Decontaminate work surfaces after completion of work and after any spill or splash of potentially infectious material with appropriate disinfectant.
- 8. Decontaminate all cultures, stocks, and other potentially infectious materials before disposal using an effective method. Depending on where the decontamination will be performed, the following methods should be used prior to transport:

- a. Materials to be decontaminated outside of the immediate laboratory must be placed in a durable, leak proof container and secured for transport.
- b. Materials to be removed from the facility for decontamination must be packed in accordance with applicable local, state, and federal regulations.
- 9. A sign incorporating the universal biohazard symbol must be posted at the entrance to the laboratory. A sign must be posted with the name and phone number of the principal investigator and another emergency contact. Agent information must only be posted during the use of viral vectors. (See Appendix A for a copy of the sign.)
- 10. An effective integrated pest management program is required. (See Appendix C.)
- 11. The laboratory supervisor must ensure that laboratory personnel receive appropriate training regarding their duties, the necessary precautions to prevent exposures, and exposure evaluation procedures. Personnel must receive annual updates or additional training when procedural or policy changes occur. Personal health status may impact an individual's susceptibility to infection, ability to receive immunizations or prophylactic interventions. Therefore, all laboratory personnel and particularly women of childbearing age should be provided with information regarding immune competence and conditions that may predispose them to infection. Individuals having these conditions should be encouraged to self-identify to the institution's healthcare provider for appropriate counseling and guidance.

B. Special Practices

- 1. All persons entering the laboratory must be advised of the potential hazards and meet specific entry/exit requirements.
- 2. Laboratory personnel must be enrolled in the Occupational Health Program and offered available immunizations for agents handled or potentially present in the laboratory.
- 3. Each institution should consider the need for collection and storage of serum samples from at-risk personnel.
- 4. A laboratory-specific hygiene plan must be prepared and adopted as policy. The hygiene plan must be available and accessible.

- 5. The laboratory supervisor must ensure that laboratory personnel demonstrate proficiency in standard and special microbiological practices before working with BSL-2 agents.
- 6. Potentially infectious materials must be placed in a durable, leak proof container during collection, handling, processing, storage, or transport within a facility.
- 7. Laboratory equipment should be routinely decontaminated, as well as, after spills, splashes, or other potential contamination.
 - 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.
- 8. Incidents that may result in exposure to infectious materials must be immediately evaluated and treated according to procedures described in the laboratory biosafety manual. All such incidents must be reported to the laboratory supervisor. Medical evaluation, surveillance, and treatment should be provided and appropriate records maintained.
- 9. Animal and plants not associated with the work being performed must not be permitted in the laboratory.
- 10. All procedures involving the manipulation of infectious materials that may generate an aerosol should be conducted within a BSC or other physical containment devices.

C. Safety Equipment (Primary Barriers and Personal Protective Equipment)

- 1. Properly maintained BSCs, other appropriate personal protective equipment, or other physical containment devices must be used whenever:
 - a. Procedures with a potential for creating infectious aerosols or splashes are conducted. These may include pipetting, centrifuging, grinding, blending, shaking, mixing, sonicating, opening containers of infectious materials, inoculating animals intranasally, and harvesting infected tissues from animals or eggs.
 - b. High concentrations or large volumes of infectious agents are used. Such materials may be centrifuged in the open laboratory using sealed rotor heads or centrifuge safety cups.

- 2. Protective laboratory coats, gowns, or smocks designated for laboratory use must be worn while working in the laboratory materials. Remove protective clothing before leaving for non-laboratory areas, e.g., cafeteria, library, and administrative offices). Dispose of protective clothing appropriately, or deposit it for laundering by the institution. It is recommended that laboratory clothing not be taken home.
- 3. Eye and face protection, goggles, mask, or face shield, must be worn at all times while in the laboratory. This includes time when active research is not being conducted and the person is still in the laboratory. Persons who wear contact lenses in laboratories should also wear eye protection.
- 4. Gloves must be worn to protect hands from exposure to hazardous materials. Glove selection should be based on an appropriate risk assessment. Alternatives to latex gloves should be available. Gloves must not be worn outside the laboratory. In addition, BSL-2 laboratory workers should:
 - a. Change gloves when contaminated, glove integrity is compromised, or when otherwise necessary.
 - b. Remove gloves and wash hands when work with hazardous materials has been completed and before leaving the laboratory.
 - c. Do not wash or reuse disposable gloves. Dispose of used gloves with other contaminated laboratory waste. Hand washing protocols must be rigorously followed.
- 5. Eye, face and respiratory protection should be used in rooms containing infected animals as determined by the risk assessment.

D. Laboratory Facilities (Secondary Barriers)

- 1. Laboratory doors should be self-closing and have locks in accordance with the institutional policies.
- 2. Laboratories must have a sink for hand washing. The sink may be manually, hands-free, or automatically operated. It should be located near the exit door.
- 3. The laboratory should be 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 nonporous 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 should be protected with liquid disinfectant traps.
- 8. An eyewash station must be readily available.
- 9. 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.
- 10. 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.
- 11. A method for decontaminating all laboratory wastes should be available in the facility (e.g., autoclave, chemical disinfection, incineration, or other validated decontamination method).

Biosafety Level 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. The following standard and special safety practices, equipment, and facility requirements apply to BSL-3.

A. Standard Microbiological Practices

- 1. The laboratory supervisor must enforce the institutional policies that control access to the laboratory.
- 2. Persons must wash their hands after working with potentially hazardous materials and before leaving the laboratory.
- 3. Eating, drinking, smoking, handling contact lenses, applying cosmetics, and storing food for human consumption must not be permitted in laboratory areas. Food must be stored outside the laboratory area in cabinets or refrigerators designated and used for this purpose.
- 4. Mouth pipetting is prohibited; mechanical pipetting devices must be used.
- 5. Policies for the safe handling of sharps, such as needles, scalpels, pipettes, and broken glassware must be developed and implemented. Whenever practical, laboratory supervisors should adopt improved engineering and work practice controls that reduce risk of sharps injuries.
- Precautions, including those listed below, must always be taken with sharp items. These include:
 - a. Careful management of needles and other sharps are of primary importance. Needles must not be bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal.
 - Used disposable needles and syringes must be carefully placed in conveniently located puncture-resistant containers used for sharps disposal.
 - c.Non-disposable sharps must be placed in a hard walled container for transport to a processing area for decontamination, preferably by autoclaving.
 - d. Broken glassware must not be handled directly. Instead, it must be removed using a brush and dustpan, tongs, or forceps. Plastic ware should be substituted for glassware whenever possible.
- 6. Perform all procedures to minimize the creation of splashes and/or aerosols.

- 7. Decontaminate work surfaces after completion of work and after any spill or splash of potentially infectious material with appropriate disinfectant.
- 8. Decontaminate all cultures, stocks, and other potentially infectious materials before disposal using an effective method. A method for decontaminating all laboratory wastes should be available in the facility, preferably within the laboratory (e.g., autoclave, chemical disinfection, incineration, or other validated decontamination method). Depending on where the decontamination will be performed, the following methods should be used prior to transport:
 - a. Materials to be decontaminated outside of the immediate laboratory must be placed in a durable, leak proof container and secured for transport.
 - b. Materials to be removed from the facility for decontamination must be packed in accordance with applicable local, state, and federal regulations.
- 9. A sign incorporating the universal biohazard symbol must be posted at the entrance to the laboratory when infectious agents are present. Posted information must include the laboratory's biosafety level, the supervisor's name (or other responsible personnel), telephone number, and required procedures for entering and exiting the laboratory. Agent information should be posted in accordance with the institutional policy.
- 10. An effective integrated pest management program is required. (See Appendix G.)
- 11. The laboratory supervisor must ensure that laboratory personnel receive appropriate training regarding their duties, the necessary precautions to prevent exposures, and exposure evaluation procedures. Personnel must receive annual updates or additional training when procedural or policy changes occur. Personal health status may impact an individual's susceptibility to infection, ability to receive immunizations or prophylactic interventions. Therefore, all laboratory personnel and particularly women of childbearing age should be provided with information regarding immune competence and conditions that may predispose them to infection. Individuals having these conditions should be encouraged to self-identify to the institution's healthcare provider for appropriate counseling and guidance.

B. Special Practices

1. All persons entering the laboratory must be advised of the potential hazards and meet specific entry/exit requirements.

- 2. Laboratory personnel must be provided medical surveillance and offered appropriate immunizations for agents handled or potentially present in the laboratory.
- 3. Each institution should consider the need for collection and storage of serum samples from at-risk personnel.
- 5. A laboratory-specific biosafety manual must be prepared and adopted as policy. The biosafety manual must be available and accessible.
- 6. The laboratory supervisor must ensure that laboratory personnel demonstrate proficiency in standard and special microbiological practices before working with BSL-3 agents.
- 7. Potentially infectious materials must be placed in a durable, leak proof container during collection, handling, processing, storage, or transport within a facility.
- 8. Laboratory equipment should be routinely decontaminated, as well as, after spills, splashes, or other potential contamination.
 - 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.
- Incidents that may result in exposure to infectious materials must be immediately evaluated and treated according to procedures described in the laboratory biosafety manual. All such incidents must be reported to the laboratory supervisor. Medical evaluation, surveillance, and treatment should be provided and appropriate records maintained.
- 10. Animals and plants not associated with the work being performed must not be permitted in the laboratory.
- 11. All procedures involving the manipulation of infectious materials must be conducted within a BSC, or other physical containment devices. No work with open vessels is conducted on the bench. When a procedure cannot be performed within a BSC, a combination of personal protective equipment and other containment devices, such as a centrifuge safety cup or sealed rotor must be used.

C. Safety Equipment (Primary Barriers and Personal Protective Equipment)

- 1. All procedures involving the manipulation of infectious materials must be conducted within a BSC (preferably Class II or Class III), or other physical containment devices.
- Workers in the laboratory where protective laboratory 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.
- 3. Eye and face protection (goggles, mask, face shield or other splash guard) is used for anticipated splashes or sprays of infectious or other hazardous materials. Eye and face protection must be disposed of with other contaminated laboratory waste or decontaminated before reuse. Persons who wear contact lenses in laboratories must also wear eye protection.
- 4. Gloves must be worn to protect hands from exposure to hazardous materials. Glove selection should be based on an appropriate risk assessment. Alternatives to latex gloves should be available. Gloves must not be worn outside the laboratory. In addition, BSL-3 laboratory workers:
 - a. Changes gloves when contaminated, glove integrity is compromised, or when otherwise necessary. Wear two pairs of gloves when appropriate.
 - b. Remove gloves and wash hands when work with hazardous materials has been completed and before leaving the laboratory.
 - c.Do not wash or reuse disposable gloves. Dispose of used gloves with other contaminated laboratory waste. Hand washing protocols must be rigorously followed.
- 5. Eye, face, and respiratory protection must be used in rooms containing infected animals.

D. Laboratory Facilities (Secondary Barriers)

- 1. Laboratory doors must be self-closing and have locks in accordance with the institutional policies. The laboratory must be separated from areas that are open to unrestricted traffic flow within the building. Laboratory access is restricted. Access to the laboratory is through two self-closing doors. A clothing change room (anteroom) may be included in the passageway between the two self-closing doors.
- 2. Laboratories must have a sink for hand washing. The sink must be handsfree or automatically operated. It should be located near the exit door. If

the laboratory is segregated into different laboratories, a sink must also be available for hand washing in each zone. Additional sinks may be required as determined by the risk assessment.

- 3. The laboratory must be designed so that it can be easily cleaned and decontaminated. Carpets and rugs are not permitted. Seams, floors, walls, and ceiling surfaces should be sealed. Spaces around doors and ventilation openings should be capable of being sealed to facilitate space decontamination.
 - a. Floors must be slip resistant, impervious to liquids, and resistant to chemicals. Consideration should be given to the installation of seamless, sealed, resilient or poured floors, with integral cove bases.
 - b. Walls should be constructed to produce a sealed smooth finish that can be easily cleaned and decontaminated.
 - c. Ceilings should be constructed, sealed, and finished in the same general manner as walls.
- Decontamination of the entire laboratory should be considered when there has been gross contamination of the space, significant changes in laboratory usage, for major renovations, or maintenance shut downs. Selection of the appropriate materials and methods used to decontaminate the laboratory must be based on the risk assessment.
- 4. Laboratory furniture must be capable of supporting anticipated loads and uses. Spaces between benches, cabinets, and equipment must 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 nonporous material that can be easily cleaned and decontaminated with appropriate disinfectant.
- 5. All windows in the laboratory must be sealed.
- 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, heavily traveled laboratory areas, and other possible airflow disruptions.
- 7. Vacuum lines must be protected with HEPA filters, or their equivalent. Filters must be replaced as needed. Liquid disinfectant traps may be required.

- 8. An eyewash station must be readily available in the laboratory.
- A ducted air ventilation system is required. This system must provide sustained directional airflow by drawing air into the laboratory from "clean" areas toward "potentially contaminated" areas. The laboratory shall be designed such that under failure conditions the airflow will not be reversed.
 - a. Laboratory personnel must be able to verify directional airflow. A visual monitoring device, which confirms directional airflow, must be provided at the laboratory entry. Audible alarms should be considered to notify personnel of air flow disruption.
 - b. The laboratory exhaust air must not re-circulate to any other area of the building.
 - c. The laboratory building exhaust air should be dispersed away from occupied areas and from building air intake locations or the exhaust air must be HEPA filtered.

HEPA filter housings should have gas-tight isolation dampers, decontamination ports, and/or bag-in/bag-out (with appropriate decontamination procedures) capability. The HEPA filter housing should allow for leak testing of each filter and assembly. The filters and the housing should be certified at least annually.

- 10. HEPA filtered exhaust air from a Class II BSC can be safely re-circulated 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. BSCs should be certified at least annually to assure correct performance. Class III BSCs must be directly (hard) connected up through the second exhaust HEPA filter of the cabinet. Supply air must be provided in such a manner that prevents positive pressurization of the cabinet.
- 11. A method for decontaminating all laboratory wastes should be available in the facility, preferably within the laboratory (e.g., autoclave, chemical disinfection, or other validated decontamination method).
- 12. Equipment that may produce infectious aerosols must be contained in primary barrier devices that exhaust air through HEPA filtration or other

equivalent technology before being discharged into the laboratory. These HEPA filters should be tested and/or replaced at least annually.

- 13. Facility design consideration should be given to means of decontaminating large pieces of equipment before removal from the laboratory.
- 14. Enhanced environmental and personal protection may be required by the agent summary statement, risk assessment, or applicable local, state, or federal regulations. These laboratory enhancements may include, for example, 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; and advanced access control devices, such as biometrics.
- 15. The BSL-3 facility design, operational parameters, and procedures must be verified and documented prior to operation. Facilities must be re-verified and documented at least annually.

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

http://www.cdc.gov/biosafety/publications/bmbl5/

SECTION VII – APPLICATION PROCEDURES FOR RESEARCH APPROVAL

Biological Materials Safeguards Committee

For approval of all biological research:

- Log into the website at <u>http://ehs1.fac.gatech.edu/EHSAweb/EHSAwebisapi.dll</u> using your Techworks (Kerberos) log-in information using a non-Internet Explorer wed application.
- 2) Select the Biological Materials Safeguards Application link in the Questionnaire box.
- 3) Select the "Add New Biological Materials Safeguards Application" link on page.
- 4) Complete the sections of the application and all sections are required to be completed so answer N/A if the question is not applicable to your research.
 - a. The beaker at the top of the application should be green if you have answered all the questions.
- 5) Attach a copy of your Biological Hygiene Plan. The Biological Hygiene Plan can be found at <u>http://www.ehs.gatech.edu/biological/</u> under the Biological Work Registrations section on the right hand side of the page.
- 6) Select the "Save and Continue" button.
- 7) This action will return you to the initial application page, select the "Submit for Review" button.
 - a. If your application is complete, you will be asked if you want to submit the application for review, select yes and your application will be submitted.
 - b. If your application is not complete, you will be given the number of questions remaining and asked to complete those before submission.
 - c. You will not be able to submit at this time but must complete the required questions.
- 8) EHS will be notified of your submission as well as a copy of the application being sent to your email.
- 9) EHS will notify you of any issues as well as questions about the application.

10) Questions:

- a. If the committee or EHS has questions about a section of the application, you will be able to answer those questions directly on the website.
- b. EHS will send you a notification email with the question number and the link to the website for answer submission.
- 11)EHS will notify you when you application has been approved by the BMSC via email.

Modifications:

Modifications and renewals can be made at the same website as the initial application.

- Log into the website at <u>http://ehs1.fac.gatech.edu/EHSAweb/EHSAwebisapi.dll</u> using your Techworks (Kerberos) log-in information using a non-Internet Explorer wed application.
- 2) Select the Biological Materials Safeguards Application link in the Questionnaire box.
- 3) On the top of the page a drop down menu will appear when the mouse moves over the words "Create New Biological Materials Safeguards Committee Application".
- 4) Select the "Amend or Change an Existing Biological Materials Safeguard Application"
- 5) Select the permit that you wish to modify.
- 6) Enter the change information in the box labeled " If this is not a new application, please briefly summarize the changes in this modification".
- 7) Review the information in the original application that is prepopulated and change as needed.
- 8) Add your updated Hygiene Plan.
- 9) Select the "Save and Continue" button.
- 10)Select the "Submit for Review" button.
- 11) Select the "Yes" button.

- 12) EHS will be notified of your submission as well as a copy of the application being sent to your email.
- 13) EHS will notify you of any issues as well as questions about the application.
- 12) EHS will notify you when you modification application has been approved by the BMSC via email.

Renewals:

Renewals are required every three years for all BMSC applications. These are also completed online at the same site as initial applications and modifications.

- Log into the website at http://ehs1.fac.gatech.edu/EHSAweb/EHSAwebisapi.dll using your Techworks (Kerberos) log-in information using a non-Internet Explorer web application.
- 2) Select the Biological Materials Safeguards Application link in the Ouestionnaire box.
- 3) On the top of the page a drop down menu will appear when the mouse moves over the words "Create New Biological Materials Safeguards Committee Application".
- 4) Select the "Renew An Existing Biological Material Safeguard Application"
- 5) Select the permit that you wish to modify.
- 6) Review the answers to each of the questions that are automatically filled in from the previous application and make any changes needed.
- 7) Attach your Biological Hygiene Plan
- 8) Select "Save and Continue"
- 9) Select "Submit for Review"
- 10) Select the "Yes"

The review will then follow the same course of actions about questions as the initial application process does.

Institutional Biosafety Committee

For approval of all rDNA research:

- 1) To apply for IBC review, fill out the IBC Registration application and attach the appropriate Biological hygiene plan, vector maps and grant proposals to the signed application.
- 2) Return all forms to the Office of Research Integrity Assurance at mail code 0420 or email the application and supporting documents to <u>biosafety@gatech.edu</u>.

Occupational Health Program

For enrollment into the Occupational Health Program:

- 1) Complete a Confidential Exposure/Risk Assessment Questionnaire.
- 2) Contact the Biosafety Officer at 404-894-6120 or the Assistant Biosafety Officer at 404-894-6119, to schedule a pick-up of forms.
- 3) Forms can also be turned in at the front desk of the IBB building

Note: Do not send OHP form via campus mail due to the sensitive nature of the research reported on the form. All OHP forms must be delivered/received in person.

SECTION VIII-BIOLOIGCAL LABORATORY INSPECTIONS

Laboratory inspections are a vital part of any good biosafety program. GT Biosafety aims to conduct 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 in the Forms 5 section of this manual.

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 in the Forms 5 section of this manual as well as online at the <u>www.ehs.gatech.edu</u> website under the Biosafety section.

SECTION IV - RECOMBINANT AND SYNTHETIC NUCLEIC ACID RESEARCH

1) Recombinant DNA- molecules meeting the following definitions:

(a) are constructed by joining nucleic acid molecules that can replicate in a living cell, i.e., recombinant nucleic acids;

(b) 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

(c) molecules that result from the replication of those described in (i) or (ii) above.

- 2) Genetic Engineering the genetic modification of organisms by recombinant DNA techniques.
- 3) Regulated Article any organism which has been altered or produced through genetic engineering, if the donor organism, recipient organism, or vector or vector agent belongs to any genera or taxa designated in 7 CFR 340.1 and meets the definition of plant pest, or is an unclassified organism and/or an organism whose classification is unknown or any product altered or produced through genetic engineering which the Deputy Administrator (USDA) determines is a plant pest or has reason to believe is a plant pest.
- 4) Viral Vector a virus that has been modified by removing all virulence genes generally leaving the capsule, envelope and polymerase genes. New target genes are introduced into the virus creating a viral vector which can now be transduced into living cells.
- 5) Human Gene Transfer/Therapy the insertion of genes into human tissues to treat a disease. Generally, human gene therapy is used to introduce a functional gene into a human, replacing a deficient gene.
- Note: GT IBC policies can be found in the manual "Policies and Procedures Governing the Possession and Use of Recombinant DNA" at http://researchintegrity.gatech.edu/about-ibc/

SECTION X- CELL LINE AND PRIMARY CELL RESEARCH

Cell line and primary cell research accounts for a large portion of the biological research activities at Georgia Tech. While most cell lines are considered to be free of human disease, those that have not been certified as free of bloodborne pathogens should be handled with caution. For the same reason, primary cells from humans and other mammals should be handled with appropriate laboratory practices. Many cell lines have been constructed with viral genes or are known carriers of viral diseases. These well characterized cell lines need to be handled at the supplier's suggested biosafety level. Researchers should take the precautions as described below 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.

- A. 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.
- B. Procedures:
 - 1) Work with cell lines and primary cells should only be conducted with the knowledge and approval of the BMSC.
 - 3) Untested cell lines and primary cells should be treated as if hazardous to human health, thus, all work with these cell types should be done with Biosafety Level 2 practices.
 - 3) Cell line or primary cell waste should be sterilized prior to disposal by means of autoclaving or liquid disinfection.
 - 4) Gloves, lab coats, and safety glasses should be worn whenever cell lines or primary cells are being handled.
 - 5) All researchers and workers handling human cell line or primary tissue should be immunized against hepatitis B. (This vaccine can be provided by the 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 should be reported to EHS immediately with copies of the tissue origin information.
- c) Cell line and primary cell research of any type must be approved by the Biological Materials Safeguards Committee prior to initiation of research.

SECTION XI–VIRAL VECTORS

Biological research at Georgia Tech is shifting to increasing use of viral vectors conduct important rDNA research. These rDNA segments are generally carried by viruses that normally produce disease in humans. These viruses have been engineered to have only the needed 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. These newest third generation viral vectors are generally considered safe due to their inability to replicate and the low odds of encountering the needed genes to regain viability. 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.

- A) General Definitions:
 - 11) Viral Vector viral particles used to deliver genetic material to cells for the purpose of transfection and/or transduction of the cell.
 - 12) Retrovirus an enveloped virus that contains an RNA genome that can be transcribed into DNA and inserted in to the host cell's genome.
 - 3) Lentivirus a subsection of the retroviruses that generally have a long incubation period.
 - 4) Adenovirus a double stranded DNA virus without an envelope that causes upper respiratory disease in a number of mammalian species.
 - 5) Adeno-Associated Virus a single stranded non-pathenogenic DNA virus carried by humans and primates that has the ability to infect both dividing and non-dividing cells. AAV requires a helper virus such as Hepatitis B or Adenovirus to be able to replicate.
- B) Procedures:

Laboratory Procedures:

- 1. All laboratory manipulation and production of viral vectors should be conducted in a Biosafety Level 2 laboratory.
- 2. Entry into rooms where viral vector experiments are being conducted will be limited to only essential personnel and all others will be expected to wait until the conclusion of the experiment to enter.

- 3. All researchers handling or cleaning up viral vectors are required to wear nitrile gloves, a laboratory coat, and safety glasses or a face mask. The decision to use a face mask should be made based on the splash potential inherent in the experimental procedures.
- 4. A universal biohazard sign with the additional phrase "Viral Vector Experiments—(particular viral vector)" will be posted on the laboratory room door at all times during the course of the research. The sign will also include the appropriate personal protective equipment to be worn, contact information (regular and emergency) for a person knowledgeable of the specific research activities, and the procedures for entry and exit of the area.
- 5. A second sign will be posted that states "Do Not Enter—Biohazard Experiment in Progress" during the time of viral vector manipulation.
- 6. A specific class II biosafety cabinet will be designated for all manipulation of viral vectors and will be cleaned with alcohol or another appropriate disinfectant before and after experiments.
- 7. All freezers and incubators containing viral vectors must be labeled with the name of the viral vector and a biohazard sign.
- 8. All sharps containers used for viral vector waste will be labeled as "(Particular Name of Vector) Waste".
- 9. All viral vectors must be transported according to Section XIX of this manual. Essentially, all items must be transported in closed primary and secondary containment to prevent the contamination of other laboratories.
- 10. All solid waste is to be disinfected with a 10% bleach solution before rinsing off of the bleach and then decontaminated in an autoclave for at least 30 minutes prior to disposal by Environmental Health and Safety (EHS).
- 11. Liquid waste is to be decontaminated with a 10% bleach solution for 30 minutes and then disposed of down the sanitary sewer.
- 12. All liquid spills will be handled by closing the laboratory and allowing 20 minutes for aerosols to dissipate. The spill can then be treated with bleach for 20 minutes before clean-up with absorbent material. All spills are to be reported to EHS. All clean-up materials shall be placed into a biohazard bag and box for disposal by EHS.
- 13. All personnel exposures to viral vectors are to be reported to the Principal Investigator (PI) and the EHS Biosafety Officer. The PI is responsible for coordinating appropriate medical evaluation with input from the EHS

Biosafety Officer. The researcher is responsible for providing a written report of the exposure to the PI and the EHS Biosafety Officer.

14. Standard emergency actions apply for viral vector exposure including 15 minutes at the eyewash station and cleaning of exposed skin with soap and water. After emergency actions are taken, treatment should be sought at the appropriate medical facility. An <u>Illness and Injury Report</u> form should be completed, along with <u>Worker's Compensation</u> notification if applicable.

PRL Procedures:

- 1. All animal experiments are to be conducted in the PRL at ABSL 1+ using the practices specified in this document.
- 2. The door to the in-use procedure suite will be labeled by the researchers with a biohazardous sign and the phrase "(Viral vector name) Virus Experiments" as well as a description of appropriate personal protective equipment to be worn, these are safety glasses, fresh scrubs, and gloves (other ppe may be required and will be based on the recombinant DNA risk assessment conducted by the Principal investigator at the time of IBC application), contact information (regular and emergency) for a person knowledgeable of the specific research activities, and the procedures for entry and exit if different from normal procedure room entry/exit. The sign is to be removed once the procedure room has been cleaned with an appropriate disinfectant by the researchers and is ready for use by another group. This sign is not to remain up overnight nor is it to be used in animal housing areas.
- 3. The Imaging Facility or other imaging room will be posted with the same signage as required in procedure rooms. All signs must be removed at the end of the procedures. The Imaging Room will be off limits to anyone other than the researchers involved with the protocol and The Imaging Facility staff during viral vector animal imaging. The sign is to be removed once the Imaging Facility or room has been cleaned with an appropriate disinfectant by the researchers and is ready for use by another group. This sign is not to remain up overnight nor is it to be used in animal housing areas. Gloves must be removed or changed after handling animals while imaging to avoid contamination of keyboards, buttons, chairs, etc. Hands must be washed before leaving The Imaging Facility or other room.
- 4. All viral vector-containing cages to be transported between different rooms in the PRL will be wiped down with an appropriate disinfectant prior to leaving the current area. The cart does not have to be labeled during transport if the animals are not leaving the PRL or will not be sitting on the cart for longer than 30 minutes. All carts leaving the PRL or

sitting for an extended period of time must be marked with a biohazard symbol.

- 5. All carts must be wiped down with an appropriate disinfectant after transport activities. The cart is to then be delivered to the dirty side of the cage wash area to allow for PRL staff to wash the cart prior to usage by the next researcher.
- 6. All animal cages will be posted with a biohazard symbol sticker by the researchers and the date of implantation/injection with the name of the viral vector for the life of the animal. PRL staff is responsible for maintaining the sticker for the life of the animal once the researcher initially labels the cage card. The researcher must inform the animal facility manager of sticker placement.
- 7. Animals are to be housed in a PRL cubicle by themselves or with other ABSL animals if at all possible. This way the infected animals will be separated from other animals to ensure compliance with air flow requirements. These airflow requirements include a negative pressure environment which is established by the cubicle hallway being negative pressure in relation to the main PRL hallway and the individual cubicles being at a negative pressure in relation to the cubicle hallway. Researchers should request usage of a cubicle on the <u>Animal Housing</u> <u>Request Form</u>. If a cubicle is not available, animals may be returned to the initial rack.
- 8. Dirty cages will be dumped in a HEPA-filtered dump station. Animal bedding will be disposed of as contaminated waste via the EHS biohazard bag and box system, or can be autoclaved prior to dumping and then handled as regular bedding waste. Water bottles may be dumped into a sink and both dirty bottles and dirty cages washed per normal protocol.
- 9. Animals infected with viral vectors should have their bedding changed at the end of cage changing procedure for the particular housing room containing the infected animals with gloves being changed and hands washed before starting cage changing procedures for another housing room. Immunocompromised animals should have cages changed at the beginning of the cage changing for a room with hands being washed and new ppe donned before handling non-viral vector mice.
- 10. Animal workers are required to don new gloves before starting the cage changes for viral vector animals and after finishing cage changes for viral vector animals.
- 11. Animal workers are required to wash their hands, upon completion of the viral vector cage changes before leaving the animal room.

- 12. The Animal Transfer Station should be disinfected with an appropriate disinfectant before the start of cage changing/handling of viral vector infected animals, as well as anytime contamination is visible and at the end of viral vector infected animal cage changes/handling.
- 13. Surgical instruments that are used during viral animal procedures should be washed with soap and water and then autoclaved.
- 14. Chambers, nosecones and other equipment that viral vector-infected animals touch during imaging, procedures, anesthesia, perfusion, etc. will be cleaned with the appropriate disinfectant by the researcher and then, if possible, taken to the dirty side of the cage washer or to a sink for washing with soap and water. If animals are to be euthanized on the open bench, the bench must be cleaned with disinfectant at the end of the procedure by the researchers. The room door must also be labeled with the same sign used on the procedure rooms and the Imaging Facility.
- 15. A sharps container should be labeled with "Viral Vector Sharps" for disposal of viral vector surgical sharps and must be provided by each research group. The sharps container shall be transported to and from the laboratory closed and in secondary containment and never left in the animal facility.
- 16. All waste solutions from surgical procedures will be transported back to the laboratory and decontaminated with bleach as described in the laboratory decontamination requirements.
- 17. All sacrificed animal carcasses will be stored in a freezer until removal and disposal by EHS and should be labeled by researchers on the individual bag as "viral vector animals". Gloves will be removed after depositing carcasses into the freezer and hands must be washed before starting a new task.
- 18. All liquid spills of research materials will be handled by closing the room for 20 minutes to allow for aerosols to dissipate. The spill can then be treated with an appropriate disinfectant for 20 minutes before clean-up with absorbent material and collected in a biohazard bag for disposal by EHS. Spills are to be cleaned by laboratory staff and reported to EHS.
- 19. Large quantity bedding spills in a room should be handled by lightly wetting with an appropriate disinfectant, carefully removed with disinfectant wetted paper towels and collected in a biohazard bag for disposal by EHS.
- 20. Standard emergency actions apply for viral vector exposure including 15 minutes at the eyewash station and cleaning with soap and water for skin

exposure. After emergency actions are taken, treatment should be sought at the appropriate medical facility. An EHS Illness and Injury report should be completed, along with Worker's Compensation notification, if a qualified employee. Injured researchers should take a copy of the Viral Vector safety information that is given to PRL visitors/contractors with them for presentation to medical staff at the chosen facility.

SECTION XII—SELECT AGENT PROGRAM

The Select Agent Program deals with infectious organisms and toxins that can be used to cause significant human health and/or agricultural animal or plant health issues. These organisms and toxins have also been classified as potential weapons of mass destruction. The Center for Disease Control and Prevention (CDC) (42 CFR 73) and the Animal and Plant Health Inspection Service (APHIS) of the USDA (7CFR 331 and 9CFR 121) are charged with regulating these organisms. The agents list contains bacteria, viruses, fungi, rickettsias, and toxins. The list includes organisms regulated only by the CDC, those regulated by the USDA, and those regulated by both groups. The regulations require reporting, inspection and security in any laboratory that houses a select agent. Information, regulations, security guidelines, and registration forms can be found on the CDC website at http://www.aphis.usda.gov/programs/ag_selectagent/.

The responsible official for Georgia Tech will help any researcher in determining the proper procedures for acquiring, housing, transferring, and destroying any select agent. Approval must be obtained from the responsible official and the appropriate agency prior to acquisition of the select agent. Once the laboratory has the proper approvals, it becomes subject to inspections by the CDC and APHIS to determine if all of the regulations are being followed properly. The program also requires all persons with access to select agents pass a rigorous background check and limits certain people from possessing select agents. The list of prohibited persons includes:

- A. Non-permanent residents on the State Department list: (Cuba, Iran, Iraq, Libya, North Korea, Sudan, and Syria)
- B. Anyone under indictment or has been convicted for a crime punishable by imprisonment for a term exceeding one year.
- C. A fugitive from justice.
- D. A user of illegal drugs.
- E. An alien illegally in the U.S.
- F. Anyone who has been adjudicated as a mental defective or has been committed to any mental institution.
- G. Anyone who has been dishonorably discharged from the Armed Services.

Along with personnel restricts, the program recommends a number of security measures to protect laboratories containing select agents. These include:

- A. 24-hour electronic card key access for the entire building.
- B. Use of identification badges.
- C. Locking down floor where lab is located.
- D. Locking stairwells to the floor.
- E. Unbreakable security door to lab
- F. Non-breakable window on the door.
- G. Closed circuit TV at building and lab entrances.
- H. Motion detectors.

- I. Procedures for reporting suspicious persons or activities, loss, theft or release, or alternation of inventory records.
- J. Security training.
- K. Procedures for reporting and removing unauthorized persons.

There are exceptions to the rules. The following toxins are exempt in limited quantities as long as an entire facility does not have more than exempt amounts. These include:

Abrin	100 mg
Botulinum neurotoxin	0.5 mg
Short, paralytic alpha Conotoxins	100 mg
Diacetoxyscrpenol (DAS)	1000 mg
Ricin	100 mg
Saxitoxin	100 mg
Staphylococcal enterotoxins (subtype A, B,C, D,	and E) 5 mg
Tetrodotoxin	100 mg
T-2	1000 mg

Procedures for the Approval and Use of Select Agents Toxins:

- 1) Professors wishing to use Select Agent toxins must have approval from the Biological Materials Safeguard Committee before initiating work.
- 2) The professor or laboratory member who will actually be using the toxins in experiments must meet with the EHS Biosafety Officer for training prior to initiation of work.
- 3) Toxins are to be stored in an EHS approved locked box at all times.
- 4) The EHS Select Agent Log should be stored in the box and completed after each experiment.
- 5) Logs are to be made available to EHS upon request.
- 6) Must notify EHS via email at least a week in advance of proposed destruction of unadulterated select agents.
- 7) EHS must attend the destruction and schedule a hazardous waste pick up of destructed select agent toxins. (only for unadulterated toxins)
- a. The method of destruction should be based upon the type of Select Agent toxin. Staphylococcus Enterotoxin, Ricin, Botulinium Neurotoxin, Clostridium perfringens epsilon toxin, Shiga toxin and the Shiga-like ribosome inactivating proteins can be autoclaved for 1 hour at 121 degrees. Tetrodotoxin, Staphyloccocus Enterotoxin, Botulinum Neurotoxin, and Ricin proteins can be inactivated by exposure to 2.5%

sodium hypochlorite (NaOCI) with .25 N sodium hydroxide (NaOH) for at least thirty minutes.

SECTION XIII – DUAL USE RESEARCH OF CONCERN

Biological research has produced a variety of important life saving measures and products over the decades. This research was conducted with the benefit of humans, animals, and environmental health in mind. Yet, a portion of the knowledge and advancements of biological research could be used in a manner that actually harms human health or the environment. This is research deemed dual use research. Dual Use Research of Concern (DURC) is research that can be reasonably anticipated to provide information that can be misapplied and that misapplication can pose a significant threat to human, animal or environmental health. The federal government is currently working through several committees and governmental offices to determine a framework for dual use research of concern oversight. This oversight is based upon the set of guiding principles listed below:

- 1) Life sciences research makes possible advances in public health, agriculture, the environment, and other pertinent areas and contributes significantly to a strong national security and economy.
- 2) Life sciences research has the potential to produce beneficial knowledge, information, technology, or products that can also be used in a manner that results in harm to public health and safety, agricultural crops and other plants, animals, or the environment. Therefore, it is appropriate to have in place a framework and tools for the responsible oversight, conduct, and communication of such research.
- Life sciences research is by nature dynamic and can produce unanticipated results, and therefore must be evaluated on an ongoing basis for dual use potential.
- 4) Oversight of DURC must recognize both the need for security and the need for research progress; as such, the degree of oversight should be consistent with the possible consequences of misuse.
- 5) Effective oversight helps maintain public trust in the life sciences research enterprise by demonstrating that the scientific community recognizes the implications of DURC and is acting responsibly to protect public welfare and security.
- 6) Federal agencies that fund DURC, the recipients of those public funds, and individuals who conduct this research share the oversight responsibility.
- 7) It is essential to have a consistent approach to the oversight of DURC.
- 8) Any oversight process for DURC should be periodically evaluated both for effectiveness and impact on the research enterprise.

- 9) The free and open conduct and communication of life sciences research is vital to a robust scientific enterprise and will continue to be the goal of the USG. It also should continue to be the goal of institutions engaged in life sciences research.
- 10) Educating the scientific community about the dual use potential of life sciences research and cultivating a sense of responsibility for dual use research among life scientists is essential for promoting responsible research behavior.
- 11) No policy or set of guidelines can anticipate every possible situation. Motivation, awareness of the dual use issue, and good judgment are key considerations in the responsible evaluation of research for dual use potential. It is incumbent on those engaged in life sciences research to adhere to the intent of this Policy as well as to the performance standards described herein.

Georgia Tech EHS will be following the development of this framework and will communicate the results to faculty as needed in the future.

SECTION XIV-BIOSECURITY

Biosecurity is a growing concern of many laboratories. Biosecurity is defined as physical protection of high-consequence microbial agents and toxins, or critical information, from loss, theft, release or intentional misuse. Biosecurity plays an important part in the select agent regulations as well as the Department of Justice and the Department of Homeland Security regulations from the Patriot Act (Public Law 107-56). But biosecurity is not limited to just those acts. Every laboratory handling hazardous biologicals should have a biosecurity plan in place. These plans to not always require fancy measures but requires competent decision making, risk assessment, and most importantly flexibility. Plans need to be updated on a regular basis as well as practiced multiple times to generate a complete and thorough plan. All biosecurity programs should mitigate the threat at the source by preventing unauthorized access to agents and other potentially hazardous biological materials located and used at a Georgia Tech facility or by a Georgia Tech community member at an off-campus location.

Biosecurity principles:

- 1) Understand what needs to be protected
- 2) Apply highest security to the most critical components
- 3) Employ an increased level of security in critical areas
- 4) Reduce risk to an acceptable level
- 5) Gain management support

Steps to creating a biosecurity plan:

- Create a biosecurity team of lab members, biosafety officers, information technology, emergency preparedness and others that will see all issues, not just those identified by lab staff.
- 2) Conduct a risk assessment and then prioritize the risk from greatest to lowest.
- 3) Conduct a threat assessment and prioritize.
- 4) Combine the risk and threat assessments to create possible scenarios to address via biosecurity measures.
- 5) Identify vulnerabilities in the laboratory that might contribute to loss, theft, or misuse.
- 6) Identify possible solutions to mitigate the risks discovered during the preceding steps.

- 7) Develop response plans to the scenarios established during previous steps.
- 8) Implement the physical solutions as well as train on the response plan.
- 9) Conduct drills and table top exercises.
- 10) Regularly revisit the plan to determine if the risks have changed and to identify new risks.

SECTION XV–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 at the Human Resources website for training at www.trains.gatech.edu:

General Biosafety—This course discusses all the guidelines, regulations, and safety practices for maintaining a safe 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.

Bloodborne Pathogens – 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.

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.

Zoonoses and Allergens (online tutorial) – Researchers and animal care workers come into close contact with potentially harmful animals on a regular basis. The allergens and in part disease of laboratory animals has become an increasing concern in occupational health and research facilities. This class will cover the potential diseases carried by laboratory animals as well as the issues surrounding allergens produced by animals. The class will also cover ways to decrease potential exposures.

Autoclaves—Autocalves are vital pieces of equipment for research laboratories. Autoclaves can be used to disinfect materials for disposal as well as sterilize media, plastics, and glassware. This training focuses on the types of autoclaves, how to properly use one, and the important tests that ensure proper functioning of autoclaves. 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.

Receipt of Hazardous Materials (Online Tutorial)—This tutorial covers the points to consider when accepting shipments of hazardous materials including how to handle shipments that are not in the appropriate condition to accept.

SECTION XVI- BIOLOGICAL 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 .15 "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.

A. General Definitions

- Bloodborne Pathogen Waste This term means blood and blood products, exudates, secretions, suctioning, and other body fluids that cannot be directly discarded into a municipal sewer system due to the potential for bloodborne pathogens.
- 2) Cultures and Stocks of Infectious Agents and Associated Biological includes cultures from medical and pathological laboratories, cultures and stocks of infectious agents from research and industrial laboratories, wastes from the production of biologicals, discarded live and attenuated vaccines, and culture dishes and devices used to transfer, inoculate and mix cultures.
- 3) Contaminated Mammalian Carcasses includes body parts, the bedding and other wastes from mammalians which are infected with or have been exposed to infectious agents capable of causing disease in humans.
- Discarded Medical Equipment and Parts not including expendable supplies and materials which have not been decontaminated, that were in contact with infectious agents.
- B. Georgia Tech's Procedures for handling biological wastes on campus
 - Biological waste shall be segregated by separate containment from other waste at the point of generation. These wastes, except for sharps, are to be placed in orange or red plastic bags clearly identified with the universal biohazard symbol or clearly marked with the word "BIOHAZARD". The bags are to have strength sufficient to preclude ripping, tearing, or bursting under normal conditions of use including autoclaving.
 - 2) The bags of non-infectious biological waste can be placed into a biohazard cardboard box without autoclaving while infectious biologicals must be autoclaves prior to placement in the biohazardous waste box. All boxes of waste must be properly marked with the Principal Investigator's name and laboratory number.

- Broken glass may or may not be considered biomedical 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. Clearly mark the biohazardous waste box with the appropriate classification of "animal carcass".
- 5) Human tissue can be disposed of two separate 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 red, orange, or clear biohazard bags or any other bag that contains biohazard waste shall be disposed of in the dumpsters outside of buildings even after autoclaving the waste.
- 7) Liquid biologicals 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. See Section XVIII's guide to liquid disinfectants to select an appropriate chemical disinfectant or autoclave the material based on standard methods of 121 degrees for 15 minutes at 20 psi.
- 8) DEA Controlled Substances require approval prior to destruction. The following link contains all the appropriate procedures. <u>http://www.ehs.uiuc.edu/css/guidesplans/dea/index.aspx?tblD=gp#Section_IX</u>
- 9) Select Agent destruction requires notification to the responsible official via email at least a week in advance. This notification is required even for exempt select agents. EHS will attend the destruction and schedule a hazardous waste pick up of the material.
 - a. The method of destruction should be based upon the type of select agent. Bacteria and viruses can be autoclaved for 15 minutes at 121 degrees. Ricin, Botulinium Neurotoxin, and Clostridium perfringens epsilon toxin can be autoclaved for 1 hour at 121 degrees. Tetrodotoxin, Staphyloccocus Enterotoxin subtypes A, B, C, D, and E, Botulinum Neurotoxin, and Ricin can be inactivated by exposure to 2.5% sodium hypochlorite (NaOCI) with .25 N sodium hydroxide (NaOH) for at least thirty minutes.
 - b. Other select agents may require different methods. Contact EHS to determine the appropriate method.

- 10) Solid infectious wastes may be treated so as to render items noninfectious wastes. Wastes may be treated by autoclaving in a recording autoclave. Recording of the temperature during each complete cycle shall be used to assure the attainment of 121°C or 250°F for a minimum of 30 minutes in order to achieve decontamination of the entire load. Monitoring of the autoclave process through the use of biological or other approved indicators (i.e. autoclave tape, spore strips) is to be accomplished by the investigator/laboratory manager and maintained along with the temperature recording as proof of decontamination. The Pl/laboratory manager must verify sterilization was successful before disposing of the treated waste.
 - a. Several factors affect the steam sterilization process including load size, distribution and compaction, altitude above sea level; and heat penetration. The investigator or personnel responsible for sterilization may have to determine the appropriate time at standard autoclave temperature and pressure for certain loads of biohazardous materials. Barbeito and Gremillion in their article "Microbiological Safety Evaluation of an Industrial Refuse Incinerator" (Applied Microbiology 16:2:291-95) reported on various times required for autoclaving selected mammalian carcasses, mammalian bedding materials, and eggs. With some loads, even extended times did not provide for sterilization.
 - b. Biomedical wastes may be treated by incineration which provides complete combustion of waste to render it nonpathogenic.
 - c. All autoclaved waste shall be packaged in a biohazard box and marked with the appropriate content information, PI, and date. No autoclaved biohazardous waste may be disposed of into a dumpster even if the bag is covered with a regular black trash bag. All autoclaved biological waste must be picked up by EHS Hazardous Materials group.
 - d. Contact the Biosafety Officer in Environmental Health & Safety at 404/894-6120 regarding questions about the proper handling of biohazardous waste.
 - e. Contact the Hazardous Materials Coordinator in Environmental Health & Safety at 404/894-6224 regarding contract arrangements for pick-up and disposal of biomedical wastes including sharps.

11) Non-infectious solid biological waste does not need to be decontaminated prior to disposal.

- C. Georgia Regulations
 - 1) Georgia Department of Natural Resources/Environmental Protection Division – rules on solid waste management covering biomedical waste (391-3-4-.15).

SECTION XVII- 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:

 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 and transported to the autoclave for sterilization prior to disposal.
- 2) Sharps should never be resheathed 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 Pl'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.

SECTION XVIII- SPILLS OF BIOHAZARDOUS MATERIALS

Primary responsibility for preventing and/or containing and cleaning up laboratory spills remains with the principal investigator or laboratory supervisor. Laboratory protocols should be carefully designed to prevent biological, chemical and/or radiation spills.

When accidents occur that involve the mishandling or escape of biohazardous materials, the principal investigator or laboratory supervisor is to be notified immediately. Spills of high risk organisms (certain Class 2 and all Class 3) should be reported to the Biosafety Officer at 404/894-6120 during normal working hours or to Georgia Tech Police at 404/894-2500 after normal working hours by the principal investigator or laboratory supervisor. All employees and/or students have an obligation to themselves and their colleagues to report accidents immediately in order to minimize potential hazards.

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 404/894-3600, 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 problem than a spill in an open laboratory as long as the spilled materials are contained in the biological safety cabinet. Decontamination of the work zone can be effected by direct application of concentrated liquid disinfectants along with a thorough wipe down procedure. Gaseous decontamination may be required to clean-up the interior sections of the cabinet.

- <u>Chemical decontamination procedure should be initiated immediately</u> while the biological safety cabinet continues to operate. Continuing the operation of the LFBSC helps to prevent the escape of contaminants from the cabinet.
- <u>Wearing protective gloves, safety glasses, a lab coat/apron, and at a</u> <u>minimum a surgical mask</u>, spray or wipe walls, work surfaces, and equipment with an appropriate decontaminating solution.
- Be sure to choose a disinfectant that takes the pathogenic properties of the organism into account. Not all organisms are killed by ethanol or chlorine and require a more powerful disinfectant.

- Flood tray top, drain pans and catch basins below work surface with decontaminating solution and allow to stand for 20 minutes.
- Drain excess decontaminating solution from tray and drain pans into cabinet base. Lift out tray and removable exhaust grille work. Clean the top and bottom (underside) surfaces using a sponge or clean cloth soaked in decontaminant solution. Following the cleaning process, replace the tray and grille work in their proper position. Place gloves and sponge or cloth in autoclave pan and autoclave these items.
- Drain decontaminating solution from cabinet base into appropriate container and disinfect according to standard liquid waste procedures.
- If gaseous decontamination of the cabinet's interior sections is needed, call the Biosafety Officer at 404/894-6120.

Biohazard Spills Outside of a Laminar Flow Biological Safety Cabinets (LFBSC)

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.

If individuals believe that their outer garments have been contaminated, they should follow the procedures found in Section XXIX –First Aid in the Laboratory. All first aid should be handled prior to cleaning up spills.

Special care in decontamination will be necessary when a spill goes under or between fixed furniture or behind base moldings (floor/wall), or if floor penetrations are involved.

For skin contamination that involves wounds, refer to Appendix H- First Aid.

- 1) Minor Spills (less than 10 ml and generating little aerosol) on equipment, laboratory benches, walls, or floors:
 - a. Warn all personnel not essential for spill containment to stay clear of the contaminated area. This may be accomplished verbally or, when appropriate, by posting warning signs on the doors.
 - b. Thoroughly wash hands and other apparently contaminated areas with soap and water. Put on clean disposable gloves.
 - c. Cover the spill area with paper towels soaked in appropriate decontamination solution.
 - d. Wipe up the spill with the soaked paper towels and place the used towels in an autoclave pan and autoclave.

- e. Pour decontaminating solution around and on the area of the spill. Let stand for 20 minutes then wipe up with paper towels. Place gloves and paper towels in biological waste bags inside of a biological waste box and allow EHS to dispose of the box.
- f. Wash hands and other apparently contaminated areas again with soap and water

2) Major Spills (more than 10 ml or with considerable aerosol):

- a. Close laboratory doors and post warning signs to prevent others from entering the laboratory.
- b. Wash hands and other apparently contaminated areas with soap and water.
- c. Report the accident to the supervisor and to the Biosafety Officer at 404/894-6120.
- d. If personal clothing is contaminated, remove all outer clothing and place it in autoclave or container for autoclaving. Put on clean garments.
- e. Leave the laboratory for 20 minutes to allow dissipation of aerosols created by the spill.
- f. Upon returning to the laboratory to start decontamination, check to see if laboratory doors are closed and appropriate signs are displayed. Put on surgical gloves. Respirators or other safety equipment may be required, depending on the microorganism involved. Check with the Principal Investigator or Laboratory Supervisor or Biosafety Officer.
- g. Pour a decontamination solution around the spill and allow this solution to flow into the spill. Do not pour decontamination solution directly onto the spill in order to avoid additional release of aerosols.
- h. Let decontamination solution microorganism mixture stand for 20 minutes or longer to allow adequate contact time.
- i. Spills kit absorbent material should be used to cover the area and soak up the disinfectant/organism mixture.
- j. Place absorbent material in a biological waste bag inside of a biological waste box and allow EHS to dispose of the box.

- k. Remove gloves and other contaminated garments and place them in the biological waste bag with the absorbent material for disposal by EHS.
- I. Thoroughly wash hands, face, and other potentially contaminated areas.

Special care in decontamination may be necessary. The Principal Investigator and/or Biosafety Officer may require the collection of sample cultures to determine that the area has been effectively decontaminated.

Liquid 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.

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

<u>Ethyl Alcohol</u>

Use Dilution: 70-95%

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

<u>Other Characteristics:</u> flammable, eye irritant, and an upper respiratory tract irritant (TLV = 1000ppm)

Isopropyl Alcohol

Use Dilution: 70%

<u>Inactivates</u>: bacteria, enveloped viruses, and fungi; does convey residual effects

<u>Other Characteristics</u>: Flammable, CNS depressant, narcotic and irritating to mucous membranes (TLV = 200 ppm)

<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. Allow a contact time of 10 to 30 minutes.

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

<u>Use Dilution</u>: 500 ppm available chlorine is recommended for vegetative bacteria and most viruses. Chlorine solutions that are neutral or slightly acidic and with a concentration of approximately 2500 ppm are needed for effectiveness against bacterial spores. Undiluted common household bleach (Clorox) is alkaline with a pH of 8. Household bleach typically contains 5.25% sodium hypochlorite.

<u>Other Characteristics</u>: 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. While chlorine compounds are not generally recommended for routine use, undiluted household bleach is frequently used with biological spills.

<u>lodophors</u>: The germicidal effect of iodophors is dependent on the free iodine released from the compound in which it is contained. Allow a contact time of 10 to 30 minutes.

<u>Use Dilution:</u> 25 to 1600 ppm of available iodine. Solutions containing 75 to 150 ppm are generally recommended.

<u>Inactivates:</u> vegetative bacteria, fungi and viruses. There is poor activity against bacterial spores.

<u>Other Characteristics</u>: Although iodophors are less harmful to man than chlorine compounds, they can irritate the skin and eyes. Iodophors are corrosive (less than chlorine), they leave a residue and may stain. Iodophor stains, however, can be readily removed with solutions of sodium thiosulfate (Na₂S₂O₃). As with the chlorine compounds, iodophors are rapidly inactivated by organic matter. One advantage is that iodophors have a built-in indicator. As long as the solution is brown or yellow it is still active.

<u>Phenolic Compounds</u>: These are effective against vegetative bacteria (including mycobacterium tuberculosis), fungi, and lipoviruses. Effectiveness against nonlipid viruses is variable depending on the virus. The phenols are ineffective against bacterial spores.

<u>Use Dilutions:</u> 1.0 – 5.0% solutions containing 0.5 – 2.0 % phenol are effective against lipoviruses.

Other Characteristics: Phenols are corrosive and may leave a sticky, gummy residue. Phenolic compounds are irritating to the skin and eyes and the cardiovascular, hepatic, renal, and neurological toxicity. – Phenol TLV is 5 ppm; it can be readily absorbed through the skin.

<u>Ouaternary Ammonium Compounds:</u> The efficacy of Ouaternary Ammonium (quats) still generates considerable controversy. Ouats 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%

<u>Other Characteristics</u>: Ouats 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, Ouats are nonirritating.

Ouaternary Ammonium compounds are rapidly inactivated by organic matter.

<u>Formaldehyde Solutions:</u> Formaldehyde in a 5-8% concentration is an effective liquid decontaminant which inactivates vegetative bacteria, bacterial spores, lipid and non-lipid viruses and fungi.

Use Dilution: 5.0-8.0%

<u>Other Characteristics</u>: Formaldehyde TLV established to minimize sensory irritation, chiefly eye and upper respiratory tract. Formaldehyde is a sensitizer and a suspected human carcinogen. TLV is set at 0.3 ppm ceiling, but this TLV might not be protective to sensitized individual.

SECTION XIX-GUIDELINES FOR MOVING BIOLOGICAL MATERIALS ACROSS CAMPUS

These guidelines apply on campus at any time a 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) The biological material should be in a closed primary container; if possible, such as a sample tube, stoppard flask, or other sealed laboratory containers.
- 2) The primary container should be placed inside a secondary container that will be able to catch any biological materials that leak from the primary container during transport. A secondary container for biological materials can be an autoclave pan, a surgical instrument tray, a plastic box, or any other container that has sides that can hold the volume of the biological material inside the primary container.
- 3) The primary container cannot extend above the top of the secondary container.
- 4) Secondary containment should be labeled with the name of the material in the primary container and all appropriate safety stickers.
- 5) A cart cannot be used as a secondary container but can be used to transport heavy items with secondary containment.
- 6) It is recommended that a layer of absorbent material be placed between the primary and secondary containment to provide an additional source of protection from contamination to others in the event of a spill as well as to provide easier clean up and disinfection.
- Spills inside the secondary containment should be cleaned up immediately following standard spill procedures and the outside of the primary container must be disinfected before being placed on another surface.
- 8) Once the secondary containment is sealed, all personal protective equipment can be removed and the materials can be transported. PPE should be re-donned before opening the secondary container for removal.

SECTION XX—SHIPMENT OF BIOLOIGCAL MATERIALS

Shipping chemical and biological material is not as simple as putting postage on a package and dropping it in the mailbox. Material leaving campus may be subject to several administrative and regulatory requirements. While the process may be involved and lengthy, especially the first time, it is only by following all the rules that you can insure your material arrives where you want it, on time, and without being subjected to delay, fines or other penalties. The Environmental Health and Safety (EHS) Office, the Office of Industry Engagement (OIE), the Office of Sponsored Programs (OSP), the Office of Research Integrity Assurance (ORIA) and the Office of Legal Affairs (OLA) have established a chemical/biological materials shipping program to assist researchers, faculty and staff in this area.

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

EXPORT LIMITATIONS AND CONTROLS

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 may need an MTA if any of the following apply: your research sponsor requires it; you received the original material via an MTA; the material contains embryonic stem cells; the material is covered under the USA PATRIOT Act (http://www.fincen.gov/pa_mail.html), or the Centers for Disease Control (CDC) List of Select Agents (http://www.cdc.gov/od/sap/docs/salist.pdf); or the receiving agency requires an MTA. 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, complete the MTA request form at http://industry.gatech.edu/researchers/forms/ Click on Material Transfer Agreements and then open the form as a Word document. When you have

completed the form, email the form to <u>mta@gtrc.gatech.edu</u>. The appropriate departments will be notified to review your request. This process can take several days to weeks so complete the paperwork well in advance of the required ship date.

FOREIGN CUSTOMS

In many instances, following the above procedures and coordination with the carrier will preclude problems at the foreign point of entry. However, be aware that customs officials may impose unexpected obstacles. If it is the first time you have shipped material to a particular country, both you and the recipient should be prepared for delays and the possibility of having to provide additional information.

The U.S. Census Bureau may require that an electronic Electronic Export Information (EEL) be filed with the U.S. Census Bureau through the Automated Export System (AES) for international shipments including Puerto Rico and U.S. Virgin Islands. (15 CFR Part 30 Foreign Trade Statistics, <u>www.census.foreigntrade</u>). Usually EELs are required if the material under a single Schedule B number (<u>www.census.gov/foreign-trade/schedules/b/</u>) is valued at \$500 or more and is being shipped via the United States Postal Service. If another carrier is used, including Fed Ex which is the preferred carrier of the EHS Office, the value under a single Schedule B number is set at \$2500 and above. In addition, EELs are required if an export license is required. EELs are also required for all shipments to Country Group E:1 of the Export Administration Regulations (EAR), 15 CFR PART 740, Supplement 1—Cuba, Iran, Sudan, Syria, N. Korea. Please note this list is subject to change.

Go to <u>http://industry.gatech.edu/researchers/forms/</u> to start the export process as explained above. If your sample is export controlled .EHS will have Fed Ex will process the EEL on your behalf for a fee of \$10. In addition, all international shipments require a Destination Control Statement on the airway bill and invoice, "[t]hese commodities, technology or software were exported from the United States in accordance with the Export Administration Regulations. Diversion contrary to law is prohibited."

MATERIAL SAFETY DATA SHEETS (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 <u>deborah.wolfe-lopez@ehs.gatech.edu</u> or 404-385-2964 to learn how to create an MSDS.

TRAINING FOR INDIVIDUALS

Due to Federal Aviation Administration (FAA) regulations, we are now requiring that all individuals involved in the shipping process to complete shipping training. 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 MS PowerPoint presentation on shipping and being tested over the material. The training can be completed at <u>www.trains.gatech.edu</u> under the online tutorials tab and is called "Shipment of Dangerous Goods". The hands-on portion of the training can be scheduled by contacting the appropriate shipper listed above. Once you have completed both the training and a hands-on portion, you will be able to bring samples over the EHS. You may not bring samples without completing this process. The training is good for 2 years and will be repeated if applicable (i.e. you or your group still has this need to ship regulated materials) at the end of that period.

MATERIALS FOR RESEARCH COLLABORATION OFF-SITE

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. Please contact Ryan Lisk @ (404) 385-9531 for questions regarding this.

SHIPPING HAZARDOUS MATERIALS / DANGEROUS GOODS

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.

For Biological Materials, contact the Biosafety Officer at 404-894-6120 or the Assistant Biosafety Officer at 404-894-6119. The Biological Shipping Request form may be found at the following link:

http://www.ehs.gatech.edu/biological.doc

For Chemical Materials, contact Ryan Lisk at <u>ryan.lisk@ehs.gatech.edu</u> or 404-385-9531. Click <u>http://www.ehs.gatech.edu/Chem_Domestic.doc</u> for The Chemical Shipping Request Forms for domestic shipments. Click

<u>http://www.ehs.gatech.edu/Chem_International.doc</u> for The Chemical Shipping Request Form for international shipments.

PROCEDURE FOR SHIPMENTS

- All shipments must have a <u>Document ID</u> number as well as the <u>PeopleSoft</u> number on the Shipping Request Form. (<u>http://www.ehs.gatech.edu/shipping/biological_shipping.pdf</u>)
- 2) All shipments must be scheduled with the appropriate "EHS Shipper" via email or phone (see contact information at the end of this email) at least 24 hours in advance so that a designated "EHS Shipper" can ensure that all the necessary paperwork is in place.
- 3) All shipments must be *handed* in person to a qualified "EHS Shipper" for paperwork inspection. If a shipper is not available, your shipment will be processed the next normal working day so that all paperwork can be verified unless the shipment was prescheduled and unforeseen circumstances has taken all the shippers out of the office.
- 4) All shipments must be in the EHS Office, with completed paperwork, by 2 pm. All shipments later than 2 pm will be processed the next day.
- 5) Shipments received or verified after 2 pm on Friday afternoons will be shipped out the following Monday.
- 6) EHS will not ship materials if the EHS Shipping Request is incomplete at the time of delivery. It can be left with EHS, and the shipment will be completed once the shipping paperwork can be verified.
- 7) As a reminder, the appropriate compliance paperwork and training includes:
 - a. Material Transfer Agreement (MTA) Initiation Form
 - i. Complete the form and have it signed by the Principal Investigator
 - ii. Submit the form to the Office of Industry Engagement for review and determination of the need for a MTA

MTA Form: http://industry.gatech.edu/researchers/forms/

- b. Export Review for International Shipments
 - i. Complete the form and have the Principal Investigator sign it

ii. Submit the form to the Office of Research Compliance for review and export regulations determination

> Export Control Website: http://www.export.gatech.edu/?section=home

> Export Review Form: http://www.export.gatech.edu/forms/MTA_EX PORT_CONTROL_REVIEW_FORM.doc

- c. On-line Shipping of Hazardous Materials Training www.trainsweb.gatech.edu
- d. Hands-on Function Specific Training by EHS Staff, call the appropriate EHS Shipper (see contacts below) to schedule this hand's on training.

Shipment of DNA, Plasmids, and Proteins

As research programs at Georgia Tech continue to expand, the EHS "dangerous goods" shipping program, which is required for all shipment of biological and chemical materials off campus, must continue to evolve to meet the increased needs of researchers. To increase efficiency, EHS Biosafety has implemented a number of changes to the process. These changes will help to ensure that biological shippers are protected in the event of a shipping audit of the campus by the Federal Aviation Administration (FAA) or the Department of Transportation (DOT). Both of these agencies have jurisdiction over shipments within the United States.

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 trained in basic knowledge of dangerous goods and be allowed to ship *select non-hazardous* items from their laboratories.

Procedures:

- 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:

www.trainsweb.gatech.edu

- 4. 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 hand's on training for all the shippers in your laboratory.
- 5. 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.

Example: rDNA from Shigella in a pUC plasmid

- IF the shipping papers are developed online a shipment notification email can be sent to meagan.fitzpatrick@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 by case basis.

SECTION XXI- WORKPLACE OCCUPATIONAL HEALTH POLICY

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 longterm 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.

Guiding Principles:

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 a number of different factors including:

- Type of hazard
- Dosage or intensity of its exposure
- o 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 a number of identified potential health risks. Protective measures should be taken to avoid/minimize exposures.

Examples of Chemical Exposures Associated with Workplace Health Risks:

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

Examples of Biological Exposures Associated with Workplace Health Risks:

- o Bacteria
- o Viruses
- o **Toxins**
- o Molds
- o Animals

Examples of Ionizing Radiation Exposures Associated with Workplace Health Risks:

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

Examples of Non-Ionizing Radiation Exposures Associated with Workplace Health Risks:

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

Examples of Other Physical Stressors Associated with Workplace Health Risks:

- o Extreme Heat or Cold
- o Noise
- o Vibration
- o 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 be worn at all times 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 applicable training courses 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 <u>www.ehs.gatech.edu</u>

SECTION XXII – OCCUPATIONAL HEALTH PROGRAM

Enrollment and Surveillance:

All Georgia Tech employees who will be working with vertebrate and invertebrate animals, human samples, cell lines, select agents, pathogenic organisms, etiologic organisms or any other biological research including but not limited to nonpathenogenic bacteria, fungi, and algae, must enroll in the OHP program by completing the Confidential Exposure/Risk Assessment Questionnaire, and all required training. Only after the enrollment process has been completed can an individual elect to "opt out" of the medical surveillance portion of the program by signing a Declination form.

The medical surveillance component of this program will be conducted by Concentra Health Services. Concentra will provide all medical examinations and health monitoring as determined through the completion of risk assessments for each affected position, and as deemed necessary by the Georgia Tech Office of Environmental Health and Safety (EHS).

Responsibilities:

A. Employee

The employee is responsible for completing all paperwork for enrollment and participation in the OHP. The employee is required to attend training in appropriate occupational health topics as related to the risks factors determined by EHS. The employee is also responsible for conducting all research as prescribed in the IACUC, IRB, IBC, or BMSC approved protocol they are working under and the laboratory safety manual. Employees are required to consult with EHS prior to any Concentra visit to determine which medical tests may be necessary. All employees must report work-related injuries and illnesses to their supervisor immediately and worker's compensation procedures must be followed, as appropriate.

B. Supervisor/Principal Investigator (PI)

The supervisor/PI is required to ensure that all individuals under their direction working with animals or performing research with biological materials have been trained in all safety procedures and are knowledgeable of all experimental protocols. The supervisor/PI is also responsible for making sure that their employees understand the reporting requirements for incidents. The supervisor/PI is required to report all injuries, illnesses and accidents to EHS and to follow worker's compensation procedures, as appropriate.

C. Environmental Health and Safety (EHS)

EHS conducts risk assessments for all enrolled employees relative to their work functions. EHS will use the risk assessment questionnaires, lab inspections, and other reviews as necessary to complete the risk assessment. EHS will also provide training to all employees based on the risks involved with their work activities. EHS is responsible for paying all fees due to Concentra.

Reassessment:

All covered employees will be required to re-enroll in Georgia Tech's Occupational Health Program every three years or any time their research, job or work status changes with the exclusion of moving to an unexposed position. At the appropriate re-enrollment time, EHS will conduct an updated risk assessment to determine if any new risks may be present, or if any new precautions are required for the employee.

Procedures:

- 1. Participant will complete the Confidential Exposure/Risk Assessment Questionnaire if working with animals, animal derived materials, or other biological materials.
- 2. Participant will schedule a time for EHS to visit the laboratory to conduct risk assessments and review research/activities.
- 3. Participant will receive personalized risk assessment from EHS. EHS will review findings and make recommendations.
- 4. Participant will attend training classes determined by EHS that are relevant to your research.
- 5. Participant may review medical screening test(s) recommended by EHS by viewing them online.
- 6. Participant can accept or decline specific screenings on the website or decline to participate in any medical screenings by completing the Waiver of Medical Screening form.
- 7. Participant will receive a Medical Authorization Form from EHS to take to Concentra that lists medical screening procedures selected from the EHS recommendations.
- 8. Participant will visit Concentra to receive medical screening.
- 9. Participant will report any work related illnesses or injuries to his/her supervisor and EHS as soon as possible.
- 10. Re-enroll every three years.

Forms for the Occupational Health Program can be found in the Forms Section of this manual as well as at the EHS website: <u>http://www.ehs.gatech.edu/</u> If you have any questions about completing the form please contact the EHS office at 404-894-6120

SECTION XXIII – LABORATORY EQUIPMENT

Georgia Tech personnel should not operate equipment that they have not been specifically trained and authorized to use. Operating manuals must be onsite and consulted or detailed operating instructions for individual pieces of equipment. Equipment known or suspected of being faulty should not be operated. Mechanically or electrically unsafe equipment should be tagged and reported to the laboratory supervisor. Many manipulations of bacterial and viral cultures commonly used in the laboratory generate aerosols of viable organisms. This principle must be remembered when evaluating a person's degree of risk. The information below addresses a number of the risks associated with laboratory equipment

Centrifuges

Centrifuges are an important tool in the microbiological laboratory and must be treated with respect. Each time you use a centrifuge you make a series of choices: Which centrifuge, which rotor, which tubes and adapters, what speed and for how long. In addition, if you are using infectious agents you must decide on the level of containment and then select the appropriate rotor and tubes. Load the infectious agents inside the biological safety cabinet to prevent aerosol exposure. Your choices will affect your research and the safety of you and others.

Always check the user manual for specific requirements as well as load limitations and speed. Specific operating procedures for each centrifuge must be established by the laboratory supervisor or principal investigator and followed by each operator. These procedures should follow the information provided in the operation manual and guidelines for centrifugation of infectious agents, chemical hazards and/or radioactive materials. Make sure the load is properly balanced – a minor error may not be a problem at low speed but may be serious at higher speeds.

Centrifuge tubes must be selected with the knowledge of the materials they will contain and the pressures they will be under. Plastic centrifuge tubes should be used whenever possible to minimize breakage. Nitrocellulose tubes should only be used when clear, without discoloration, and flexible so that tubes are maintained in good working condition. It is advisable to purchase small lots several times a year rather than one large lot. The nitrocellulose tubes should be stored at 4°C to extend the shelf life. Nitrocellulose tubes must not be used in angle-head centrifuges.

Tubes to be used in angle-head centrifuges must never be filled to the point that the liquid is in contact with the lip of the tube when it is placed in the rotor, even though the meniscus will be vertical during rotation. When the tube lip is wetted, high G force drives the liquid past the cap seal and over the outside of the tube. Inspect all centrifuge tubes prior to use. Broken, cracked, or damaged tubes must be discarded.

Capped centrifuge tubes should be used whenever possible.

Carrier Cups and Rotors

It has been estimated that 80% of centrifuge accidents are due to operator error. The most common operator errors are: (1) Failure to secure the rotor to the drive shaft; (2) Failure to place lid on the rotor; and (3) Failure to secure the lid. Additionally, it is very important not to run the rotor above its rated maximum and not to overfill it.

Cryogenic Liquids

Cryogenic liquids are gases that have been transformed into extremely cold refrigerated liquids, which are stored at temperatures below minus 90°C. They are normally stored at low pressures in specially constructed multi-walled, vacuum-insulated containers.

The hazard potential presented by cryogenic liquids may result from the extreme cold, and pressure, which can result from rapid vaporization, and asphyxiation due to the displacement of air.

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

Lasers are a tool of biological research and as such must be used in accordance with applicable safety precautions. The Laser Safety Policy can be found at: <u>http://www.ors.gatech.edu/laser/laser_safety_policy.pdf</u> Refer to the Laser Safety Officer at 404-894-3605 for further guidance in laser safety.

Ultra Violet Light

Under certain conditions of radiation intensity and exposure time UV radiation may kill certain types of microorganisms. Its greatest effect is against vegetative forms. UV is not a sterilizing agent except in certain exceptional circumstances. It is used to reduce the numbers of microorganisms on surfaces and in the air. 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.

Contact the Chemical Safety Manager at 404-385-2964 for additional information and safety requirements.

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.

Laboratory Vacuum Lines

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

Repair and Maintenance of Equipment and Facilities and New Construction

Institute employees or outside vendors undertaking facility expansion, equipment repair and maintenance, and general maintenance activities should not be unnecessarily exposed to biological hazards.

New Construction and Renovation – It is expected that new construction and renovation projects involving biohazard 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.

Preventive Maintenance –routine preventive maintenance of mechanical or laboratory equipment in biohazard areas is not to be initiated from the Biosafety Officer.

Removal of equipment – Potentially contaminated equipment is not to be removed from biohazard laboratories for repair, servicing, cleaning or to surplus properties or repair shops or other areas until decontamination and removal of biohazard labels have 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.

SECTION XXIV - AUTOCLAVE GUIDELINES

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, certain plastics, and biological waste. There are two types of autoclaves: gravity displacement and vacuum pump. In a gravity displacement autoclave, hot steam is pumped in forcing cold air down and out through a drain at the bottom of the chamber while any remaining air is effectively removed by means of gravity. This autoclave type is recommended for loads that include liquid or media, disintegrable lightweight plastics, and some items that may otherwise collapse in a vacuum pump autoclave. A vacuum pump autoclave forcibly removes the air out of the chamber prior to steam being pumped into the unit. This autoclave type is recommended for loads that include items that could trap air and prevent steam penetration.

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 decontamination of biomedical waste may regularly require 60 minutes at 121°C. The needs for sterilizing liquids differ from the needs of sterilizing solids.

- Liquids require the use of slow exhaust in order 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, nonflammable liquids, liquid biowaste, and other biological waste.
- 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, report issues to your building manager and EHS Biosafety immediately.
- Your building manager and Environmental Health and Safety serve as the liaisons for research labs and the preventive maintenance contractor.

- Duties for EHS include educating researchers how to both safely and properly use the autoclave units, coordinating repairs and maintenance on the units, and serving as an informational resource for any researchers that may have questions regarding autoclaves.
- The preventive maintenance contractor is required to perform annual 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.

Before work begins at the autoclave, there are some safety considerations to be aware of. Not all items are safe to use in an autoclave. The pressure and temperatures of an autoclave do not neutralize chemicals, and in many cases can actually 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. However, most other biohazardous bags are autoclavable. 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. Even open bags and containers hold air in the same way that a cup holds water. Be mindful when loading these objects by keeping packages open and on their side when possible to maximize efficiency.
- 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.

- Contain bags of waste in autoclave approved pans in order to catch any debris or liquid that may spill out during the sterilization cycle.
- Use double autoclave approved bags around waste that may potentially puncture the bag, such as pipettes, as to avoid any loss of contents.
- 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, goggles or a face-shield, 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 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 actually boiling. Disturbing such liquids can cause them to boil over!
- Autoclaved waste is NOT to be disposed of in normal trash, but is to be boxed up and disposed of through EHS.

SECTION XXV – Biosafety Cabinets

Biosafety cabinets (BSC) come in a variety of types and configurations. The main purpose of a BSC is to protect workers, the product, or the environment. Not all BSC protect all three categories 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.

Class I

- Similar to a chemical fume hood but with a HEPA filter in the exhaust system
- Generally used to enclose equipment and handle activities that produce aerosols
- Protects personnel and the environment only
- Hard ducted to the buildings exhaust system but some models will recirculate air back into the room

Class II

- Protects personnel, the environment, and the product
- Has four types with slight variations on air flow and recirculation of air into the room
 - o **A1**
 - Has a velocity of 75 linear feet per minute flow into the front grille
 - Recirculate 70 % of the air to the work area with 30 % exhausted to the room or a canopy for exhaust outside
 - The canopy has an air gap that allows air from the room to be pulled into the exhaust
 - Cannot be used to work with volatile chemicals due to recirculation of air that can cause build-up of vapors
 - Should not be hard ducted to a building's exhaust system
 - o **A2**
 - Formally called the A/B3

- Also recirculate 70 % of the air to the work area with 30 % exhausted to the room
- The inward air velocity must be 100 lfpm
- The positively pressured plenum is housed within a negatively pressured plenum that helps to pull contaminated air back into the plenum if a leak happens.
- Minute quantities of volatile chemicals can be used if the cabinet is ducted to the outside
- o **B1**
 - Has a 75 lfpm velocity through the front grille
 - Originally designed by the National Cancer Institute for use with limited quantities of carcinogens
 - Must be hard ducted to the building exhaust system but it is preferable to hard duct the unit on an independent system
 - Due to the flow of air, use of volatile chemicals should be use only in the back of the cabinet
 - May need a charcoal filter to capture volatile chemicals
- o **B2**
 - All air exhausted to the environment
 - Chemical usage must be limited and planned appropriately since some chemicals have the ability to degrade filters, housings, and gaskets
 - May need a charcoal filter to capture volatile compounds as well as a spark proof motor
 - Can exhaust up to 1200 cubic feet per minute of conditioned room air

Class III

- Designed for work with highly infectious materials
- It is gas tight and has a viewing window
- Materials are placed into the unit via a double-door pass through box (autoclave) or a dunk tank for disinfection

- Supply and exhaust air are both HEPA filtered
- Air must be filtered through 2 HEPAs or a HEPA and air incinerator prior to exhausting via an independent duct to the environment

Laminar Flow Modules/Clean Benches

- Can be horizontal or vertical in the nature of air flow.
- Protects only the product and not the environment or personnel.
- The horizontal clean bench flows HEPA filtered air from the back of the cabinet across the surface.
- The vertical clean bench flows HEPA filtered air down onto the surface and discharges air through the sash area.
- Both types of clean benches should never be used with infectious or toxic materials.
- BSC require proper operations and maintenance to provide consistent protection. The following topics provide detailed information for usage and maintenance of BSC on Georgia Tech campuses.

Working in a BSC

- Collect all materials prior to work and add at the same time
- Move arms in and out of the cabinet slowly, perpendicular to the grill
- Wear lab coats, gloves, and safety glasses
- Rest arms at an angle to decease fatigue and keep the front grille open to collect air
- Do not store items on the front grille
- Perform operations at least four inches from the grille
- If the cabinet has to be shut down, allow the unit to run for at least 4 minutes before conducting work
- Clean with an appropriate disinfectant such as 70% ethanol or 1:100 dilution of bleach before, during , and after any experiment
 - A 1:100 solution is used because the strength of a 1:10 dilution of bleach can damage the stainless steel in the BSC

• Wipe the cabinet with sterile water after the bleach is applied to remove residual chlorine that can corrode stainless steel

Wipe down all surfaces of materials prior to placing the item in the cabinet

Place aerosol generating equipment as far back as possible

Place bulky items like pipette holders, biohazard bags, and vacuum flasks to one side of the cabinet

• Open flames in a BSC create turbulence; try alternatives like electric furnaces or touch-plate micro burners.

Maintenance

- BSCs should be placed away from high traffic areas, doors, windows, air supply registers, and chemical fume hoods.
 - All of 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
- HEPA filters must be decontaminated in place prior to removal
- UV lamps in the units are not required for usage and must be properly maintained by:
 - Cleaning weekly to remove dirt and dust that decreases efficiency
 - Monitored weekly for wavelength of light being produced
 - Not used when people are in the same room as the cabinet

Certification

- Must be done before initial usage and anytime that the cabinet moves to a new location
- Must be performed by a experienced, qualified person
- Annual inspections and certifications after the initial inspection
- Georgia Tech uses a contractor that inspects and certifies BSCs
- EHS must be notified prior to purchase of a BSC and then when the unit is installed to ensure timely certification prior to usage new BSCs

• EHS should also be notified prior to a BSC being moved to a new locations to coordinate the decontamination of the cabinet prior to the move and recertification once the BSC is in the new location

SECTION XXVI – GUIDELINES FOR MOVING EQUIPMENT

Typically there are two types of moves involving equipment in biological laboratories:

- Equipment going to Surplus because it is not being used or is broken.
- Internal move of equipment within an Institute building or to another Institute building.

Decontamination

- 1. 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).
- 2. After notifying the Biosafety Officer, all equipment used to handle 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.
 - Spray disinfectant or a 1:10 bleach solution should be used to disinfect biological agents. Consult the Biosafety Officer if necessary.
 - Allow disinfectant to remain on the equipment and/or work surfaces for the appropriate contact time (20 to 30 minutes).
 - Completely remove (by wiping with a disposable towel) the disinfectant from the equipment or work surface.
 - After decontamination, equipment can be sent to surplus or moved.
- 3. Biosafety cabinets (BSCs) are not to be decontaminated by laboratory staff.

Disposing and Moving of Biological Materials

 Dispose of any waste materials (partially full sharps containers, used pipette tips, unwanted plastic/glassware) prior to moving. Biohazardous materials and sharps must be segregated into proper containers by the generator at the point of origin. Biohazardous boxes and sharps containers must be sealed with tape, labeled with the principal investigator's name and room number.

- Assess all of your biological materials and determine which materials will be transferred to your new laboratory. If you wish to dispose of any stock cultures in order to discontinue research with a particular agent, you must contact the Biosafety Officer for advice, as some materials require notification of regulatory agencies prior to disposal. Dispose of any working stocks in the same way as you would have during the course of your normal experimentation.
- 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 should 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. Consider using the EHS OnSite web system to create with inventory.

Biological Safety Cabinets

- Biological Safety Cabinets must be decontaminated before they are moved or surplused. See section XXIV for directions on how to schedule decontamination of a BSC.
- Certification is site specific, so they must be recertified after moving. Decontamination and recertification is provided by the GT Biosafety contractor.
- Laboratory personnel are responsible for emptying the cabinet and wiping down all interior surfaces, including the window, with an effective disinfectant. Do not remove the work tray or disassemble the cabinet during this surface wipe down.

Once in your new lab

- If you have filed an application to 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.

Moving Your Lab Safely – A final Note

- Don't move more than you need to move
- Minimize the amount of material to be moved
- Don't move waste materials
- Pack Safely
- Obtain clearances and certifications
- Clean and decontaminate
- Prepare equipment to move safely
- Once in you new lab notify the Biosafety Officer

For assistance or additional information, contact the Biosafety Officer in the EH&S Office at 404-894-6120.

SECTION XXVII – HAND WASHING

According to the Centers for Disease Control and Prevention (CDC), one of the most important steps you can take to avoid infection is to wash your hands. Infectious diseases spread in the laboratory can cause serious illness.

The proper way to wash your hands to gain the most germ killing benefits:

- Dispense the towel if there is a towel dispenser (like most bathrooms on campus), but do not rip the paper off just yet.
- Wet your hands and wrist
- Dispense soap and work into lather. Use regular soap for general activities, antibacterial soap for laboratory and medical settings where antiseptic hand washing is required.
- Rub together all surfaces of your hands for at least 15 seconds. Soap helps the surface tension of water to carry dirt from your hands; cleaning is accomplished by rubbing the dirt from your skin so that the soap and water will carry the dirt from your hands. If this seems too long, just think, if you were visiting the Intensive Care unit of the hospital, you must wash your hands for approximately 2 minutes!
- Rinse your hands, making sure to point your hands downward so all the dirty water will run down and into the sink.
- DO NOT TURN THE FAUCET OFF YET.
- Dry hands completely with the paper towel you have just ripped off the dispenser.
- Take the used paper towel and now turn off the faucet.

Alcohol based Hand Sanitizers can be used on campus. These water-less hand sanitizers cannot be used in the place of having a hand washing sink in a laboratory. They should be selected carefully and should contain alcohol. Not all hand sanitizers contain alcohol so be sure that one you select for use in a laboratory contains alcohol.

SECTION XXVIII- BLOODBORNE PATHOGENS

Universal Blood and Body Fluid Precautions

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.

Personnel Practices

Hand-washing:

- 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

Contaminated Needles and Other Sharps:

- 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

Personal Protective Equipment for Blood or Body Fluid Contact

- Gloves when touching blood or body fluids, mucous membranes, or infected skin of patients
- Gloves when handling items or surfaces soiled with blood or body fluids
- Gloves when performing vascular access procedures (phlebotomy)
- Appropriate gowns or aprons when splashes or soiling of skin or clothing with blood or body fluids is likely
- Masks and goggles, or face shield during procedures likely to generate splashes of blood or body fluids into the mouth, nose, or eye

Environmental Controls

General Housekeeping:

• Maintain work area in clean and sanitary condition

- Decontaminate work surfaces after procedures and at the end of the day
- Remove any protective work surface coverings when contaminated or at least once a week

Spill Kit

• All laboratories must have a spill kit with enough absorbent to handle any amount of hazardous material that spills in the laboratory

Blood or Body Fluid Spills:

- Soak up spills with absorbent material
- Decontaminate area with appropriate disinfectant
- Dispose of contaminated material appropriately

Transport:

- Consider all laboratory specimens of human or mammalian origin as potentially infectious
- Use leak proof containers for laboratory specimens
- Place container in a sealable secondary container for transport

Exposure to blood or body fluids via broken skin or needle sticks or mucous membrane contact:

- Wash affected area immediately and apply first aid
- If the injury is serious, call campus police at 404-894-2500 to inform them of the situation, they will dispatch the appropriate medical personnel.
- If a student, contact Health Services as soon as possible for post exposure follow-up. If faculty/staff, contact EHS to determine if the situation is covered under the Occupational Health Program.
- Report injury to the Biosafety Officer at 404-894-6120

SECTION XXIX — First Aid in the Laboratory

Adapted from "National Research Council. 1995. Prudent Practices in the Laboratory: Washington, D.C. (p. 87-88)"

If an individual is injured or contaminated with a hazardous substance, tending to the injury or contamination takes priority over implementing the spill control measures. The laboratory should not be left unless the spilled material creates a hazardous environment. 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 404/894-2500.

For spills covering small areas of skin that can be easily placed under a sink, follow these procedures:

- 1. Immediately flush with flowing water for no less than 15 minutes.
- 2. If there is no visible burn, wash with warm water and anti-microbial soap, removing any jewelry to facilitate clearing of any residual materials.
- 3. Seek medical attention for even minor chemical burns.
- 4. Do not use creams, lotions, or salves.

Take the following steps for spills large spills that are in areas not easily placed under a sink:

- 1. Do not attempt to wipe the clothes.
- 2. Quickly remove all contaminated clothing, shoes, and jewelry while using the safety shower.
- 3. Seconds count, so do not waste time because of modesty.
- 4. Take care not to spread the biological on the skin or, especially, in the eyes.
- 5. Use caution when removing pullover shirts or sweaters to prevent contamination of the eyes; it may be better to cut the garments off.
- 6. Immediately flood the affected body area with warm water for at least 15 minutes. Resume if pain returns.
- 7. Seek medical attention as soon as possible.

8. Discard contaminated clothes

For splashes into the eye, take these steps:

- 1. Immediately flush with tepid potable water from a gently flowing source for at least 15 minutes.
- 2. Hold the individuals' eyelids away from the eyeball, and instruct him or her to move the eye up and down and sideways to wash thoroughly behind the eyelids.
- 3. Use the eyewash. If one is not available, place the injured person on his or her back and pour water gently into the eyes for at least 15 minutes.
- 4. Seek medical attention as soon as possible.

If the victim is unconscious, has trouble breathing, has chest pain/pressure, is bleeding severely, has possible broken bones, has persistent pain/pressure in the abdomen, is vomiting/passing blood, has headache, seizures, or slurred speech seek medical care by calling 404-894-2500. The police will then inform the medical responders as to where you are located.

SECTION XXX- LINKS TO OTHER GUIDELINES, POLICIES, AND MANUALS

Individuals working in any laboratory should be familiar with the Georgia Tech Laboratory Safety Manual. This manual covers topics of interest including chemical usage, toxic gases, and much more. The manual can be found at:

http://www.ehs.gatech.edu/chemical/ehslsm.pdf

Individuals working in research involving nanotechnology should be familiar with the Georgia Tech Guidelines for Safe Handling of Nanomaterials found at: <u>http://www.ehs.gatech.edu/chemical/nanotechnology.doc</u>

Individuals working with radioactive materials must coordinate their laboratory activities with the Radiation Safety Committee and be familiar with the Radiation Safety Policy Manual. <u>http://www.ors.gatech.edu/rsm.pdf</u>

Individuals working with vertebrate animals need to coordinate their laboratory activities with the Institutional Animal Care & Use Committee (IACUC). Regulations, guidelines, and forms can be found at the Office of Research Compliance IACUC website. http://researchintegrity.gatech.edu/about-iacuc/

Individuals working with human subjects need to coordinate their activities with the Institutional Review Board (IRB). Regulations and guidelines can be found at the Office of Research Compliance IRB website. http://researchintegrity.gatech.edu/about-irb/

Biosafety in Microbiological and Biomedical Laboratories 5th Edition (BMBL): The BMBL is a standard set of guidelines published by the CDC and the NIH. The main section of the BMBL covers broad topics including risk assessment, basic principles of biosafety, laboratory and vertebrate animal biosafety level requirements, biosecurity, occupational health, and Select Agent descriptions. The appendices cover specific topics like selection and use of biosafety cabinets, decontamination, and transportation of infectious substances, agriculture and arthropod pathogens, integrated pest management, and working with toxins. The fifth edition for the BMBL can be downloaded in PDF form at:

http://www.cdc.gov/biosafety/publications/bmbl5/

The Public Health Agency of Canada has created a series of "MSDS" fact sheets for a variety of infectious agents that are commonly found in biological research laboratories. The MSDS sheets can be found at: http://www.phac-aspc.gc.ca/lab-bio/res/psds-ftss/index-eng.php The American Biological Safety Association has created a chart listing numerous infectious and non-infectious biological agents. This chart contains prescribed biosafety levels from several US governmental agencies, the European Council, and several countries. The information can be found at:

http://www.absa.org/riskgroups/

APPENDIX A

BIOSAFETY SIGN



APPENDIX B

Georgia Tech Laboratory Emergency Procedures

<u>DO THIS NOW</u>

1. If the incident poses a hazard to the building/occupants outside of this lab pull the fire alarm and evacuate the building

- a. If possible, call GT PD from a cell phone outside
- b. Stay close by and identify yourself to first responders- you may be the only one who knows the nature of the emergency
- 2. If the incident involves a biological or chemical exposure you will either
 - a. Remove the victim to fresh air
 - b. Have them remove all contaminated clothing and shower in an emergency shower for 15 minutes
 - c. Have them rinse their eyes in an eyewash for 15 minutes

3. Call GT Police by dialing 911.

- a. Information that Responders need:
 - i. I am on the Georgia Tech Campus
 - ii. The Street Address of this Building is _____
 - iii. My room number is____
 - iv. Describe the nature of the emergency:
 - o *Spill with human* o Electrocution

exposure

- Large spill, no human
 Seizure, amputation, etc exposure
- v. Tell them if you think you will need an ambulance

4. If the exposure involved hydrofluoric acid (HF) apply calcium gluconate to the exposed area

5. If the chemical or biological is known, print out 3 copies of the MSDS or other safety information, one for First Responders, One for Ambulance Crew, One for the police/EHS

6. Give this sheet (and an MSDS) to the ambulance crew

7. Do not transport the victim yourself

8. EH&S Recommends that all chemical exposure cases go to Grady Hospital because it is a Level 1 Trauma Center with personnel who are trained to deal with chemical exposures.

DO THIS AFTER THE POLICE COME

9. Try to locate the victim's identification, wallet, and cell phone to take to the hospital with them

10. Contact the victim's supervisor to initiate worker's compensation reporting procedures.

All bills and medical reports should be sent to the address listed below:

Georgia Department of Administrative Services (DOAS) Risk Management – Workers' Compensation Unit 205 Jesse Hill Drive, East Tower, Suite 260 PMB 38198 Atlanta, GA 30334

Students requiring assistance may call the Georgia Tech Student Affairs Office/Dean of Students

During regular work hours call 404-894-6367 Option 9 After Hours or on Weekends call the GT Police at 404-894-2500 and ask

them to

page the Dean on Duty

Updated 1/18/10 GT EHS 404-894-4635

Appendix C Integrated Pest Management

Pest management is an important part of managing a research facility. Many pests, such as flies and cockroaches, can mechanically vector disease pathogens and compromise the research environment. Even the presence of innocuous insects can contribute to the perception of unsanitary conditions.

The most common approach to pest control has been the application of pesticides, either as a preventive or remedial measure. Pesticide treatments can be effective and may be necessary as a corrective measure, but they have limited long-term effect when used alone. Pesticide applications also present the potential to contaminate the research environment through pesticide drift and volatilization.

To control pests and minimize the use of pesticides, it is necessary to employ a comprehensive program approach to pest management that integrates housekeeping, maintenance, and pest control services. This method of pest control is often referred to as Integrated Pest Management (IPM). The primary goal of an IPM program is to prevent pest problems by managing the facility environment in such a way as to make it less conducive to pest infestation. Along with limited applications of pesticides to control pests, pest control is achieved through proactive operational and administrative intervention strategies to correct conditions that foster pest problems.

IPM is a strategy-based service. The decision to implement an IPM program should be based not only on the cost of the services, but on the effectiveness of the program's components. IPM is site-specific, and each program should be tailored to the environment where it is applied. IPM services in a laboratory will be different from those in an office building or an animal care facility.

Integrated pest management programs can be delineated into various interrelated components which contribute to the environmental management" approach to controlling pests. These are:

- *Facility Design:* The inclusion of pest management issues and requirements in a facility's planning, design, and construction provides an opportunity to incorporate features that help to exclude pests, minimize pest habitat, and promote proper sanitation. This can help to reduce the need for future corrective pest management services that can be disruptive to research operations.
- *Monitoring:* Traps, visual inspections, and staff interviews are used to identify areas and conditions that may foster pest activity. Monitoring is the central activity of an IPM program and is used in place of preventive Pesticide treatments.
- Sanitation and Facility Maintenance: Many pest problems can be prevented or corrected by using proper sanitation, reducing clutter and pest habitat, and by performing repairs that exclude pests and reduce pest habitat. Maintaining records of structural deficiencies and housekeeping conditions can help to track problems and determine if corrective actions are completed in a timely manner.

- *Communications:* A staff member can be designated to meet with pest management personnel to assist in resolving facility issues that impact on pest management. Information on pest activity, and recommendations on personnel practices and facility conditions that impact pest management, can be relayed verbally and in writing to that person. Training on subjects such as pest identification, biology, and sanitation can also promote understanding and cooperation with the goals of the IPM program.
- *Record Keeping:* A logbook can be used to record pest activity and conditions pertinent to the IPM program. It may contain protocols and procedures for IPM services in that facility; Material Safety Data Sheets on pesticides; pesticide labels; treatment records; floor plans; survey reports; etc.
- *Nonpesticide Pest Control:* Pest control methods such as trapping, exclusion, caulking, washing, and freezing can be applied safely and effectively when used in conjunction with proper sanitation and structural repair.
- *Pest Control With Pesticides:* Preventive applications of pesticides should be discouraged, and treatment should be restricted to areas of known pest activity. When pesticides are applied, the least toxic product(s) available should be used and applied in the most effective and safe manner.
- *Program Evaluation and Quality Assurance:* Quality assurance and program review should be performed to provide an objective, ongoing evaluation of IPM activities and effectiveness. This is to ensure that the program is controlling pests and meeting the specific needs of the facility program(s) and its occupants. Based upon this review, current pest management protocols can be modified and new procedures implemented.
- *Technical Expertise:* A qualified entomologist can provide helpful technical guidance in developing and implementing an IPM program. Pest management personnel should be licensed and certified through examination by the appropriate regulatory agency.
- *Safety:* By limiting the scope of pesticide treatments and using nonpesticide control practices, IPM can minimize the potential of pesticide exposure to the research environment and the staff.

Prior to initiating any type of pest management program, development of an operational framework for IPM services can help to promote collaboration between pest management specialists and facility personnel. This framework can also be used to incorporate facility restrictions and operational and procedural issues into the IPM program. An effective pest management program is an integral part of the facility's management. Including an IPM policy statement in the facility's standard operating procedures can increase awareness of the program.

Training on the principles and practices of structural (indoor) integrated pest management and information on IPM programs is available from many sources. Some of these are Institute entomology departments, county extension offices, the Entomological Society of America, state departments of agriculture, state pest control associations, the National Pest Control Association, suppliers of pest control equipment, and pest management consultants or pest management firms. There are also correspondence courses available from several universities as well as short courses and training conferences on structural pest management.

Additional Information:

Urban Entomology. 1996. Insect and Mite pests in the Human Environment. W. H. Robinson. Chapman and Hall. New York.

Advances in Urban Pest Management. 1986. Gary W. Bennett and John M. Owens, eds. Van Nostrand Reinhold Company. New York

Common Sense Pest Control. 1991. Least-toxic solutions for your home, garden, pests and community. William Olkowski, Sheila Daar, Helga Olkowski. The Taunton Press., Inc.,

Internet:

 National Pest Control Association: <u>http://www.pestworld.org</u> Forms 1- Biological Materials Safeguards Committee Forms

Date Prepared:___

Biological Hygiene Plan for Biological Materials Safeguards Committee Registrations Involving Biological Materials <<PI's Name>> Laboratory <<Unit Name>>

> Georgia Institute of Technology Institutional Biosafety Committee www.compliance.gatech.edu

1. <u>The Biological Hazard Standard</u>

Standard practices for occupational exposure to biological materials have been defined by Georgia Institute of Technology in accordance with the federal regulations set forth in the *NIH Guidelines for Research Involving Recombinant DNA Molecules (Guidelines)* and/or the *Centers for Disease Control (CDC) Biosafety for Biological and Biomedical Laboratories (BMBL).*

2. Exposure Control Plan

We will adopt the Georgia Tech Biohazardous Safety Manual and the Policies and Procedures Governing the Possession and Use of Recombinant DNA as our standard. The present document provides specific instruction regarding the use of <<*biological material*>>. In accordance with recommendations of the <<*CDC or NIH*>> for this agent, we will apply the criteria recommended for biosafety level <<*BSL*>> in terms of practices, safety equipment, and facilities, and we will adopt the concept of "universal precautions," which assumes that all instruments coming in contact with concentrated or dilute solutions of <<*biological material name* >> are potentially hazardous. Criteria for biosafety level <<*BSL*>> are incorporated into the following sections.

3. <u>Training</u>

All employees and students in the laboratory will receive <<*General Biosafety Training* >>, conducted by Environmental Health and Safety, where such training will be documented. Training in the recognition and prevention of occupational exposure to biological materials as well as research protocols will be given by <<*name*>>, to all personnel whose employment or academic responsibilities may expose them to biological materials. Written records of those training sessions will be maintained by <<*name*>>. Employees and other personnel who will be working with rDNA and <<*biological material name* >> will also receive "Protocol Specific Training" regarding its use and appropriate handling in the laboratory.

3. <u>Statement of Specific Hazard for << biological material name>></u> << Provide a description >>

4. <u>Engineering Controls</u>

<<Describe location of experiments to be performed, plus safety
precautions, as suggested in the following example>>. All experiments
using <<biological material name>> will be performed in Room <<room
number >> <<building name >>. All manipulations for preparations of
concentrated stocks of <<biological material>> will be performed in the
tissue culture facility in <<location>>, using Class <<BSC class >>
biological safety cabinets. Safety cabinets will be certified annually. This
facility will be off-limits at all times to children 12 years of age or
younger. Older children may enter only when supervised. When
<
biological material name>> manipulation is under way, traffic into the
room will be limited to only that which is unavoidable.

5. <u>Work Practice Controls</u> << modify the following as appropriate >>

a. Mechanical pipetting and suctioning devices will be used for manipulations of potentially hazardous fluids; pipetting or suctioning by mouth is strictly prohibited.

b. Employees will place all used needles, scalpels, and other sharps directly into a labeled, puncture-proof sharps container immediately following use, without any effort made to recap by hand, destroy or remove needles from the syringes

c. The following activities are prohibited from Room <<*location>>* during use of the <<*biological material>>*: eating; drinking; smoking; application of cosmetics or lip balm; handling of contact lenses; storage or preparation of food or drink.

d. Employees with increased risk (broken skin, immunocompromised) should avoid working with potentially biological materials. All researchers working with <<<u>biological material</u>>> are required to enroll in the EHS Occupational Health Program.

e. Work surfaces are decontaminated at least once per day, and after any spill of biological material. In practice, the surface of the biological safety cabinet will be cleaned with << 70% isopropanol or 10% bleach or another appropriate disinfectant>> before and after use.

f. Containers for potentially hazardous laboratory waste will be labeled, leak-proof, and closeable.

g. All recording chambers for experimental platforms that are used for experiments with the <<*biological material*>> will be treated for 10 min. with a solution of 0.5% sodium hypochlorite at the end of the experiment.

h. Aspiration bottles for liquid waste from the experimental chambers used for experiments with the <<*biological material*>> will contain concentrated sodium hypochlorite at a volume large enough that the final concentration of sodium hypochlorite will not go below 0.5% as the bottle is filled.

i. All potentially hazardous liquid or solid waste is decontaminated by treatment with 0.5% sodium hypochlorite and allowed to stand for at least 20 minutes. Liquid waste, which will include sodium hypochlorite, shall be discarded via sink disposal with copious amounts of water.

j. Hazardous waste that has been autoclaved (for a minimum of 20 minutes at 120 degrees Celsius) shall be discarded via biohazard bag and box supplied by EHS. Biological materials that have been autoclaved are not allowed to be disposed of via regular solid waste means.

k. There will be no unattended operations using << *biological material*>>.

l. All procedures are performed carefully to minimize the creation of aerosols.

m. During experiments utilizing the <<*biological material*>>, which will be performed in Room <<*location*>>, the door to the laboratory will remain closed and locked. Only <<*PI's name* >> laboratory personnel will be allowed entry during these times. During experiments using <<*biological material*>>, a biohazard warning sign will be posted which includes the universal biohazard warning symbol. A second card shall be placed on the door to the laboratory that includes the *<PI's name*>> name and emergency contact as well as the emergency contact information for another responsible member of the laboratory. During use of biohazards, personnel not affiliated with the laboratory will be warned against entering by the placement of a sign reading: "DO NOT ENTER – BIOHAZARD EXPERIMENT IN PROGRESS".

n. A safety shower and wall-mounted eyewash station is located <<*spot in room*>> in the laboratory.

o. Stock solutions of <<*biological material*>> will be held in microfuge tubes as aliquots inside a clearly-labeled, sealed container(s), in <<refrigerator, freezer, located in Room>>. This refrigerator is clearly labeled as a NON-FOOD storage location.

p. The following key phrases will remain standard in this laboratory:

- Acquire training in handling biological materials

- Observe "universal precautions"

Wear protective clothing and gear, including gloves,

goggles,

and face mask

- Avoid sharps
- Control splash hazards
- Decontaminate waste materials
- Decontaminate the equipment
- Avoid increased risk
- Control aerosols
- Respond correctly to exposure

- When handling solutions containing <<*biological material*>>, remain vigilant, leave nothing to ambiguity, follow established protocols, and remain focused on your work.

6. <u>Personal Protective Clothes and Devices</u> <<modify the following as appropriate >>

a. The use of personal protective apparel constitutes the most important barrier in avoidance of occupational exposure to biological materials.

b. When there is a potential for occupational exposure to biological material, protective clothing and devices must be used.

c. When manipulating <<*biological material name*>>-containing solutions in the biological safety cabinet, employees shall wear gloves, a biohazard-designated laboratory coat (not to be worn outside of Room <<*location*>>), safety glasses with side shields and any other personal protective equipment that may be necessary to prevent overt exposures. Long hair must be pulled back and contained.

d. Lab coats, gloves and goggles will be worn during all experiments involving <<<u>biological material</u>>>.

e. Lab coats, gloves and goggles will also be worn during all cleaning and decontamination procedures, and during handling of biological waste that has not yet been autoclaved.

f. When potentially contaminated, laboratory coats designated for use in Room <<*location*>> will be removed from this room in a protective container that is closed before removal from the laboratory, and immediately autoclaved. Coats must be decontaminated before laundering.

g. When manipulating either dilute or concentrated solutions of <<*biological material*>>, or when handling of hazardous waste, employees shall wear clothing that fully covers their legs (*e.g.*, long pants) and closed-toe shoes.

7. <u>Post-Exposure Procedures</u> << modify as appropriate>>

a. Employees must report exposure incidents to <<*PI's name*>>, who will arrange for appropriate medical evaluation and follow-up, and to <<*name*>>, departmental safety officer.

b. Medical evaluation, surveillance, counseling, laboratory testing, prophylaxis, and treatment will be provided to individuals who have occupational exposure to <<*biological material*>>.

c. Employees who experience on the job injuries, accidents, or exposures to biological materials or agents must prepare a brief narrative report of the incident, as well as an official Illness and Injury Report Form, submit these to <<*PI's name*>>, and have them forwarded to the Biosafety Officer at EHS.

8. <u>Emergency Actions</u> << modify the following as appropriate>>

a. In case of emergency, such as spill of potentially biological material, the only issue of importance is the health and safety of the individual(s) at risk: the experiment or procedure is unimportant. All personnel should evacuate the area immediately.

b. Spills and accidents that result in overt exposures to <<*biological material*>>-containing material are immediately reported to <<*PI's name*>>, and then to EHS.

c. All spills shall be immediately contained and cleaned up by appropriately trained individuals. Do not allow the hazard to be spread outside of <<*location*>>.

A copy of this Biological Hygiene Plan for Biosafety Registrations Involving biologicals shall be provided to all personnel in the laboratory who work with the material described in this plan. Forms 2 – Institutional Biosafety Committee Forms

Date Prepared:___

Biological Hygiene Plan for Biosafety Registrations Involving rDNA <<PI's Name>> Laboratory <<Unit Name>>

Georgia Institute of Technology Institutional Biosafety Committee www.researchintegrity.gatech.edu

1. <u>The Biological Hazard Standard</u>

Standard practices for occupational exposure to biological materials have been defined by Georgia Institute of Technology in accordance with the federal regulations set forth in the *NIH Guidelines for Research Involving Recombinant DNA Molecules (Guidelines)* and/or the *Centers for Disease Control (CDC) Biosafety for Biological and Biomedical Laboratories (BMBL).*

2. <u>Exposure Control Plan</u>

We will adopt the Georgia Tech Biohazardous Safety Manual and the Policies and Procedures Governing the Possession and Use of Recombinant DNA as our standard. The present document provides specific instruction regarding the use of <<*biological material*>>. In accordance with recommendations of the <<*CDC or NIH*>> for this agent, we will apply the criteria recommended for biosafety level <<*BSL*>> in terms of practices, safety equipment, and facilities, and we will adopt the concept of "universal precautions," which assumes that all instruments coming in contact with concentrated or dilute solutions of <<*biological material name* >> are potentially hazardous. Criteria for biosafety level <<*BSL*>> are incorporated into the following sections.

3. <u>Training</u>

All employees and students in the laboratory will receive <<*General Biosafety Training and/or Recombinant DNA Training*>>, conducted by Environmental Health and Safety, where such training will be documented. Training in the recognition and prevention of occupational exposure to biological materials as well as research protocols will be given by <<*name*>>, to all personnel whose employment or academic responsibilities may expose them to biological materials. Written records of those training sessions will be maintained by <<*name*>>. Employees and other personnel who will be working with rDNA and <<*biological material name* >> will also receive "Protocol Specific Training" regarding its use and appropriate handling in the laboratory.

3. <u>Statement of Specific Hazard for << biological material name>> << Provide a description >></u>

4. <u>Engineering Controls</u>

<<Describe location of experiments to be performed, plus safety
precautions, as suggested in the following example>>. All experiments
using <<biological material name>> will be performed in Room <<room
number >> <<building name >>. All manipulations for preparations of
concentrated stocks of <<biological material>> will be performed in the
tissue culture facility in <<location>>, using Class <<BSC class >>
biological safety cabinets. Safety cabinets will be certified annually. This
facility will be off-limits at all times to children 12 years of age or
younger. Older children may enter only when supervised. When
<
biological material name>> manipulation is under way, traffic into the
room will be limited to only that which is unavoidable.

5. <u>Work Practice Controls</u> << modify the following as appropriate >>

a. Mechanical pipetting and suctioning devices will be used for manipulations of potentially hazardous fluids; pipetting or suctioning by mouth is strictly prohibited.

b. Employees will place all used needles, scalpels, and other sharps directly into a labeled, puncture-proof sharps container immediately following use, without any effort made to recap by hand, destroy or remove needles from the syringes

c. The following activities are prohibited from Room <<*location>>* during use of the <<*biological material>>*: eating; drinking; smoking; application of cosmetics or lip balm; handling of contact lenses; storage or preparation of food or drink.

d. Employees with increased risk (broken skin, immunocompromised) should avoid working with potentially biological materials. All researchers working with <<<u>biological material</u>>> are required to enroll in the EHS Occupational Health Program.

e. Work surfaces are decontaminated at least once per day, and after any spill of biological material. In practice, the surface of the biological safety cabinet will be cleaned with << 70% isopropanol or 10% bleach or another appropriate disinfectant>> before and after use.

f. Containers for potentially hazardous laboratory waste will be labeled, leak-proof, and closeable.

g. All recording chambers for experimental platforms that are used for experiments with the <<*biological material*>> will be treated for 10 min. with a solution of 0.5% sodium hypochlorite at the end of the experiment.

h. Aspiration bottles for liquid waste from the experimental chambers used for experiments with the <<*biological material*>> will contain concentrated sodium hypochlorite at a volume large enough that the final concentration of sodium hypochlorite will not go below 0.5% as the bottle is filled.

i. All potentially hazardous liquid or solid waste is decontaminated by treatment with 0.5% sodium hypochlorite and allowed to stand for at least 20 minutes. Liquid waste, which will include sodium hypochlorite, shall be discarded via sink disposal with copious amounts of water.

j. Hazardous waste that has been autoclaved (for a minimum of 20 minutes at 120 degrees Celsius) shall be discarded via biohazard bag and box supplied by EHS. Biological materials that have been autoclaved are not allowed to be disposed of via regular solid waste means.

k. There will be no unattended operations using << *biological material*>>.

l. All procedures are performed carefully to minimize the creation of aerosols.

m. During experiments utilizing the <<*biological material*>>, which will be performed in Room <<*location*>>, the door to the laboratory will remain closed and locked. Only <<*PI's name* >> laboratory personnel will be allowed entry during these times. During experiments using <<*biological material*>>, a biohazard warning sign will be posted which includes the universal biohazard warning symbol. A second card shall be placed on the door to the laboratory that includes the *<PI's name*>> name and emergency contact as well as the emergency contact information for another responsible member of the laboratory. During use of biohazards, personnel not affiliated with the laboratory will be warned against entering by the placement of a sign reading: "DO NOT ENTER – BIOHAZARD EXPERIMENT IN PROGRESS".

n. A safety shower and wall-mounted eyewash station is located <<*spot in room*>> in the laboratory.

o. Stock solutions of <<*biological material*>> will be held in microfuge tubes as aliquots inside a clearly-labeled, sealed container(s), in <<refrigerator, freezer, located in Room>>. This refrigerator is clearly labeled as a NON-FOOD storage location.

p. The following key phrases will remain standard in this laboratory:

- Acquire training in handling biological materials

- Observe "universal precautions"

Wear protective clothing and gear, including gloves,

goggles,

and face mask

- Avoid sharps
- Control splash hazards
- Decontaminate waste materials
- Decontaminate the equipment
- Avoid increased risk
- Control aerosols
- Respond correctly to exposure

- When handling solutions containing <<*biological material*>>, remain vigilant, leave nothing to ambiguity, follow established protocols, and remain focused on your work.

6. <u>Personal Protective Clothes and Devices</u> <<modify the following as appropriate >>

a. The use of personal protective apparel constitutes the most important barrier in avoidance of occupational exposure to biological materials.

b. When there is a potential for occupational exposure to biological material, protective clothing and devices must be used.

c. When manipulating <<*biological material name*>>-containing solutions in the biological safety cabinet, employees shall wear gloves, a biohazard-designated laboratory coat (not to be worn outside of Room <<*location*>>), safety glasses with side shields and any other personal protective equipment that may be necessary to prevent overt exposures. Long hair must be pulled back and contained.

d. Lab coats, gloves and goggles will be worn during all experiments involving <<<u>biological material</u>>>.

e. Lab coats, gloves and goggles will also be worn during all cleaning and decontamination procedures, and during handling of biological waste that has not yet been autoclaved.

f. When potentially contaminated, laboratory coats designated for use in Room <<*location*>> will be removed from this room in a protective container that is closed before removal from the laboratory, and immediately autoclaved. Coats must be decontaminated before laundering.

g. When manipulating either dilute or concentrated solutions of <<*biological material*>>, or when handling of hazardous waste, employees shall wear clothing that fully covers their legs (*e.g.*, long pants) and closed-toe shoes.

7. <u>Post-Exposure Procedures</u> << modify as appropriate>>

a. Employees must report exposure incidents to <<*PI's name*>>, who will arrange for appropriate medical evaluation and follow-up, and to <<*name*>>, departmental safety officer.

b. Medical evaluation, surveillance, counseling, laboratory testing, prophylaxis, and treatment will be provided to individuals who have occupational exposure to <<*biological material*>>.

c. Employees who experience on the job injuries, accidents, or exposures to biological materials or agents must prepare a brief narrative report of the incident, as well as an official Illness and Injury Report Form, submit these to <<*PI's name*>>, and have them forwarded to the Biosafety Officer at EHS.

8. <u>Emergency Actions</u> << modify the following as appropriate>>

a. In case of emergency, such as spill of potentially biological material, the only issue of importance is the health and safety of the individual(s) at risk: the experiment or procedure is unimportant. All personnel should evacuate the area immediately.

b. Spills and accidents that result in overt exposures to <<*biological material*>>-containing material are immediately reported to <<*PI's name*>>, and then to EHS.

c. All spills shall be immediately contained and cleaned up by appropriately trained individuals. Do not allow the hazard to be spread outside of <<*location*>>.

A copy of this Biological Hygiene Plan for Biosafety Registrations Involving rDNA shall be provided to all personnel in the laboratory who work with the material described in this plan. Forms 3 – Occupational Health Program Forms

Georgia Institute of Technology Occupational Health Program Confidential Exposure/Risk Assessment Questionnaire

Date:	
Last Name:	First Name:
Job Title:	Department:
PI:	Work Phone:
E-mail:	Gender:

Be sure to answer each question that pertains to your research or work.

1. Have you ever worked with, do you currently work, or will you be working

with laboratory animals or animal cell lines?

 \Box Yes \Box No

1-5 years

If no, proceed to question 11.

2. How long have you worked with animals?

🗆 0-1 year

6 or more years

3. Categorize your **current/future estimated** laboratory animal contact (Complete

both A and B):

A. Duration (weekly average):

 \Box > 8 hours per week

□ 1-8 hours per week

 \Box <1 hour per week

🗆 None

B: Activities (Check all that apply):

□ Performs surgery or necropsy

- □ Hands-on work with awake animals
- Tissues/fluids/bone

Animal cell lines

No direct contact, enters facility or observes animals

4. Check the boxes below if you have worked with the following animals or animal cell lines.

Animal	Previously	Currently
Rats		
Mice		
Rabbits		
Guinea Pigs		
Hamsters		
Gerbils		
Non-human primate		
Dogs		
Cats		
Fish		
Goats/Sheep		
Swine		

Lizards	5			
Frogs				
Inverte	ebrates			
Other				
	If other, please specify:			
	lf non-human primate, ple	ase specify:		
	If invertebrates, please spe	cify:		
	If all experience previous p	proceed to q	uestion 11.	

5. What is the location where research will be taking place?

6. Describe your specific duties related to animal research or animal cell line research.

8. Do you inject animals with recombinant DNA microorganisms?

□ Yes □ No

If yes, at what BSL containment level are the animals housed?

9. Do you work with animals that have been implanted or injected with human cells or

other human tissues?

□ Yes □ No □ N/A

If yes, are these certified to be free of human pathogens?

□ Yes □ No □ N/A

10. Do you work with animals that are exposed to the following?

Doxorubicin
Isoflurane

Paclitaxel
 Retinoic Acid

□ Other _____ □ N/A

11. Do you work with human subjects, human tissues, cells, or blood, microorganisms, rDNA, insects, or non- animal cell lines?

□ Yes □No

If no, proceed to question 17.

12. How long have you worked with these biological materials?

□ 0-1 year □ 1-5 years □ 6 or more years	🗆 0-1 year	□ 1-5 years	6 or more years
--	------------	-------------	-----------------

13. Categorize your **current** contact with biological materials (Complete both A and B):

A. Duration (weekly average):	B: Activities (Check all that apply):
> 8 hours per week	Recombinant DNA
1-8 hours per week	🗆 Bacteria, viruses, fungi, or parasites
1 hour per week	
🗆 None	Human Cell Lines (Like 59M or Jurkat)
	Human organs/tissue/ blood/fluids
	Human Subjects
	Microorganisms cultured from human
	samples

14. Please list the *specific* biological agents you are using. (list any cell line names)

15. Briefly describe your research or work activities.

16. While working with biological materials, have you ever had an allergic reaction?

 \Box Yes \Box No If yes, please describe.

17.	Do you use or wear any	of the following iten	ns when working o	r conducting
	research?			

 Protective safety glasses Surgical mask Respirator 		 Lab Coat N-95 mask 		Gloves
•	□ Sc □ Ту	rrubs /vek Jumpsuit	□ Shoeco □Surgical	
18. If you will be or currently medically screened and complete a				e
process?	□ No		□ N/A	
19. Do you work with a DE	A controlle	ed substance or a CDC	/USDA Select	Agent?
	□ Se	elect Agent		□ N/A
List:				
20. Do you work with any o	f the follo	wing materials?		
Hazardous Chemica	als	🗆 Radioacti	ve Isotopes	□ N/A
Please list:				
21. Do you use an ethylene	oxide steri	ilizer?		
□ Yes	□ No	If yes, where is the u	unit located?	

22. If you do not work with any biological materials, list all duties related to the research environment.

22. Other Comments:

Please be informed that certain medical conditions can increase your potential risk of health problems when working with animals/biological materials. These medical conditions could include but are not limited to allergies to animals and/or animal dander, asthma, heart valve disease, and immunosuppression.

Signature

Date

*This form must be completed by all members of laboratories that deal with animals or biological materials.

**The option to decline participation in the medical monitoring program will be offered after a risk assessment has been completed by the EHS department. You will be informed in writing of any further steps.

***Due to the sensitive nature of the information collected on this form, please call the Biosafety Officer at 404-894-6120 or the Assistant Biosafety Officer at 404-894-6119 to schedule a time for pickup.

Georgia Institute of Technology Occupational Health Program Waiver of Medical Screening or Declination (refusal) Form						
Name						
Last Middle		First				
Work Phone	Home Phone	Employee ID Number				
Email		Department				
Date of Birth		Supervisor				
 CONSENT TO PARTICIPATE IN MEDICAL SCREENING I understand that due to my occupational exposure to animals or other potentially infectious materials I may be at risk of contracting certain diseases. I have read the information provided to me about risks associated with conducting animal and/or biological research. I have had an opportunity to ask questions and understand the benefits of participation in the Medical Screening Program, including but not limited to, protection from the risk of infection associated with animal/biological research. I understand that failure to take part in the program may result in an increased risk of disease, possibly even fatal disease to me and my family. I understand that I will not be charged for the medical screening. 						
program must be signed in and understand, the guida conducting animal and bia medical screening program charge to you. This decline participate in the medical I understand that due to m infectious materials I may I	f you choose not to particl ance provided regarding r ological research and ben m. You understand that th pation statement is not a w screening program at a laid ny occupational exposure be at risk of infection by ar ith animal or biological res	<i>ie in the medical screening</i> <i>ipate.</i> You must have read, risks associated with efits of participation in a the program is provided free of vaiver; you can request to ter date. to blood or other potentially nimal associated organisms or search. I have been given the				

however, I decline at this time. I understand that by decl	ining these			
vaccines/procedures, I continue to be at risk of acquiring	the associated serious			
diseases. If in the future I continue to have occupational exposure to animals or				
other potentially infectious materials and I want to be screened, I can participate				
at no charge to me.				
Signature	Date			

January 17, 2008

Georgia Institute of Technology Occupational Health Program Hepatitis B Vaccination Acceptance or Declination Form (This form will be kept on file in Environmental Health & Safety).								
Name	Name							
Last Middle	First							
Work	Home	Employee						
Phone	Phone	ID Number						
Email		Department						
Date of Birth		Supervisor						
 CONSENT TO BE VACCINATED I have read the information about the hepatitis B virus and hepatitis B vaccination. I have had an opportunity to ask questions and understand the benefits and risks of hepatitis B vaccination. However, as with all medical treatment, there is no guarantee that I will become immune or that I will not experience an adverse side effect from the vaccine. I request that the vaccination be given to me. I understand that you will not be charged for the vaccine or vaccination series. 								
Signature	D	Pate						
	VACCINATED OR IMMUNE							
☐ I have already received the	hepatitis B vaccine. Date of vacci	nation:						
Vaccination is contraindicat	ed for medical reasons.							
Signature		Date						
HEPATITIS B VACCINATION DECLINATION The following statement of declination of hepatitis B vaccination must be signed if you choose not to accept the vaccine. You must have read, and understand, the guidance provided regarding hepatitis B, hepatitis B vaccination, the efficacy, safety, method of administration, and benefits of vaccination, and that the vaccine and vaccination are provided free of charge to you. This declination statement is not a waiver; you can request and receive the hepatitis B vaccination at a later date if you remain occupationally at risk for hepatitis B. I understand that due to my occupational exposure to blood or other potentially infectious materials I may be at risk of acquiring hepatitis B virus (HBV) infection. I have been given the opportunity to be vaccinated with hepatitis B vaccine, at no charge to me; however, I decline hepatitis B vaccination at this time. I understand that by declining this vaccine I continue to be at risk of acquiring hepatitis B, a serious disease. If, in the future I continue to have occupational exposure to blood or other potentially infectious								
hepatitis B vaccine, I can receive Signature	the vaccination series at no char	ge to me. Date						

Hepatitis B Vaccine Information

What are the dosages and schedules for hepatitis B vaccines?

The vaccination schedule most often used for adults and children has been three intramuscular injections, the second and third administered 1 and 6 months after the first. Recombivax HB® has been approved as a two dose schedule for aged 11-15 years. Engerix-B® has also been approved as a four dose accelerated schedule.

How long does hepatitis B vaccine protect you?

Recent studies indicate that immunologic memory remains intact for at least 23 years and confers protection against clinical illness and chronic HBV infection, even though anti-HBs levels might become low or decline below detectable levels.

What should be done if there is an interruption between doses of hepatitis B vaccine?

If the vaccination series is interrupted after the first dose, the second dose should be administered as soon as possible. The second and third doses should be separated by an interval of at least 2 months. If only the third dose is delayed, it should be administered when convenient.

Is it harmful to have an extra dose(s) of hepatitis B vaccine or to repeat the entire hepatitis B vaccine series if you have forgotten whether or not you had the vaccine or do not have written documentation?

No. If necessary, getting extra doses of hepatitis B vaccine is not harmful.

Can hepatitis B vaccine be given after exposure to HBV?

Yes. After a person has been exposed to HBV, appropriate treatment, given in an appropriate time frame, can effectively prevent infection. The mainstay of <u>post</u> <u>exposure immunoprophylaxis</u> is hepatitis B vaccine, but in some settings the addition of HBIG will provide some increase in protection.

Who should get post-vaccination testing?

Testing for immunity is advised only for persons whose subsequent clinical management depends on knowledge of their immune status (e.g., infants born to HBsAg-positive mothers, immune compromised persons, healthcare workers, and sex partners of persons with chronic HBV infection).

When should post-vaccination testing be done?

When necessary, post-vaccination testing, using the anti-HBs test, should be performed 1 to 2 months after completion of the vaccine series – EXCEPT for post-vaccination testing of infants born to HBsAg-positive mothers. Testing of these infants should be performed 3 to 9 months after the completion of the vaccination series.

Are booster doses of hepatitis B vaccine needed routinely?

No, booster doses of hepatitis B vaccine are not recommended routinely for persons who are not immune compromised. Data show that vaccine-induced anti-HBs levels might decline over time; however, immune memory remains intact

indefinitely following immunization. Immune competent people with declining antibody levels are still protected against clinical illness and chronic disease.

Can hepatitis B vaccine be given during pregnancy or when breastfeeding?

Yes, neither pregnancy nor breastfeeding should be considered a contraindication to vaccination of women. On the basis of limited experience, there is no apparent risk of adverse effects to developing fetuses when hepatitis B vaccine is administered to pregnant women. The vaccine contains noninfectious HBsAg particles and should cause no risk to the fetus. HBV infection affecting a pregnant woman might result in severe disease for the mother and chronic HBV infection for the newborn.

Can hepatitis B vaccine be given to immune compromised people? (e.g., people on hemodialysis or people with AIDS)

Yes, however larger vaccine doses or an increased number of doses are required to induce protective antibody in a high proportion of hemodialysis patients and might also be necessary for other immune compromised people (e.g., those who take immunosuppressive drugs or who have AIDS). For immune compromised people, it is important that post vaccination testing, using the anti-HBs test, be done 1-2 months after the last dose of vaccine to check that the vaccine worked. In addition, immune compromised people need periodic testing and possibly booster doses of hepatitis B vaccine to assure that anti-HBs is still adequate.

Who should not receive the vaccine?

A serious allergic reaction to a prior dose of hepatitis B vaccine or a vaccine component is a contraindication to further doses of hepatitis b vaccine. The recombinant vaccines that are licensed for use in the United States are synthesized by Saccharomyces cerevisiae (common bakers' yeast), into which a plasmid containing the gene for HBsAg has been inserted. Purified HBsAg is obtained by lysing the yeast cells and separating HBsAg from the yeast components by biochemical and biophysical techniques. Persons allergic to yeast should not be vaccinated with vaccines containing yeast.

Reference: Centers for Disease Control and Prevention, September 2007 http://www.cdc.gov/ncidod/diseases/hepatitis/b/faqb.htm#vaccine Forms 4– Georgia Tech Select Agent Forms

Select Agent Access

The following individuals have been granted access to the locked freezers,
refrigerators, cabinets, and other containers where stocks of select agents are
stored.Authorized PersonAuthorized AccessAuthorized by:

Select Agent Log

							-	,					
For													
101	_	_	-	_	_	_	_	_	_	_	_	_	_

Date	Amount	Action	 Disposal	Signature

Forms 5 – Laboratory Inspection Forms

Georgia Tech Laboratory Self-Inspection Checklist

Fill out the following sections answering with yes, no, or not applicable. The last section is to document particular issues that might arise in the laboratory. These may change from month to month or stay relatively constant. This form is to help laboratories determine areas that need attention between EHS inspections. These are not mandatory but if you do choose to participate please sign the bottom of the form and send a copy of the inspection to EHS at mail code 0465.

Personal Protective Equipment			
1. Lab Coats/Protective Clothing worn while working in laboratory?	Y	N	N/A
2. Eye/Face protection used for potential splashes or sprays when outside the BSC?	Y	N	N/A
3. Gloves worn when hands may contact potentially infectious materials, contaminated surfaces, or equipment?	Y	N	N/A

Restricted and Pathogenic Agents			
1. Does the laboratory possess any restricted or pathogenic agents? Specify:	Y	Ν	N/A
2. Are doors lockable for facilities that house restricted agents (as defined in 42 CFR 73)	Y	N	N/A
3. Are the agents kept under lock and key? Is access to the key limited?	Y	N	N/A
4. Does the laboratory have limited access to all non-personnel?	Y	Ν	N/A

Safe Practices			
2. Access to laboratory is limited when experiments are in progress?	Y	Ν	N/A
3. Does hand washing occur on a regular basis and prior to leaving the lab?	Y	N	N/A
4. Is food is stored outside the work area in designated cabinets or refrigerators? Where?	Y	N	N/A
5. Are all experiments that may create an aerosol or splashing conducted in a BSC or fume hood?	Y	N	N/A
6. Are exposed work surfaces decontaminated at the end of the day and after any spill or splash? What disinfectant is used?	Y	N	N/A
7. Are papers that cover bench tops changed? How often?	Y	Ν	N/A
8. All cultures, stocks, and other regulated wastes are sterilized before disposal by an approved sterilization method such as autoclaving.	Y	N	N/A
10. Is appropriate clothing been worn by lab workers (i.e. no	Y	Ν	N/A

shorts, open-toed shoes)?		

Training/Proficiency			
1. Bloodborne Pathogens Training is required for all staff members that are potentially exposed to blood or bodily fluid. Have all lab workers had this training?	Y	N	N/A
2. Have workers been trained in general biosafety practices? By whom?	Y	Ν	N/A
2. Are proficiency levels of lab workers checked?	Y	Ν	N/A

Warning Signs			
1. Have proper biohazard signs been posted on all outside doors to work areas?	Y	Ν	N/ A
2. Does lab equipment have proper biohazard signage? This includes refrigerator, incubators, cold rooms, freezers, storage cabinets, and biosafety cabinets.	Y	N	N/ A
3. Other:	Y	N	N/ A

Biological Waste Disposal			
1. Are sharps disposed into properly labeled sharps containers? (Date and PI listed)	Y	Ν	N/A
	V	NI	
2. Are sharps containers no more than ³ / ₄ full?	Y	Ν	N/A
3. Are there red bags for biological waste disposal? (Date & Pl		Ν	N/A
listed)			
4. Are liquid biological waste autoclaved? disinfected?	Y	Ν	N/A
5. Are there pathological waste procedures in place?	Y	Ν	N/A
6. Does this lab use an autoclave? Specify location.	Y	Ν	N/A
8. Is bleach available for disinfection?		Ν	N/A
9. Are unpreserved or preserved animals double bagged and	Y	Ν	N/A
refrigerated/frozen until pick up?			

Emergency Procedures			
1 Are there disinfectant/absorbent materials available for spills?	Y	Ν	N/A
2. Are emergency phone numbers easily accessible?	Y	Ν	N/A
3. Does the laboratory have specific written emergency	Y	Ν	N/A
procedures in place? Where is the information posted?			
4. Does the lab have the Institute Biosafety Manual?	Y	Ν	N/A
5. Does the lab have the "Policies & Procedures for the Use of	Y	Ν	N/A
Recombinant DNA Materials"?			

Issues Specific to Your Laboratory			
	Y	Ν	N/A
	Y	Ν	N/A
	Y	N	N/A
	Y	N	N/A
	Y	N	N/A
	Y	Ν	N/A
	Y	Ν	N/A
	Y	Ν	N/A

Printed name:_____ Signature:_____

Date:_____

Georgia Institute of Technology Biosafety Laboratory Inspection Checklist

Investigator Inform	ation
Principal Investigator:	
Department:	
Committee Approvals:	
Phone Number:	
Email:	
Laboratory Manager/Contact Other than PI:	

Laboratory Infor	mation		
Location (s):			Phone:
Location (s):			Phone:
Emergency			Emergency Phone #:
Contact:			
Post Docs:	Technicians:	Grad Stu	dents:
Undergrads:	Interns:	M.D.	

Facilities			
1. Hand Sink available?	Y	Ν	N/A
2. Soap and Paper towels available at the hand sink?	Y	Ν	N/A
2. Laboratory floors easily cleaned? Carpets and rugs are inappropriate	Y	N	N/A
3. Bench tops easily disinfected with smooth surfaces?			N/A
4. Laboratory furniture is capable of supporting anticipated loading and uses. Chairs covered with an easily cleaned (non-fabric) material?	Y	N	N/A
5. Eyewash available and what is the last inspection date?	Y	Ν	N/A
6. Are the Eyewashes and safety showers blocked?	Y	Ν	N/A
7. Are there any processes or equipment that uses large amounts of water at one time? Continuously?	Y	Ν	N/A

Equipment			
1. Biological Safety Cabinets in use?	Y	N	N/A

(i) Class:	Make:	Model:	Serial #:			
Certifier:		Date Last C	Certified:			
(ii) Class:	Make:	Model:	Serial #:			
Certifier:	Date Last Certified:					
(iii) Class:	Make:	Model:	Serial #:			
Certifier:	Date Last Certified:					
2. Clean air ben	ches/laminar flow h	loods in use?		Y	Ν	N/A
Make:		Model:				
3. BSC located away from doors and heavily traveled areas so as to maintain cabinet's airflow parameters for containment?				Y	N	N/A

Personal Protective Equipment			
 Lab Coats/Protective Clothing worn while working in laboratory? 	Y	N	N/A
2. Eye/Face protection used for potential splashes or sprays when outside the BSC?	Y	N	N/A
3. Gloves worn when hands contact biologicals materials, contaminated surfaces, or equipment?	Y	N	N/A
4. Other:	Y	N	N/A

Restricted and Pathogenic Agents			
1. Does the laboratory possess any restricted or pathogenic agents? Specify:	Y	N	N/A
2. Are doors lockable for facilities that house restricted agents (as defined in 42 CFR 73)	Y	N	N/A
3. Are the agents kept under lock and key? Is access to the key limited?	Y	N	N/A
4. Does the laboratory have limited access to all non-personnel?		Ν	N/A
5. Does the laboratory use the inventory log for restricted or pathogenic agents? (review log)	Y	Ν	N/A

Safe Practices			
1. Does Facilities Custodial Service staffs enter your laboratory to remove trash and/or clean?	Y	N	N/A
2. Access to laboratory is limited when experiments are in progress?	Y	Ν	N/A
3. Does the laboratory use mechanical pipettes instead of mouth pipetting?	Y	Ν	N/A
3. What are the standard hand washing guidelines?	Y	Ν	N/A
4. Is food stored outside the work area in designated cabinets or refrigerators? Where?	Y	N	N/A
5. Are all experiments that may create an aerosol or splashing conducted in a BSC?	Y	N	N/A
6. Are exposed work surfaces decontaminated?	Y	Ν	N/A
7. When are surfaces decontaminated?			N/A
8. What is used to decontaminate surfaces?	Y	Ν	N/S
7. Are papers that cover bench tops changed? How often?			N/A
9. Are materials to be transported outside of the laboratory are done so in a leak proof container? (Discuss procedure)	Y	N	N/A
10. Is the laboratory using the lab self-check list from the latest edition of the Biosafety Manual	Y	N	N/A
10. Is appropriate clothing been worn by lab workers?	Y	Ν	N/A

Training			
1. General Biosafety is required for all staff members that work with biological materials. Has all staff attended? (View Certificates, if available)	Y	N	N/A
2. Bloodborne pathogens training are required of those that work with any human derived material. Has the laboratory staff taken this training?	Y	N	N/A
2. Have workers been trained in laboratory specific biosafety practices? By Who?	Y	Ν	N/A
3. How is the proficiency levels of lab workers checked?			N/A
4. Are the laboratory members enrolled in the Occupational Health Program?	Y	Ν	N/A
5. Have all members of the laboratory completed the Biosafety Manual signature page? (Review all available)	Y	Ν	N/A

Warning Signs			
1. Have proper biohazard signs been posted on all outside doors to work areas?	Y	N	N/A
2. Does lab equipment have proper biohazard signage? This includes refrigerators, incubators, cold rooms, freezers, storage	Y	Ν	N/A

cabinets, and biosafety cabinets.			
3. Other:	Y	N	N/A

Biological Waste Disposal			
1. Are sharps disposed into properly labeled sharps containers? (Date and PI listed)	Y	N	N/A
2. Are sharps containers no more than ³ / ₄ full?	Y	N	N/A
3. Are there red bags for biological waste disposal? (Date & Pl listed)	Y	N	N/A
4. Are liquid biological waste autoclaved? disinfected?	Y	Ν	N/A
5. Does the laboratory use an autoclave to sterilize solid biological waste?	Y	N	N/A
6. Where is the autoclave located and has it recently been reviewed by EHS?	Y	N	N/A
7. Are the autoclave records for waste available?	Y	Ν	N/A
9. Are unpreserved or preserved animals double bagged and refrigerated/frozen until pick up?	Y	N	N/A

Emergency Procedures			
1 Are there disinfectant/absorbent materials available for spills?	Y	N	N/A
2. Is bleach available for disinfection of biological spills?	Y	N	N/A
2. Are emergency phone numbers easily accessible?	Y	N	N/A
3. Does the laboratory have specific written emergency procedures in place? Where is the information posted?	Y	N	N/A
3. Does the lab have the Institute Biosafety Manual?	Y	N	N/A
5. Does the lab have the "Policies & Procedures for the Use of Recombinant DNA Materials"?	Y	N	N/A

Forms 6—Biological Shipment Form



Biological Shipping Request Form

MTAs, Export Reviews, Exportation/importation permits and any needed customs forms are the responsibility of the shipper. The shipper must also confirm with the recipient that the package is in route.

Call the Biosafety Officer at 404-894-6120 or the Assistant Biosafety Officer at 404-894-6119 to schedule a time to deliver the package to the Environmental Health and Safety office.

Shippers Information:

Name:	Department:
PI:	Phone Number:
Email:	Date to reach Destination:
People Soft Number:	Document ID Number:
Destination Information:	
Contact:	Company name:
Address:	
Cit/State/Zip Code/Country (if outside	
	·
Phone Number:	Email:
Package Details:	
Material to be shipped:	
Amount:gmg	
Number of containers to be shipped: _	
Physical State: Solid	
Temperature Requirements:	
Chemicals in the sample: Yes No	
Radioactive Materials: Yes No	
Genetically modified:	
Purpose of Shipment: Diagnosis	
Infectious to: Humans Animals	
CDC/ USDA permit required: Yes	
Exotic: Yes No	-

Shipping Services: All packages go by Fed Ex if possible. All ship times are approximate. Domestic:

- □ First Overnight (by 8 or 8:30 a.m.)
- Priority overnight (by 10:30 a.m.)
- □ Standard overnight (by 3 p.m.)
- Fed Ex 2-day (2 days by 4:30 p.m.)
- □ Fed Ex Express Service Saver (3 days by 4:30 p.m.)
- Ground (1-5 business days Allow one day for pick-up)

International:

- □ International Priority (1-3 days)
- □ International Economy (2-5 days)
- □ International First (2 days to Europe)

Declared Shipment value (US\$): _____

I certify that all the information provided on this form is true and accurate. I am aware that there are substantial penalties and fines associated with misrepresentation of the information associated with the shipment of hazardous materials. Signature: _____ Date: _____ Forms 7—Material Transfer Agreement Forms

Material Transfer Initiation Form-Georgia Tech Research Corporation

OUTGOING

Complete form and send to: <u>mta@gtrc.gatech.edu</u> Questions? Please call (404) 894-6940

Georgia 1	Tech P	r <mark>ovider</mark>	Information
-----------	--------	-----------------------	-------------

Principal Investigator:	 	
Department/School:	 	
Mail Code:	 	
Phone:	 	
Email:	 	
Admin. Email:		

Material Information

- 1. Name/Description of Material:
- 2. Has the Material been shipped before?
 □ YES □ NO
 If YES, to whom, when, and what MTA ID (if known)?
- 3. Please provide a concise statement of work for Recipients' use of the Material:

4. Is the Material associated with an invention already disclosed to the

 □ YES
 □ NO
 Office of Innovation Commercialization and Translational Research?
 If YES, please provide the (IC)³ ID: ______

- 5. If NO, are there other reasons why you believe an MTA is necessary? □ YES □ NO
- 6. Please list all funding sources and OSP Project Numbers for the research in which the Material was created:

Sponsor:	Project	No.:	PeopleSoft No.:	
----------	---------	------	-----------------	--

Sponsor:	Project No.:	Peor	pleSoft No.:	
Sponsor.	110jeee110ii		220010101011	

- 7. Was the Material (or any part of the Material) created by or purchased from
 □ YES □ NO
 a third party, or generated in a lab other than your current facility at GIT?
- 8. Will the Material be shipped outside of the United States?
 - \Box YES \Box NO

If YES, please visit

http://www.export.gatech.edu/forms/MTA EXPORT CONTROL REVIEW FORM.doc

- and complete the form for material transfers.
- 9. Is the Material human embryonic stem cells? □ YES □ NO

Recipient Information

Organization:	
Technical Contact:	
Email:	
Administrative Contact:	
Email:	

Principal Investigator Certification:

I certify that the information I have provided is true and accurate; I will comply with any terms or conditions of any Material Transfer Agreement that may be executed.

Signature of Georgia Tech Principal Investigator

Date

All shipments are handled through Environmental Health & Safety. Please contact EHS for packaging and shipment of the approved materials.

Material Transfer Initiation Form-Georgia Tech Research Corporation

INCOMING

Complete form and send to: <u>mta@gtrc.gatech.edu</u> Questions? Please call (404) 894-6940

Georgia	Tech	Recipient	Information
---------	------	-----------	-------------

Principal Investigator:		
Department/School:		
Mail Code:		
Phone:	 	
Email:	 	
Admin. Email:	 	

Material Information

- 1. Name/Description of Material:
- 2. Please provide us a concise statement of work for your use of the Material (requirement of most third-party MTAs):

	If NO, skip to	Ouestion 8		
	\Box YES	\Box NO		
3.	Does the Provider require a Material Transfer Agreement?			

- 4. Will the Material be used in research with any GTRC IP? □ YES □ NO
- 5. Will the Material be used with any materials you have received or will receive from any other institution, corporation, or business entity?
 □ YES □ NO
- 7. Please list all funding sources and OSP Project Numbers for the research in which the Material will be used.

Sponsor:		Project No.:		PeopleSoft No.:	
----------	--	--------------	--	-----------------	--

Sponsor: _____ Project No.: _____ PeopleSoft No.: _____

- 8. Is the Material human embryonic stem cells?
 □ YES □ NO
- 9. Will the Material be used in animal or human subjects? □ YES □ NO
- 10. Is the Material recombinant DNA? \Box **YES** \Box **NO**
- 11. Please provide all relevant protocols:
 - IRB Protocol No.:

IBC Registration No. (rDNA):

IACUC Protocol No: BMSC Registration No.:

Provider Information

Organization:	
Technical Contact:	
Email:	
Administrative Contact:	
Email:	

Principal Investigator Certification:

I certify that the information I have provided is true and accurate; I will comply with any terms or conditions of any Material Transfer Agreement that may be executed.

Signature of Georgia Tech Principal Investigator

Date