ATLANTA VA MEDICAL CENTER

RESEARCH SERVICE LINE
SAFETY AND SECURITY MANUAL
2018 - 2019

Research Service Safety and Security Plan

Approved by SRS on December 11, 2018

C. Michael Hart, MD — **Date**
ACOS, Research Service Line

December 12, 2018

William Shafer, Ph.D. — **Date**
Chair, SRS Committee

TABLE OF CONTENTS

SECTION I

RESEARCH SERVICE SAFETY PROGRAM

RESEARCH SERVICE SAFETY PROGRAM

1. **PURPOSE:** To establish a safety program within Research Service Line that will provide for and ensure that every patient, visitor, and employee is provided an environment where safety and health hazards are minimized. The Research Service Safety Manual delineates mandatory procedures with respect to handling potential hazards encountered in these settings, including, but not limited to:
    a. Biohazards
    b. Pathogens and/or etiologic agents corresponding to Biosafety Levels 2-3.
    c. Organisms and viruses containing recombinant DNA molecules.
    d. Chemical Hazards
    e. Physical Hazards
    f. Radiation Hazards

This manual covers only safety issues unique to research; it is not intended to replace general safety policy applicable to all Department of Veterans Affairs (VA) employees, whether or not involved with research.

The biosafety standards in the following documents were considered in the development of this biosafety plan:

a. Biosafety in Microbiological and Biomedical Laboratories (BMBL), including all appendices except Appendix F.
b. 29 CFR part 1910.1450, Occupational Exposure to Hazardous Chemicals in Laboratories
c. 29 CFR part 1910.1200, Hazard Communication
d. NIH Guidelines for Research Involving Recombinant DNA Molecules, (NIH Guidelines).
e. Blood Borne Pathogen Standards

2. **POLICY:** Research Service will strive to eliminate accidents and injuries within the service and the facility by establishing an active Subcommittee on Research Safety (SRS). The SRS is a subcommittee of the Research and Development Committee (RDC) and will assist the medical center and the research program in defining the responsibilities of management and employees, providing training, monitoring performance, providing advice on protective equipment, inspecting area, investigating and following up on any accident, and evaluating performance of biohazard, chemical and radioisotope controls. The Research Service has also established an Institutional Biosafety Committee (IBC) to review rDNA work, as needed.

3. DEFINITIONS:

a. **Biohazards-** Biohazards include, but are not limited to, the following:
    i. Pathogens and/or etiologic agents, human and non-human primate tissues including blood and body secretions, and human cell lines corresponding to BSL 1-4 (see subpar. 6a);
    ii. Toxins produced by microbial organisms (see Centers for Disease Control and Prevention (CDC)-National Institutes of Health (NIH). Biosafety in Microbiological and Biomedical Laboratories 5th Edition Section VIII-G , and Federal Regulation, Title 42 CFR 73);
    iii. Poisonous, toxic, parasitic and venomous animals or plants;
    iv. Recombinant DNA molecules NIH Guidelines for Research Involving Recombinant DNA Molecules (see subpar. 6g.);
    v. Select agents, as specified in Federal Regulation, Title 42 CFR 73 and 7 CFR 331 (see reference listed at paragraph 5b);
    vi. Animals experimentally or naturally exposed to any of the above (see CDC-NIH. Biosafety in Microbiological and Biomedical Laboratories 5th Edition Section V).

b. **CHEMICAL HAZARDS**- Include any substance or mixture of substances with properties capable of producing adverse effects on the health and/or safety of humans. Chemical hazards categories include, but are not limited to the following:
   i. Corrosives;
   ii. Toxic substances (poisons, irritants, asphyxiates);
   iii. Sensitizers;
   iv. Carcinogens, mutagens and/or Teratogens;
   v. Flammables;
   vi. Explosives.

c. **ENVIRONMENTAL PHYSICAL HAZARDS**- Include, but are not limited to the following (see 6c(4)):
   i. Ionizing and non-ionizing radiation (see Radiation Safety Plan);
   ii. Noise;
   iii. Vibration;
   iv. Extremes of temperature and pressure;
   v. Compressed Gases
   vi. Cryogenic Liquids
   vii. Explosive hazards;
   viii. Electrical hazards; and
   ix. Mechanical hazards.

4. SCOPE:

a. The Safety Program scope covers all areas of Research including the Clinical Studies Center, Laboratories, Heath Services R&D and Rehab R&D. The SRS reports directly to the RDC, which is responsible for the overall Research Program. The scope also includes:

   i. Bloodborne Pathogens- The risk of exposure to Bloodborne pathogens will be minimized in the research setting by ensuring that all research personnel are aware of, and utilize, Standard Precautions in the handling of biological fluids of any type according to the specifications of the Bloodborne Pathogens Standard. Similarly, the risk of exposure to airborne pathogens such as Mycobacterium tuberculosis must be minimized and strict adherence to all applicable federal statutes, regulations, policies and guidelines must be rigorously upheld.
   ii. Recombinant DNA-
      A. VA investigators planning to conduct recombinant DNA research must comply with the current NIH Guidelines for Research Involving Recombinant DNA Molecules regardless of the source of research funding. It is the responsibility of the individual principal investigators to ensure that all laboratory personnel utilizing recombinant DNA technology have received appropriate specified training related to how to safely handle these molecules in the laboratory environment of the Atlanta VA Medical Center. Documentation of training of specific personnel involved in the cloning processes of particular genes of interest must be made available for review when requested by the research biosafety office (See 6, g.). This information is potentially necessary to track clones involved in accidents, incidents and/or exposures.
      B. All funded and unfunded projects and proposals must be reviewed and approved according to the procedures described in the most current NIH Guidelines for Research Involving Recombinant DNA Molecules (http://oba.od.nih.gov/rdna/nih_guidelines_oba.html). Local IBC), SRS and R&D committee approvals are also required.
      C. The Principal Investigator must report project progress and status annually according to the procedures

described in the NIH Guidelines for Research Involving Recombinant DNA.

b. The provisions of this program apply to all VA laboratories located and personnel working within the Atlanta VA Medical Centers and its affiliated VA facilities, including leased space, and VA laboratories located in approved off-site facilities (Emory University).

c. All personnel are required to take Research Safety Training prior to beginning work assignments. Additionally, each year after the initial new employee training, laboratory personnel are required to complete annual biosafety refresher training modules. Documentation of the employee training are maintained in the research office.

5. RESPONSIBILITIES AND PROCEDURES:

a. **Medical Center Director** The Medical Center Director is responsible for:
   i. Ensuring that the research safety program is staffed adequately and making available resources to maintain full compliance with all applicable regulations and standards of safety.
   ii. Ensuring that all Research personnel are included in the facility Occupational Safety and Health program and that research space is included in annual workplace inspections.
   iii. Ensuring the resolution of any facilities-related deficiencies identified in inspections.
   iv. Providing engineering support in conducting ventilation maintenance and validation of required specifications.
   v. Providing technical assistance of facility safety and health professionals as needed.
   vi. In cooperation with the Associate Chief of Staff (ACOS) for Research and Development (R&D) ensuring that measures for the security of the research laboratories and surrounding space will be developed (see Research Security Plan).
   vii. Providing adequate administrative support for the SRS, including space sufficient to provide privacy for conducting sensitive duties related to biosafety, and the personnel to support the review and record-keeping functions of SRS, and the timely preparation of investigator correspondence and other documents.

b. **Associate Chief of Staff, Research Service (ACOS R&D)**
   i. Ensuring that safety related communications from the Chief Research and Development Officer (CRADO) are disseminated to appropriate personnel in a timely manner after receipt.
   ii. Ensuring the responses to safety "holds".
   iii. Ensuring that research activity ceases until a particular "hold" is lifted.
   iv. Appoint a Research Biosafety Officer.
   v. Continuously develops and evaluates performance standards of the research safety program.
   vi. Act as a referral point in scientific issues.

c. **Director of Research Operations and Administrative Officer, Research Service**
   i. Ensure that all employees are offered appropriate training required by the program (s) and facility.
   ii. Assure that an on-the-job safety training program pertinent to each employee job requirement is developed and implemented.
   iii. Establish and maintain an active, positively reinforced RDC.
   iv. Act on recommendations from the SRS.
   v. Act on recommendations from the Environment of Care Committee.
   vi. Actively promote and support safety and fire prevention programs conducted at the facility.
   vii. Report on safety and fire prevention activities and service accidents at staff meetings.
   viii. Assure that any accident occurring within Research Service is investigated immediately by the appropriate

supervisory person, the CA-1 or CA-2 is completed and forwarded to Human Resource Management Service within 5 workdays of the incident, and the **VAF 2162** is completed and forwarded to Engineering Service within 5 workdays of the incident.

ix. Recruit a Research Biosafety Officer.
x. Take or request corrective action after an accident to ensure that no recurrences of an accident of a similar nature will take place.
xi. Provide appropriate disciplinary action where it is evident that safety and health standards are violated.
xii. Provide light duty or alternative duty for injured employees.
xiii. Ensure follow-up on status of injured employees and provide notification of change of status to the appropriate person.
xiv. Review performance of safety responsibilities of supervisors during annual evaluations.
xv. Ensure that the facility safety manual is maintained, updated, and available to all employees.

d. **Research and Development Committee (RDC)**

i. Establish a SRS that meets the requirements set forth herein section 5.f, and carries out the functions detailed in the following section.
ii. Review all R&D proposals.
iii. Ensuring the SRS review of proposals that involve safety hazards to personnel and/or the environment.
iv. Prior to review of a proposal, ensuring that a complete list of chemicals designated or identified by OSHA and/EPA as "hazardous" has been reviewed and approved by the Research Biosafety Officer.
v. Review and act upon SRS action items and minutes.
vi. Ensure the development and implementation of the Laboratory Chemical Hygiene Plan, and update of this plan on an annual basis.
vii. Provide oversight of compliance of this VHA Handbook by Principal Investigators (PI) conducting research at the facility.
viii. Provide the ACOS R&D and facility safety official information needed to evaluate the occupational safety and health program for the Research Service.
ix. Ensuring the development and implementation of safety protocols by the Principal Investigator (PI) for individual research projects as needed.
x. Assure that the Research Office provides support to the SRS to assist in their functions.
xi. Ensuring that the minutes of the SRS meetings are documented correctly and maintained by the Research Office.
xii. Providing the ACOS R&D and facility or Veterans Integrated Service Network (VISN) safety officials with adequate information to evaluate the performance of the R&D safety program.
xiii. Ensuring coordination with other regulatory programs or committees such as the Radiation Safety Officer and/or Radiation Safety Committee.
xiv. Reviewing accident and injury trends reported by SRS. Recommending and ensuring the implementation of corrective action.
xv. Reviewing all citations issued by regulatory agencies and ensuring that prompt corrective actions are taken by appropriate committee members and PI, and coordinating the necessary responses to regulatory agencies.

e. **Research Biosafety Officer (BSO)**

i. Assists in maintaining the highest standards of research safety and manages the research Biosafety program.
ii. Conduct at least an annual inspection of all laboratories (including offsite labs) and reports findings to the SRS. BSO will make every attempt to schedule laboratory audits with faculty members. However, if the faculty member is unavailable or is unresponsive, BSO will proceed with the safety audit. BSO m ay conduct unannounced inspections and accident investigations.

iii. Maintain an updated Master Chemical Inventory and Safety Data Sheets (SDS) inventory.
iv. Trains Research Service employees with regard to all research safety and security related topics prior to personnel beginning their work assignments at the facility.
v. Revises and updates the Research Safety Manual with all its components as needed and ensures is available to all employees.
vi. Reviews and evaluates every accident occurring within the Research Service and makes recommendations to the Director of Research Operations, the Service chief and the SRS to implement and enforce appropriate guidelines to prevent accidents from recurring. Additionally, any accidents that occur at the Atlanta VA Medical Center will be documented.
vii. Provides administration with advice and guidance on safety concerns and issues.
viii. Reports to and updates the Biosafety Office on newly mandated regulations and standards that are required to be implemented at the facility.
ix. Annually evaluates the effectiveness of the laboratory's Chemical Hygiene Plan and making necessary revisions.
x. Acts as liaison between Research Service Line and other services for biosafety matters by being an active member on the Infection Control Committee, Safe Environment, Fire Prevention, Emergency Management Subcommittee, and the Waste Management Committee.
xi. Coordinates the certification of all biological safety cabinets and chemical fume hoods, and verifies that certification is current.
xii. Coordinates all safety related activities in research laboratories including mandatory and non-mandatory training, safety inspections, and accident reporting.
xiii. Assist in laboratory decommissioning and relocation.
xiv. Reviews and annually updates all Research Service Line safety and security plans.
xv. Reviews weekly access logs to all Research limited access areas. Any incidents or discrepancies are reported to the Director of Operations and corrective measures initiated.
xvi. Coordinates security and monitoring system changes and updates.
xvii. Manages Research security/access system.

f. **Subcommittee on Research Safety (SRS)**

i. Members of the SRS are nominated by the ACOS R&D and appointed by the Medical Center Director. The SRS shall comprise no fewer than five members (exclusive of ex-officio members) so that they collectively have expertise in each area of potential biohazards if such research programs are conducted at this institution. Membership should include the following:
   A. The Director of Research Operations (non-voting Ex-Officio).
   B. The Research Biosafety Officer (voting Ex-Officio)
   C. The Facility Radiation Safety Officer and/or alternate
   D. The Facility Safety Officer and/or Industrial Hygienist (one may serve as the alternate for the other)
   E. The Facility Infection Control Officer and/or alternate
   F. The Institutional Veterinarian
   G. Selected Principal Investigators
   H. Selected laboratory technicians
   I. Two members not affiliated with the Institution (the second member would allow constitution of an IBC and is only required when an IBC is in session)
   J. An employee union safety representative or other union designee (non-voting Ex-Officio).
ii. Hold meetings at least quarterly.
iii. Review all research activities involving biological, chemical, physical, and radiation hazards, including use of recombinant DNA, for compliance with all applicable regulations, policies, and guidelines prior to submission to R&D. This includes a review of all VA funded research applications that will be conducted at the VA facility or by VA personnel with VA funding located off-site

A. The review of the Laboratory Annual Self-Inspection Form [LASIF] must include a risk assessment, level of containment, laboratory procedures, practices, training and expertise of personnel involved in the specific research conducted including recombinant DNA research. The LASIF is submitted electronically through the ERRRP website at https://vaww.gateway.research.va.gov/errrp/login.cfm .

B. All research projects involving biological, chemical, physical, and radiation hazards must be approved by SRS and then by the RDC prior to commencement. SRS may review proposed research at convened meetings at which a quorum is present or by designated review. Designated review can only be utilized when a laboratory already has an approved LASIF and the hazard(s) proposed for use are approved as part of the LASIF. In the event of new hazards being introduced, those protocols will be assigned to a convened meeting.

iv. Provide written notification of the results of SRS review to the RDC, the Research Office, and the PI.

v. Annual review of all active research protocols involving biological, chemical, physical, and radiation hazards, including recombinant DNA, regardless of funding status or source. The date of continuing review will be based on the date of SRS approval. Research protocol changes not included in the original application must be documented on a Biosafety Project Modification Form and must be submitted to and reviewed by SRS prior to the implementation of the changes. This is accomplished by the LASIF submission.

vi. Ensure that a completed list of all products containing chemicals designated or identified by OSHA and/or EPA as "hazardous" has been submitted to the BSO for review and approval prior to the submission of a protocol for local review using the Chemical Inventory Form and electronically attached to the annual LASIF (see App. A).

vii. Coordinate follow-up evaluations to ensure that deficiencies cited during inspections are permanently and effectively abated, and report follow-up results to the RDC.

viii. Identify the need and duration for health surveillance of personnel involved in individual research projects; and if appropriate, advising RDC and Occupational Health Practitioner on the need for such surveillance and possible medical treatment. Documentation of this medical surveillance should be maintained and made available for review by the Research Biosafety Office when requested.

ix. Maintaining adequate documentation of all SRS or equivalent subcommittee activities.

x. Review of previous meeting's minutes.

xi. Ensure that all laboratory personnel receive annual research specific training.

xii. Ensure coordination with other regulatory programs, personnel, or committees, such as the Radiation Safety Officer and/or Radiation Safety Committee.

xiii. Ensure the collection of appropriate personnel samples to make employees exposure determinations whenever the proposed use of laboratory chemicals may potentially exceed OSHA Permissible Exposure Limits or Action Levels.

xiv. Ensure the review of investigators reports of all lost-time injuries and all significant adverse environmental events.

xv. Ensure the proper reporting of injury and illness trends to the RDC, as appropriate.

xvi. When appropriate, request the appointment of an ad hoc committee consisting of members with appropriate expertise, to investigate and report on occupational injuries, illnesses, and adverse environmental events.

xvii. Cooperate with appropriate medical center personnel to review the quantity and type of hazardous waste generated by each PI annually.

xviii. Provide technical assistance in the reduction of the quantity of waste and/or recycling programs, where appropriate.

xix. Provide support to the Research BSO as needed.

g. **PI or Laboratory Director**

i. Must submit a completed LASIF to the Research Science Information Office annually. The LASIF must contain a risk assessment for each employee, and the complete Chemical Inventory for each lab, also all

additional supporting documentation such as but not limited to Standard Operating Procedures (SOPs), -80 Freezer Inventories, IBC Registration Form and/or IBC Letter of Approval may also be required.

ii. Ensure that active protocols and new projects have been reviewed by the SRS, regardless of funding status or source;

iii. Identify laboratory specific hazards, and;
   A. Ensure that all personnel receive training specific to the hazard(s) and maintain these records;
   B. Advise laboratory personnel of any potential risks to themselves or the research environment at the same time that risk assessment form is filled out in conjunction with each of the employee;
   C. Establish and enforce standards of practice which minimize employee exposure to biological, chemical, physical, and radiation hazards.

iv. Supervise the performance of the laboratory staff to ensure the correct use of required safety practices and techniques, including personal protective equipment (PPE).

v. Ensure that Biological Safety Cabinets are certified annually.

vi. Report problems and concerns about operation and containment practices and procedures to the BSO, facility Safety Officer, Veterinary Medical Officer (VMO), Radiation Safety Officer, and other appropriate authorities.

vii. Ensure that all accidents are reported to the Occupational Health Office and the facility safety office using appropriate VHA forms, and ensure that any accident occurring within the area of responsibility is investigated immediately, the CA-1 or CA-2 is filled through the ASIST system and submitted to Human Resource Management Service within 3 workdays of the occurrence, and the **VAF 2162** is completed and submitted to Engineering Service within 5 workdays of the occurrence.

viii. Take corrective action after an accident to prevent recurrence.

ix. Secure approval of the RDC through the SRS for any significant changes made in the original research plan.

x. Actively promote and support safety and fire prevention programs conducted at the facility.

xi. Ensure all items are not stored within 18 inches of sprinkler heads in all areas of the research facility.

xii. Coordinate with appropriate safety staff such as the BSO and Radiation Safety Officer for removal or disposal of all chemicals, biological agents, radioisotopes, and waste generated by these materials.

xiii. Notify all pertinent personnel prior to departure from the laboratory.

xiv. Notify all pertinent personnel prior to relocating the research laboratory space.

xv. Ensure that a copy of the laboratory's Chemical Hygiene Plan is readily available to all employees in their work area, that employees have been trained in the contents of the Plan and that all provisions of the Plan are implemented in all laboratories under the PI's supervision.

xvi. Maintain employee exposure to hazardous chemicals in laboratory activities at the lowest possible levels. At no time may employee exposure to chemicals exceed the Permissible Exposure Limits established by OSHA. (http://www.osha.gov/SLTC/pel/)

xvii. Maintain an up-to-date inventory of all hazardous chemicals located in the laboratory using the Chemical Inventory Form. This list must be updated every six (6) months or every time a new chemical is received in the laboratory.

xviii. Ensure that all laboratory personnel know the location of this inventory.

xix. Provide this inventory to the facility BSO every time it is updated.

xx. Manage all biological and chemical waste in accordance with Federal, state, and local regulations and all VA, VHA, and facility policies.

xxi. Seek technical assistance when needed to ensure proper waste management.

xxii. Implement waste reduction techniques, where appropriate.

xxiii. Investigate and correct deficiencies cited during all inspections of work areas. Submit a written abatement plan for all deficiencies cited during inspections to SRS within the specified time limits.

xxiv. Identify physical hazards and unsafe practices in the area of responsibility through continuous inspections.

xxv. Report unsafe conditions and practices to the Service Chief and initiate corrective action.

xxvi. Submit electronic work orders to correct non-emergent identified deficiencies; contact work order desk at x 206104 to correct emergency deficiencies immediately.

xxvii. Provide personal protective equipment (PPE) as needed and ensure that employees are trained in the use, maintenance, and wearing of PPE; ensure that employees use PPE when required.
xxviii. Review performance of safety responsibilities of employees during annual evaluations.
xxix. Must not conduct, unless approved by the HHS Secretary, experiments using recombinant DNA that involve the deliberate transfer of a drug resistance trait to select agents that are not known to acquire that trait naturally, if such acquisition could compromise the use of the drug to control disease agents in human, veterinary medicine or agriculture.
xxx. Must not conduct, unless approved by the HHS Secretary, experiments involving the deliberate formation of recombinant DNA containing genes for the biosynthesis of select toxins or vertebrates at a LD 50 <100ng/kg

h. **Employees**
i. Comply with safety and security rules and regulations for safe job performance and fire prevention.
ii. Use and maintain PPE when required and provided.
iii. Promptly report all accidents to the PI and the BSO no matter how small.
iv. Promptly notify supervisor of unsafe or unhealthful conditions in the work place.
v. Attend all scheduled training sessions.
vi. Participate in safety promotions at the facility and service levels as directed by supervisor.
vii. Know the fire drill and emergency plans for the work area, including knowledge of location and use of fire extinguishers, manual pull stations, window keys where applicable, fire and smoke barriers, fire plans, and all emergency apparatus.
viii. Know the locations and proper use of emergency eyewash and shower stations within the research areas.
ix. Know the location of the facility's Chemical Hygiene Plan and produce it when requested.
x. Read, understand and follow all provisions and plans in this manual.
xi. Adhere to the Medical Center's Smoking policy.

6. REFERENCES:

a. CDC-NIH. Biosafety in Microbiological and Biomedical Laboratories 5th Edition. CDC-NIH, Washington, DC, Revised 2009.
b. Title 42 CFR Part73, Possession, Use and Transfer of Select Agents and Toxins; Interim Final Rule.
c. Title 29 CFR Part 1910, Occupational Safety and Health Standards.
i. Title 29 CFR Part 1910.38, Employee Emergency Plans and Fire Prevention Plans.
ii. Title 29 CFR Part 1910.134, Respiratory Protection.
iii. Title 29 CFR Part 1910.139, Respiratory Protection for m. Tuberculosis.
iv. Title 29 CFR Part 1910.269, Electric Power Generation, Transmission, and Distribution.
v. Title 29 CFR Part 1910.1000, Subpart Z, Toxic and Hazardous Substances.
vi. Title 29 CFR Part 1910.1020, Access to Employee Exposure and Medical Records.
vii. Title 29 CFR Part 1910.1030, Bloodborne Pathogens.
viii. Title 29 CFR Part 1910.1200, Hazard Communication.
ix. Title 29 CFR Part 1910.1450, Occupational Exposure to Hazardous Chemicals in Laboratories.
d. Title 10 CFR Chapter 1, Nuclear Regulatory Commission, Parts 0-199.
i. Title 10 CFR Part 19, Notices, Instructions and Reports to Workers; Inspections and Investigations.
ii. Title 10 CFR Part 20, Standards for Protection Against Radiation.
iii. Title 10 CFR Part 35, Medical Use of Byproduct Material.
e. Title 40 CFR Chapter 1, Environmental Protection Agency.
i. Title 40 CFR Part 260, Hazardous Waste Management System: General.
ii. Title 40 CFR Part 261, Identification and Listing of Hazardous Waste.
iii. Title 40 CFR Part 262, Standards Applicable to Generators of Hazardous Waste.
f. "Radiologic Protection in Biomedical Research," Annals of the ICRP, Vol. 22, No., 3, 1991.

g. “National Institutes of Health Guidelines for Research Involving DNA Molecules,” NIH Guidelines. National Institutes of Health, Bethesda, MD, May 11, 1999. http://oba.od.nih.gov/oba/index.html.
h. VHA Directive 1105.1, Management of Radioactive Materials.
i. VHA Handbook 1105.1, Procedures for Management of Radioactive Materials.
j. VHA Manual M-1, Part VII, Chapter 14, Waste Management, dated September 19, 1994, or superseding VHA policy provision.
k. VHA Handbook 1200.08
l. VA Directive 7700, Occupational Safety and Health.
m. National Council on Radiation Protection and Measurements reports:
    i. Number 107, Implementation of the Principle of As Low as Reasonably Achievable (ALARA) for Medical and Dental Personnel (Bethesda, MD, 1990), and
    ii. Number 116, Limitation of Exposure to Ionizing Radiation (Bethesda, MD, 1993).
    iii. NCRP 105, Radiation Protection for Medial and Allied Health Personnel (1989).

SUMMARY OF RECOMMENDED BIOSAFETY LEVELS FOR INFECTIOUS AGENTS

Bio-Safety Level (BSL)	Agents	Practices	Safety Equipment (Primary Barriers)	Facilities (Secondary Barriers)
1	Not known to consistently cause disease in healthy adults.	Standard Microbiological Practices	None required	Open bench top sink required
2	Associated with human disease. Hazard: percutaneous injury; ingestion; mucous membrane exposure.	BSL-1 practices plus: a. Limited access. b. Biohazard warning signs. c. "Sharps" precautions. d. Biosafety manual defining any needed waste decontamination or medical surveillance policies.	Primary barriers = Class I or II Biosafety Cabinet (BSC)s or other physical containment devices used for all manipulations of agents that cause splashes or aerosols of infectious materials; Personal Protective Equipment (PPE)s: laboratory coats; gloves; face protection as needed	BSL-1 plus: • Autoclave available
3	Indigenous or exotic agents with potential for aerosol transmission; disease may have serious or lethal consequences.	BSL-2 practices plus: a. Controlled access. b. Decontamination of all waste. c. Decontamination of lab clothing before laundering. d. Baseline serum.	Primary barriers = Class I or II BSCs or other physical containment devices used for all open manipulations of agents; PPEs: protective lab clothing; gloves; respiratory protection as needed	BSL-2 plus: a. Physical separation from access corridors. b. Self-closing, double-door access. c. Exhausted air not recirculated. d. Negative airflow into laboratory.
4	Dangerous and/or exotic agents, which pose high risk of life-threatening disease; aerosol-transmitted lab infections; or related agents with unknown risk of transmission.	BSL-3 practices plus: a. Clothing change before entering. b. Shower on exit. c. All material decontaminated on exit from facility.	Primary barriers = All procedures conducted in Class III BSCs or Class I or II BSCs in combination with full-body; air-supplied, positive pressure personnel suit	BSL-3 plus: a. Separate building or isolated zone. b. Dedicated supply and exhaust, vacuum, and decontamination systems. c. Other requirements outlined in the text.

BIOSAFETY LEVELS FOR ACTIVITIES IN WHICH EXPERIMENTALLY OR NATURALLY INFECTED VERTEBRATE ANIMALS ARE USED

BSL	Agents	Practices	Safety Equipment (Primary Barriers)	Facilities (Secondary Barriers)
1	Not known to consistently cause disease in healthy human adults.	Standard animal care and management practices, including appropriate medical surveillance programs.	As required for normal care of each species.	Standard animal facility: a. No recirculation of exhaust air. b. Directional airflow recommended. c. Hand washing sink recommended.
2	Associated with human disease. Hazard: percutaneous exposure; ingestion; mucous membrane exposure.	Animal Biosafety Level (ABSL)-1 practices plus: a. Limited access. b. Biohazard warning signs. c. "Sharps" precautions. d. Biosafety manual. e. Decontamination of all infectious wastes and of animal cages prior to washing.	ABSL-1 equipment plus primary barriers: Have containment equipment appropriate for animal species; PPEs: laboratory coats, gloves, face and respiratory protection as needed.	ABSL-1 facility plus: a. Autoclave available. b. Hand washing sink available in the animal room. c. Mechanical cage washer used.
3	Indigenous or exotic agents with potential for aerosol transmission; disease may have serious health effects.	ABSL-2 practices plus: a. Controlled access. b. Decontamination of clothing before laundering. c. Cages decontaminated before bedding removed. d. Disinfectant foot bath as needed.	ABSL-2 equipment plus: a. Containment equipment for housing animals and cage dumping activities. b. Class I or II BSCs available for manipulative procedures (inoculation, necropsy) that may create infectious aerosols. PPEs: appropriate respiratory protection	ABSL-2 facility plus: a. Physical separation from access corridors. b. Self-closing, double-door access. c. Sealed penetrations. d. Sealed windows. e. Autoclave available in facility.
4	Dangerous and/or exotic agents that pose high risk of life-threatening disease; aerosol transmission; or related agents with unknown risk of transmission.	ABSL-3 practices plus: a. Entrance through change room where personal clothing is removed and laboratory clothing is put on; shower on exiting. b. All wastes are decontaminated before removal from the facility.	ABSL-3 equipment plus: Maximum containment equipment (i.e., Class III BSC or partial containment equipment in combination with full body, air-supplied positive-pressure personnel suit) used for all procedures and activities	ABSL-3 facility plus: a. Separate building or isolated zone. b. Dedicated supply and exhaust, vacuum, and decontamination systems. c. Other requirements outlined in the text.

Appendix A

Creating a New and/or Editing an Existing Chemical Inventory Online

1) Go to https://vaww.gateway.research.va.gov/errrp/login.cfm
2) Login (for issues with login credentials please contact: errrp@atlaref.org))
3) Click "New Chemical Inventory" blue menu on your left-hand side
4) Select "PI Name" from a drop-down menu
5) For existing inventories, answer "Would you like to copy the last inventory from previous date?" otherwise skip to Step 6
    a) Click "Yes" for a new chemical inventory which will inherit all data from your previous inventory
    b) Click "No" for a blank new chemical inventory
6) Check "Yes, please begin" checkbox to initiate a new chemical inventory
7) Click "Add Chemicals" button to add/edit your chemical inventory
8) On the "Add Approved Chemical" screen enter chemical's name, quantity and unit of measure
9) For chemicals stored in common areas, select "Common room" storage checkbox and select all common rooms that apply, otherwise skip to step 10
10) Click "Submit "button
11) Repeat steps 7-10 until all chemical entries are complete
12) Click "sign this Chemical Inventory" hyperlink at the top of your screen
13) Confirm signature by clicking "Yes, I would like to sign this Chemical Inventory" checkbox. Your new chemical inventory (PDF) is submitted online
14) To access your PDF file, click again on "Chemical Inventories" blue menu on your left hand side
15) Click "View" button next to access your most recent chemical inventory
16) Print out and post hard copies for each lab door(s)

*****HELPFUL INFORMATION*****

1. **Web sites where you can get SDS and chemicals information:**
   http://vaww.ceosh.med.va.gov/ceosh/MSDS.shtml

2. **SDS can also be obtained from the distributors' customer service. It is a requirement that manufacturers provide SDS sheets for every chemical and reagent distributed. Every time you order a new chemical you should request the SDS on your Purchase Order specifying that it be sent directly to your mailing address. Also, the Research Biosafety Officer is working on a master SDS inventory which will be available from above provided web site link.**

3 **Laboratory personnel are responsible for ensuring that all chemicals are properly labeled and stored.**

4. **The Chemical Inventory must contain all chemicals, whether hazardous or not, present in your laboratory.**

5. **PIs and laboratory personnel with access must ensure the proper storage and use of any controlled substances that have been issued under the PIs' responsibilities. This inventory must be secured within a locked container and access to its contents limited and monitored. Additionally, an inventory of the controlled items must be maintained and regularly reconciled.**

6. **Each new chemical addition to your actual inventory requires an update to the laboratory's chemical inventory online. Once submitted, an updated version of your chemical inventory will be available online on the ERRRP site. Chemical Inventory must be updated every 6 months or anytime there is a change into your actual chemical inventory (adding new chemicals, quantities, etc.). See Appendix A for creating new and/or editing existing Chemical Inventory online.**

7. **Print updated chemical inventories on paper and posts it on the outside of your laboratory door. Only the chemical inventory list and the hazardous signs such as radioactive and biohazard signage must be posted on the outside of your laboratory door. To ensure compliance with the safety regulations, any other kind of posters, pictures, articles, or displays should not be posted on the outside of the laboratory doors.**

If there are any questions concerning laboratory procedures and facility requirements regarding chemical inventories, please contact the Research Biosafety Officer at the following contact information.

Ioana St. Amand
Research Biosafety Officer
(404) 321-6111 x20207273 or 1569
VA Medical Center
Atlanta, GA

RADIATION SAFETY

1. The use of radioactive materials within Department of Veterans Affairs (VA) facilities must comply with the statutory and regulatory requirements of the Nuclear Regulatory Commission (NRC) and with Veterans Health Administration (VHA) policies and procedures for the safety and control of such materials. These policies, procedures, and regulations collectively control the receipt, uses, and disposal of radioactive materials in the VHA research programs. The Facility Radiation Safety Officer must be consulted for the specific requirements regarding the receipt, use and disposal of substances that contain radioactive material.

2. X-ray devices and their uses, while generally not subject to regulation in Federal facilities, are nevertheless subject to actual standards of practice and the important recommendations of influential national and international councils and commissions. There may be specific local facility requirements, which are implemented by the Facility Radiation Safety Officer (RSO). The Facility Radiation Safety Committee (RSC) and the RSO are the primary facility resources for ensuring safe and effective uses of ionizing radiation in research and always need to be consulted.

3. While Federal regulation and the weight of authoritative commissions establish upper limits for the permissible radiation dose to workers and the public, one of the most effective tools for education on dosage is the facility specific As Low As Reasonably Achievable (ALARA) programs. This is a mandatory commitment to maintain individual and collective radiation doses as low as reasonably achievable and requires participation of management, safety personnel, and individual research users.

4. REFERENCES

a. VHA Directive 1105.1, Management of Radioactive Materials.

b. Handbook 1105.1, Procedures for Management of Radioactive Materials.

c. Title 10 Code of Federal Regulations (CFR) Chapter 1, Nuclear Regulatory Commission, Parts 0-199.

(1) Title 10 CFR Part 19, Notices, Instructions and Reports to Workers; Inspections, and Investigations.

(2) Title 10 CFR Part 20, Standards for Protection Against Radiation.

(3) Title 10 CFR Part 35, Medical use of Byproduct Material.

SECTION II

Research Service
Laboratory Security Plan

Research Service Laboratory Security Plan

1. **Purpose:** To detail security guidelines for the medical research laboratory areas and maintain a safe and secure environment. This document has established policies to perform the following:
   a. Detail requirements to secure select agents and/or toxins, and other hazardous agents that could possibly pose a threat to the health of personnel, visitors, or the environment.
   b. Documents procedures and policies ensuring the security of physical areas where these potentially hazardous agents are stored and/or used.
   c. Provide a plan to identify possible threats, and ultimately vulnerabilities and risks contributed to these hazardous agents.
   d. Include provision of contractor / visitor hazard awareness training provided for those needing to access Research areas.

The Research Service Laboratory Security Plan must be reviewed at least on an annual basis and after any incident compromising security. Additionally, annual drills are conducted to evaluate the plan's effectiveness.

2. **Background:**
   a. The scope of this Plan includes the physical and organizational controls surrounding the storage and use of hazardous agents and research laboratories. Applicable security requirements must be applied to all research areas as described in VA Handbook 0730, "Physical Security Requirements and Options"
   b. The availability of human pathogens, their products, chemicals, gases, radioactive materials, and/or radioactive sources for VA research is essential for advancing medical knowledge relevant to improving the health care needs of the veteran population. In the past decade, biological and chemical terrorist events in the United States and in other countries have become a reality. It is the responsibility of the VA Office of Research and Development (ORD) to develop policies to prevent illegal entry into research areas and the improper use and/or theft of hazardous materials. The protection of VA personnel, patients, visitors, and the surrounding community from terrorist events demands stringent controls on the use of hazardous agents capable of being used as weapons of mass destruction.
   c. Policies, procedures, and responsibilities for BSL-2 laboratory security, personnel identification and training, inventory controls, and the interactions with other facility personnel such as security are addressed here. For BSL-3 laboratories and laboratories using or storing exempt and non-exempt select agents please refer to the Hazardous Agents Control Program.
   d. Only authorized individuals with medical clearance, approved background check, and documented training are allowed to have access to designated biomedical laboratories. The minimum education requirements for access to these areas, including select agent and toxin laboratories, are a high school education, or equivalent, unless the PI and RO, or ARO grant special provisions.

3. **Definitions:**
   a. **Terrorist Event**. A terrorist event is the unauthorized removal or theft of hazardous agents capable of being used as weapons of mass destruction from VA research laboratories, or other VA assigned space (including off-site space) and/or the unlawful use of such hazardous agents. It specifically encompasses the illicit and unauthorized use of VA laboratory facilities (including equipment, supplies, computers, faxes, phones, etc.) for the production, purification, or dissemination of any hazardous agent. The term also refers to the illegal transfer of agents into or out of VA research laboratories and other research space such as animal care facilities, storage areas, offices, etc.
   b. **Hazardous Agent**. A hazardous agent is a biological material including, but not limited to, the CDC list of Select Agents and products of such a biological material, i.e., toxins. For purposes of this Directive, the term also includes highly toxic chemicals or gases that have the potential for being used as weapons of mass destruction, as well as radioactive materials and/or radioactive sources. Refer to **Attachment A** for a list of biological and chemical agents and a description of radioactive materials and/or radiation sources recognized as meeting this classification.
   c. **Select Agent**. A Select Agent is one of a group of agents (viruses, bacteria, rickettsia, fungi, toxins, and

recombinant deoxyribonucleic acid (DNA) designated by the CDC as requiring registration with the CDC Laboratory Registration Program. The regulation of Select Agents is codified in Title 42 Code of Federal Regulations (CFR) Part 73 for CDC and also Title 7 CFR 331 for USDA. Additional Requirements for Facilities Transferring or Receiving Select Agents are detailed in these federal registers. All Select Agents are included in the list of hazardous agents listed in Attachment A. For purposes of this Directive, Select Agents and Hazardous Agents are synonymous, and are to be handled at the same level of security.

d. **Weapons of Mass Destruction**. Weapons of mass destruction include any of the classes of hazardous agents as defined in paragraph 2.d (2) and identified in Attachment A, or combinations of these agents that are capable of inflicting morbidity and mortality on a widespread basis.

e. **Laboratories.** Laboratories are research laboratories under the control of VA ORD. In the context of this VHA Directive, the laboratory director is the VA investigator responsible for a particular laboratory. ***NOTE:*** *Laboratories include: (1) VA laboratories located within VA medical centers or other VA facilities, including leased space ;(2) VA laboratories located in approved off-site facilities such as affiliate universities; and (3) laboratories within the VA medical center in space that is leased to a private entity.*

f. **Sensitive Materials.** Sensitive materials include, but are not limited to, any hazardous agents as defined in paragraph 2.d(2) and identified in Attachment A, as well as research equipment and/or supplies used to store, test, destroy or otherwise handle hazardous agents, and laboratory notebooks or other written or computerized records documenting possession of and/or research using hazardous agents.

g. **USA Patriot Act.** The USA Patriot Act, Public Law 107-56, October 26, 2001, was passed by Congress in response to the terrorist attacks of September 11, 2001. The purpose of the Act is to unite and strengthen America by providing appropriate tools to intercept and obstruct terrorist acts. The law includes provisions to deter and punish terrorist acts, enhance law enforcement investigatory tools, and other purposes such as aid to victims of terrorism. The Act also prohibits certain restricted persons from possessing biological agents or toxins that are identified as select agents in Title 42 CFR Part 72. This provision of the Act, codified at Title 18 United States Code (U.S.C.) § 175b, defines a "restricted person" as including, among others, an alien (other than an alien lawfully admitted for permanent residence) who is a national of a country that has repeatedly provided support for acts of international terrorism. ***NOTE:*** *The Secretary of State makes such determinations; as of 10/2011; identified countries include Cuba, Iran, Sudan, and Syria.*

4. **Responsibilities:**

a. **ACOS for R&D**

i. All activities in the Research Service including the implementation of all requirements set forth in this Plan.

ii. Appointing the Research Biosafety Officer (BSO) as liaison with appropriate facility security personnel, health and safety staff, and oversight committees.

iii. Ensuring the Medical Center Director remains informed of all activities involving sensitive materials.

iv. Ensuring that all non-VA persons working in research areas, or in VA-space leased to another institution, conform to all VA standards for security.

v. Completing the annual vulnerability assessment of research areas.

vi. Informing the Office of Safety and Law Enforcement of any changes in research affecting the facility security rating.

b. **Research and Development Committee (RDC)**

i. Review all minutes from the SRS to make sure the handbook requirements are being met.

c. **Subcommittee on Research Safety (SRS)**

i. Control access to laboratory areas housing hazardous agents by:

1. Reviewing and approving requests for individual's access submitted by laboratory directors.

2. Reviewing the status of personnel granted access at least semi-annually

ii. Reviewing and approving requests to destroy hazardous materials that could be used as weapons of mass destruction, and reviewing and approving requests for a CDC laboratory registration number to document the receipt, transfer, or use of select agents.

d. **Responsible Official (RO) –** Medical Center Director
   i. Be approved for access to biological agents and toxins under 73.8;
   ii. Be familiar with the requirements of the part 73 regulations;
   iii. Have authority and responsibility to ensure that the requirements of the part 73 are met, on behalf of the entity.
   iv. Must identify one or more individuals to serve as an Alternate Responsible Official (ARO) when the RO is unavailable.

e. **Alternate Responsible Official (ARO) –**
   i. Be approved for access to biological agents and toxins under 73.8;
   ii. Be familiar with the requirements of the part 73 regulations;
   iii. Have authority and responsibility to ensure that the requirements of the part 73 are met, on behalf of the entity.

f. **Research Biosafety Officer (BSO)**
   i. Conduct a review of access records to all research areas on a weekly basis. Any irregularities identified during the review must be immediately reported to VA Police Service, and the Director of Research Operations.
   ii. Provide safety and security training for all employees annually.
   iii. Will serve as liaison between the Research Service Line and the Police Service Line.
   iv. Ensure that all contractors have been cleared through Police Service, previous to rendering their service in any Research area.
   v. Ensure that all contractors and visitors to Research areas have been provided information on the hazards associated with the Research areas.
   vi. Maintain an updated record of all contractors allowed in Research areas.
   vii. Managing and distributing security access cards for Research areas.

g. **VA Investigator**
   i. Identify the level of security access required of research laboratory staff being considered for employment or work within the lab.
   ii. Responsible for ensuring that laboratories adhere to VAMC's policies regarding safety and security.
   iii. Educate the Research laboratory staff specific to the hazardous nature of materials they will be using and the security precautions to be followed in handling, transferring or destroying such materials.
   iv. Regularly review and account for the inventory of hazardous agents at least every six (6) months.
   v. Forward a copy of the inventory to the Research BSO or Radiation Safety Officer as appropriate to the nature of the materials on or at least every six months.
   vi. Reports any unidentified individual in his or her areas.
   vii. Notifies the BSO in advance of the need for service from any contractor so proper clearance can be arranged.
   viii. Must notify each employee of authorized times of entry depending on employee's status.

h. **Research Office**
   i. Maintain all documents and records for all requests, projects and related issues.
   ii. Maintain a record of keycard assignments, including a record of the expiration date, current at all times.
   iii. Manages HR processing including background checks through HR.

5. **Laboratory Area**: (4th and 5th floor Clinical Addition-building A-, 12th floor Tower-building C)
   a. Laboratory and animal care areas are to be locked at all times. Access to Research laboratories is controlled and limited to authorized individuals on 24-hour, 7-days per week schedule.
   b. Access cards are to be issued to authorized personnel only to permit entry to Research laboratory areas.

1. Proximity cards are issued to laboratory personnel and administrative staff for entry into laboratory and office areas for 4A, 5A, and 12C. These proximity cards are issued to individuals once they have undergone an approved security background assessment by the VA Police, they have a documented medical surveillance, and they have documented training prior to their work assignments, and at least annual refreshers.
2. Furthermore, containment rooms inside the areas previously described above have limited access via, personal PINs, physical laboratory keys, and access cards, that are only issued to personnel whose work assignments require their entry into these laboratories.

c. Access to visitors and students, etc. is to be limited to regular work hours (7:00 am to 3:30 pm) or when authorized employees are present.
d. All visitors must sign in the Research Service Visitor's Logbook (located outside main doors on each Research floor.) A valid personal identification containing a photograph of the individual must be provided prior to being admitted to laboratory areas.
e. Visitors must be accompanied at all times by an authorized VA employee when entering the laboratory area. This employee is responsible for serving as the visitor's escort during their visit to the laboratory areas, activities and conduct, ensuring that the visitor does not have any access to restricted or hazardous agents / chemicals, and for ensuring that the escorted visitor exits the area at the appropriate time.
f. Routine cleaning, maintenance, and repairs of Laboratories and equipment must be performed during regular work hours unless properly authorized by the Director of Research Operations.
g. The Research BSO conducts and documents a monthly review of high containment facilities access records. These records are kept under lock in the Research Biosafety Office. Irregularities identified during a review or in the course of daily activities are immediately investigated and reported to the VA Police Service, the Research office and other appropriate personnel.
h. A record of access cards assignments is kept current always.
i. Vendors must be restricted from all laboratory areas. If a PI or employee would like to meet with a vendor, he must schedule an appointment with him in the Research's conference room (5A110). Contractors in need to render any kind of service in a laboratory must be cleared through VA Police Service with a background check; this must be done prior to presenting to Research areas. Once cleared and on the day that the service will be rendered, contractors must first present to the Research Administration Office where they will sign the Contractors Log Book and ID card & access card will be assigned. Additionally, the contractor must document acknowledgment of being provided the hazard awareness training on his/her initial visit to the Research facility.
j. The contractor will render their service during regular work hours (7:00 am to 3:30 pm) before leaving Research areas contractors must return to the Research Administration Office return ID and access card and sign out.

6. Employees:

a. All personnel must obtain formal authorization prior to beginning work in laboratory areas.
b. All staff (including regular employees, students, visiting scientists and other short-term workers) is to wear visible identification red badges all the time.
c. Laboratory supervisors and Principal Investigators are responsible for ensuring that visitors follow all safety and security regulations when in the Research area.
d. All staff are responsible for security and should challenge or question unknown, unfamiliar or unidentified persons in the laboratory area.
e. No employee should grant access to individuals visiting other employees or to unknown individuals.
f. All employees must attend the new employee Research Laboratory Safety & Security training upon starting their job appointments, and the annual safety refresher found at http://www.citiprogram.org/default.asp?language=english.
i. Personnel are working on VA funded projects at the CDC or Emory University should complete the required safety training required at their institution on an annual basis and provide documentation to the Atlanta VA Biosafety Office.
   1. If CDC complete CDC safety Survival Skills.

2. If Emory, complete Emory Laboratory Biosafety Training

g. Atlanta VA personnel that are not at risk of or working with hazardous agents (i.e. chemicals, biological or viral agents) are required to complete the HAZWHOPPER training on a one-time basis upon beginning work in Research. This training consists of abbreviated biosafety training, with the addition of blood borne pathogen and infection control for the hospital.
h. All employees are responsible on an annual basis to read and familiarize themselves with the Research Service Line Laboratory Security Plan and Emergency Preparedness Plan.
i. Personnel, including WOC appointees and contract employees as well as non-citizens, leaving VA employment or no longer working in the research laboratory must adhere to full clearance and checkout procedures. This includes turning in all identifications, passes, keycards, and other access items.
j. Returned keycards are deactivated within 24 hours of returned.
k. An alien (other than an alien lawfully admitted for permanent residence) who is a national of a country determined by the Secretary of State to have repeatedly provided support for acts of international terrorism may not be granted access to any sensitive areas in which select agents (as defined in Title 42 CFR Part 72) may be present.
l. Laboratory directors must submit a written request to the facility R&D Committee to obtain permission for individuals to access restricted areas in which hazardous agents are used.
m. The appropriate facility managers must be notified of the approval or disapproval of requests for laboratory access.
n. Changes in personnel status are immediately reported to VA Police Service and Research office

7. **Responsibilities and Procedures for Securing the Restricted Areas:**

a. Loss of unique means of accessing restricted areas (proximity cards, keys, personal PINs) should be reported immediately to the RO, ARO, or BSO for immediate deactivation of these means of access, and reassignment of new access means to necessary personnel.
b. Deactivation of unique means of accessing restricted areas occurs immediately after a change in personnel due to reassignment, termination, etc. to ensure that there is no possibility of a breach of security. The RO, ARO, or BSO collects all keys and proximity and slide cards prior to an employee leaving a work assignment.
c. All authorized personnel are required to wear their VA issued identifications on their person always. At any time that an unfamiliar person is observed in the in the restricted laboratory area, it is the responsibility of the authorized person to contact the RO, ARO, or BSO to report the breach of security, and the VA Police is contacted to remove the individual from the area. The authorized person should stay with the unauthorized individual until the VA Police arrives to remove him or her.
d. Sharing of unique means of entering restricted areas (keys, proximity cards, personal PINs) is strictly prohibited. This is prohibited for select agent / toxin areas and non- select agent / toxin laboratories and areas.

8. Cleaning, Maintenance and Repairs in Laboratories with Hazardous Agents: BSL-2 Laboratories:

a. Environmental Management Service personnel, Engineering Service personnel, or any other VA service provider assigned to areas where Hazardous Agents are used/stored must be cleared through the Police Service.
b. Housekeepers, engineers and service providers must be escorted when entering laboratories using/storing Hazardous Agents.
c. Any service to be provided to laboratories using/storing select agents (exempt or non-exempt) must be provided during regular business hours when an authorized employee is present.
d. An access log for all visitors, including maintenance and deliveries will be maintained. The access log should record date, time, name of the unauthorized person, and the authorized individual escort the unauthorized person into the laboratory area.

9. Security Reporting Requirements:

a. Each employee authorized to work in the containment areas / laboratories for VAMC must report any of the

following to the Responsible Official:

b. Any loss or compromise of their badges, keys, or combinations
c. Any suspicious persons or activities
d. Any loss or theft of select agent, toxin, or hazardous chemical
e. Any sign that the inventory and use records of hazardous materials have been altered or compromised; this includes select agents and / or toxins.

Note: In the case of the theft, loss, or release of select agents or toxins, this occurrence should be immediately reported to the biological safety office and the appropriate personnel should notify the Centers for Disease Control and Prevention (CDC) via a completed APHIS/CDC Form 3. Also take note that an exposure to a select agent and / or toxin is considered a possible release, and should be reported to the CDC by the previously discussed procedure.

10. Biological/Chemical Material:

a. Freezers, refrigerators, cabinets and other containers where stocks of biological agents, hazardous chemicals, or radioactive materials are to be stored need to be locked when they are not in direct view of staff.
b. All biological agents, toxins and chemicals listed in the VA Weapons of Mass Destruction list must be labeled and kept inside a laboratory under lock always. The BSO must be notified of content.
c. A very strict day-to-day log of all select agents must be kept by laboratory personnel using/storing select agents, whether they are exempt or not
d. Packages containing specimens, bacterial or virus isolates, or toxins are to be opened inside a biosafety cabinet or other appropriate containment device.
e. Biological material and/or toxins for shipment to other laboratories are to be packaged and labeled in conformance with all applicable local, federal and international shipping regulations. All Research personnel involved in packaging and/or shipping of infectious agents must take the Packaging / Shipping of Category 6.2 hazardous agents every two years found at http://www.citiprogram.org/ . This training covers all DOT, IATA, and CDC regulations for shipping infectious agents.
f. All laboratory Principal Investigators must keep a log (inventory control) of all materials transferred to and from their laboratory.
g. Inventory transfers must comply with DOT, OSHA, NRC, and CDC regulations. Transfer of any hazardous materials, including but not limited to those specifically identified as CDC select agents, must be documented as to the identity of the receiver of said materials, where it is being transferred, and the date of the transfer.
h. For transfer of Select Agents:
    i. Register with CDC Laboratory Registration Program. The ACOS for R&D submits a letter of intent on behalf of the investigator to CRADO through the facility Chief of Staff, Medical Center Director, and VISN Director.
    ii. The letter of intent must contain a detailed justification for the use of select agents in a VA Research laboratory. It must also include a description of measures ensuring physical security of the select agents and a list of all personnel who will be granted access to the select agent.
    iii. The completed CDC application must be reviewed and approved by the local SRS, RDC, Chief of Staff, Medical Center Director, and VISN Director.
    iv. Following receipt of a CDC laboratory registration number, a site inspection of the Research laboratory must be scheduled with the ORD prior to acquisition and use of the select agent.
    v. Freezers, refrigerators, cabinets, and their containers where stocks of Select Agents (SAs) stored must be locked when they are not in direct view of workers.
    vi. Prior to ordering any amount of SA, the order must be submitted to the BSO for approval.

11. References:

a. National Institutes of Health Issuance of Director's Decision: The NIH Incident, Federal Register, September 24, 1997, 62 (185): 50018-50033.
b. Atlas RM, "Biological Weapons Pose Challenge for Microbiology Community," ASM NEWS 1998; Vol. 64; 383-389.

c. Ruys, Theodorus, “Laboratory Design Principles” In: Handbook of Facilities Planning. Ruys, T, ed. New York: Van Nostrand Reinhold, 1990; 257-264.
d. VHA Handbook 1200.06
e. Title 18 U.S.C. § 175b.
f. Title 29 CFR 1910.120.
g. Title 42 CFR Part 72.
h. VHA Handbook 1200.8, “Safety of Personnel Engaged in Research,”
i. VA Directive and Handbook 0730, “Security and Law Enforcement,”
j. Public Law 107-188, “Public Health Security and Bioterrorism Preparedness and Response Act of 2002.”
k. Title 10 CFR Parts 19 and 30, the Civil Service Reform Act of 1978, and the Whistleblower Protection Act of 1989.

HAZARDOUS BIOLOGICAL AND CHEMICAL AGENTS

1. The Centers for Disease Control and Prevention (CDC) has identified certain biological, chemical and radioactive materials or agents as having potential for use as weapons of mass destruction. Improper use and/or containment of these materials or agents pose a risk to national security because of their: 1) ease of dissemination or transmittal between individuals; 2) potential for high mortality rates and major public health impact; 3) potential for causing public panic and social disruption; and 4) risk for public health preparedness.

2. Storage and/or use of these materials or agents in any quantity in a Department of Veterans Affairs (VA) research laboratory requires special consideration for physical security, personnel access, inventory control, and emergency preparedness.

   a. Biological Agents

   Abrin
   Aflatoxins
   Bacillus anthracis (anthrax)
   Botulinum toxin
   Brucella abortus, B. melitensis, B. suis
   Burkholderia (Pseudomonas) mallei
   Burkholderia (Pseudomonas) Pseudomallei
   Clostridium botulinum
   Clostridium perfringens epsilon toxin
   Coccidioides immitis
   Conotoxins
   Coxiella bumetii
   Crimean-Congo hemorrhagic fever virus
   Diacetoxyscirpenol
   Eastern Equine Encephalitis Virus
   Ebola Virus
   Equine Morbillivirus
   Francisella tularensis
   Lassa Fever Virus
   Marburg Virus
   Ricin
   Rickettsia prowazekii
   Rickettsia rickettsii
   Rift Valley Fever Virus
   Saxitoxin
   Shigatoxin
   South American Hemorrhagic Fever Viruses (Junin, Machupo, Sabia, Flexal, Guanarito)
   Staphylococcal enterotoxins
   T-2 Toxin
   Tetrodotoxin
   Tick-borne Encephalitis Complex Viruses
   Variola Major Virus (Smallpox Virus)
   Venezuelan Equine Encephalitis Virus
   Viruses causing Hantavirus Pulmonary Syndrome

Yellow Fever Virus
Yerseinia pestis

b. Chemical Agents

3-quinuclidinyl benzilate (BZ)
Chlorine gas
Cyanogen chloride (CK)
Cyclosarin (GF)
Diphosgene (DP)
Hydrogen cyanide (AC)
Lewisite (L) – note there are 3 individuals chemicals included in this category
Lysergic acid diethylamide (LSD)
Nitrogen mustard (HN-1, HN-2, or HN-3)
Phosgene (CG) – also known as carbonyl chloride
Phosgene oxime (CX)
Sarin (GB)
Soman (GD)
Sulfur mustard (H, or HD, or HT), also called mustard gas or mustard agents
Tabun (GA)
VX (VX is both the name and symbol)

c. Radioactive Materials and/or Radiation Sources
   1. The special considerations required for radioactive materials and/or radiation sources should be based on the specific radionuclide, the half-life, and the quantity present. For a "radiation high-risk" situation, more restrictive security measures should be followed. For a "radiation low-risk" situation, basic security measures should be followed.
   2. "Radiation high-risk" is a single location or room where the total activity of a single radionuclide with a half-life of more than 3 days is greater than one Curie and the radionuclide is received, stored, or used. "Radiation low-risk" is any location other than a "radiation high-risk" location and where radioactive materials and/or radiation sources are received, stored, or used.
   3. As additional agents or materials are identified by the CDC, those agents or materials will be considered by VA as hazardous agents, and will be subject to the same security requirements as those agents or materials identified in paragraph 2 above.

SECTION III

Hazardous Agents Control Program

Hazardous Agents Control Program

I. Purpose: To ensure that VA research laboratories using or storing hazardous agents including select agents, toxins and associated sensitive materials maintain an appropriate level of security and safety. This pertains to specific guidelines in utilizing, storing, handling, acquiring, transferring, transporting and disposing of hazardous materials.

II. Scope: This program will include the physical security requirements for the storage and use of select agents, toxins and other highly dangerous hazardous agents. Policies, procedures, and responsibilities for VA research laboratory security, personnel identification and training, inventory controls, and the interactions with other VA facility personnel such as security and law enforcement will be addressed.

III. Definitions:

A. Hazardous Agent. A hazardous agent is biological material included in the CDC list of select agents and toxins, APHIS biological agents, and products of such biological material, i.e. toxins. The term also includes highly toxic chemicals, exempt quantities of toxins, or gases that have the potential for being used as weapons of mass destruction, as well as radioactive materials and/or radioactive sources.

B. Select Agent. A select agent is one of a group of agents (viruses, bacteria, rickettsiae, fungi, toxins, and recombinant DNA) designated by the CDC as requiring registration with the CDC Laboratory Registration Program. For purpose of this program, select agents and hazardous agents are synonymous, and are to be handled at the same level of security.

C. Sensitive Materials. Sensitive materials include, but are not limited to, any hazardous agents as defined in subparagraph III a and identified in attachment A, as well as research equipment and/ or supplies used to store, test, destroy or otherwise handle hazardous agents, and laboratory notebooks or other written or computerized records documenting possession of and/or research using hazardous agents.

IV. Responsibilities:

A. Office of Human Resource Management (OHRM). The Human Resource Management Service (HRMS) is responsible for assisting the research program in issues related to personnel, including new personnel actions, appointment of WOC employees, developing the position risk and sensitivity designation of all Research employees, and initiating the appropriate background investigations. HRMS is also responsible for reviewing applications for employment for citizenship and visa status.

B. Office of Security and Law Enforcement (OSLE). The Police Service, OSLE, is responsible for assisting with background investigations, assisting with security of research laboratories, emergency response, vulnerability assessments and research offices with the development and implementation of this Hazardous Agents Control Program.

C. Chief Research and Development Officer (CRADO), VA Central Office. The CRADO is responsible for the overall VA Research laboratory antiterrorism policy, the planning and coordination of system-wide plans to prevent terrorist events from occurring in VA Research laboratories, and maintaining the highest level of laboratory and inventory security for hazardous agents including select agents and toxins, as well as the associated sensitive materials. The CRADO, in consultation with the Under Secretary for Health, is also responsible for identifying specific training requirements for persons working in VA research laboratories and for those persons working with hazardous agents, including select agents and toxins. The training requirements also apply to research administrators responsible for VA research laboratories. These training

requirements include information on safety, containment, and security of hazardous agents including select agents, toxins and the associated sensitive materials.

D. Chief, Office of Research Oversight (ORO). The Chief, ORO, is responsible for oversight or evaluation of issues related to compliance with this Handbook and other applicable Federal regulations addressing biosecurity.

E. Associate Chief of Service for R&D (ACOS/R&D)**.** The ACOS for R&D is responsible for:

(1) All activities in the Research Service, including the implementation of all requirements set forth in this Program.

(2) Appointing, or serving as, the designated research point of contact for interacting with facility security personnel, health and safety staff, Medical Center Director-RO, ARO, and oversight committees (e.g., R&D Committee (RDC), Subcommittee on Research Safety (SRS), Radiation Safety Committee).

(3) Ensuring the Medical Center Director, or designee, remains informed of all activities involving hazardous agents, select agents, toxins and other sensitive materials in VA research laboratories.

(4) Ensuring that changes in facility security procedures are made known to all staff in the research service expeditiously.

(5) Ensuring that all non-VA persons (i.e., those that are not appointed as VA employees or VA contractors) working in VA research laboratories, in VA research laboratories in approved off-site locations, leased space or in VA space leased to another institution, conform to all VA standards for security described in this Program.

(6) In conjunction with the BSO and The Police Service, completing the annual vulnerability assessment of research areas.

(7) Informing OSLE of any changes in research affecting the facility security rating.

F. Investigators, Laboratory Directors, Research Investigators VA research investigators and staff, regardless of appointment status (paid, WOC, or fee basis), are required to comply with all provisions of this Program. ***NOTE:*** *Those requiring WOC appointments include, but are not limited to, students, fellows, residents, university employees, other non-VA employees working at VA, and visiting scientists who are not compensated by VA for their employment.* All contractors must comply with all requirements of this Program.

(1) Appropriate authorizations and approvals must be obtained prior to beginning work in area of the Research Service Line. This includes a successful background check by the VA Police Department.

a. Principal Investigators (PIs) must ensure that those they supervise have received approval to access laboratories prior to beginning work.

i. If it is a laboratory (BSL-3 or non-BSL-3 laboratory) using or storing select agents or toxins, employees must have written authorization to both access these areas and to work within them.

ii. If select agents or toxins are not used or stored in a BSL-3 laboratory, persons working in the BSL-3 laboratory must obtain specific approval from the RDC to do so. (The completion of the Federal Bureau of Investigation (FBI) Form FD-961, Federal Bureau of Investigation Bioterrorism Preparedness Act: Entity/Individual Information and obtaining a Security Risk Assessment is not required.)

b. Laboratory directors and investigators are responsible for:

i. Identifying the level of security access required for laboratory staff (paid or WOC) being considered for employment or being approved to work within the investigator's research laboratory. For those working with select agents and/or toxins a Security Risk Assessment must be completed by the FBI prior to being authorized to work in the laboratory as required by 42 CFR 73.8(d), 7 CFR 331.10(h), or 9 CFR 121.11(h). The Security Risk Assessment is in addition to the background investigation required by VA Handbook 0710.

ii. Ensuring that all their staff have received the required training and are familiar with information specific to the hazardous nature of materials they will be using and the security precautions to be followed in handling, storing, transferring or destroying such materials as well as containment procedures.
iii. Regularly reviewing and accounting for inventory of hazardous agents including select agents or toxins (non-exempt and exempt quantities). The review must be documented in form of a log.
iv. Forwarding a copy of the inventory to the SRS and the Research Biosafety Officer or the Radiation Safety Officer as appropriate, at least semi-annually. The SRS will report to RDC on inventory controls. (See section VII (5).

c. Select agents or toxins (non-exempt and exempt quantities) may be used only after receiving appropriate approvals.
d. VA research laboratory directors and investigators are responsible for all aspects of their research including the supervision of their staff.

G. Individuals Working in VA Research Facilities. Everyone must immediately report the following to the RO or Alternate RO(s):

(1) Any loss or compromise of their keys/cards, passwords, combinations, etc.
(2) Any suspicious persons or activities.
(3) Any loss, release or theft of select agents or toxins (non-exempt and exempt quantities).
(4) Any sign that inventory and use of records of select agents or toxins (non-exempt and exempt quantities) have been altered or otherwise compromised.

V. Theft, Loss or Release of Select Agents or Toxins: When the theft, loss, or release of a select agent or toxin is discovered, the VA research laboratory must immediately notify the appropriate supervisor, the ACOS/R&D, the VA Police Service, the RO, Alternate RO(s) (Biosafety Officer), VA OIG, ORD, ORO, and APHIS or CDC as applicable. Please keep in mind that a potential exposure to a select agent or toxin is also considered a potential release, and should therefore be reported to the CDC through the proper processes. The facility's Safety Officer and the Network Safety and/or Industrial Hygiene Officer must also be notified.

A. All reporting procedures in 42 CFR 73.17, 7 CFR 331.16, or 9 CFR 121.17, whichever is applicable, must be followed immediately upon discovery of the theft, loss or release.
B. Thefts, loss, or release must be reported whether the select agents or toxins are subsequently recovered or the responsible party(ies) identified (see 42 CFR 73.17(b)).
C. A complete investigation must be done, documenting each aspect of the process. Any select agent or toxin lost, stolen, or otherwise unaccounted for must be maintained by VAMC to document the incident.
D. APHIS/CDC Form 3 should be used to report the incident to the CDC after appropriate consultation with VAMC's assigned point of contact with the CDC Select Agent Program. Additionally, this completed form must be submitted to the CDC within 7 days of the discovered theft, loss, or release.

VI. Cleaning, Maintenance and Repairs in Laboratories with Hazardous Agents:

A. BSL-2 Laboratories:
(1) Environmental Management Service personnel, Engineering Service personnel, or any other VA service provider assigned to areas where Hazardous Agents are used/stored must be cleared through the Police Service.
(2) Housekeepers, engineers and service providers must be escorted when entering laboratories using/storing Hazardous Agents.
(3) Any service to be provided to laboratories using/storing select agents (exempt or non-exempt) must be provided during regular business hours when an authorized employee is present.

(4) An access log for all visitors, including maintenance and deliveries will be maintained. The access log should record date, time, name of the unauthorized person, and the authorized individual escort the unauthorized person into the laboratory area.

VII. Security for BSL-2 Laboratories and Laboratories with Select Agents: (The following procedures apply only to BSL-3 laboratories, when active, and laboratories working with select agents. For security procedures on all other Research areas please refer to The Research Service Laboratory Security Plan.)

A. Access

(1) **For Select Agent Laboratories:**

a. Definition of ***Authorized*** Personnel: Individuals registered w/ Select Agent Program (SAP)

i. **42 CFR Part 73.8(b)**

ii. Security Risk Assessment (SRA) performed by the Attorney General

iii. On VAMC's Select Agent Program registration

iv. Those with documented training

B. Personnel:

(1) Prior to beginning work in the BSL-2 or a laboratory using or storing exempt quantities of select agents and / or biological toxins as identified by 42 CFR 73, Human Resources Management Service (HRMS) will verify the person's credentials. In conjunction with the Police, Service HRMS will submit a Standard Form (SF)-85 and Questionnaire for Non-Sensitive Positions. Fingerprints will also be submitted to the Office of Personnel Management (OPM) for completion of a background check. Employees that will be working in the BSL-3 research laboratory not containing select agents will obtain approval to do so from the R&D Committee.

(2) Prior to beginning work in a VA BSL-3 laboratory or a VA laboratory using or storing select agents or toxins a formal authorization must be granted by the Medical Center Director from recommendation by the RDC. The RDC recommendation will be based on an approved security risk assessment performed by the Attorney General. This security risk assessment will be in addition to the background investigation required in Handbook 0710 and mentioned above.

C. Contractors:

(1) Contractors that need access to high security areas must be cleared through VA police by a background check.

(2) Contractors must provide their service during regular business hours (7:00 am to 3:30 pm), any day of the week except weekends and holidays. Exceptions will be reviewed on a case-by-case basis.

a. Contractors with cleared backgrounds checks that need access must report to the Research Administration Office (room 5A104), before rendering any service. The contractor will present valid company/photo ID, sign the contractor logbook, and check out a contractor ID badge with access key/card. Contractors that must enter the research suites for service should undergo the VA police background check and once cleared contact the Research Administration Office, extension, 207632, for entry. The contractor will complete the access log outside the area and will be escorted into the suite by an authorized person, which will accompany the individual while the service is being provided.

b. Contractors that will provide service in the BSL 2 or select agent lab will follow the above procedure plus will be escorted during the duration of their service by an authorized person.

c. Any contractor that has not gone through a background check and must enter Research areas must first be approved by the Director of Research Operations and will not be allowed to check out an access key. This contractor will be escorted during the entire time he/she is in Research and will not have access to select agent room or BSL 3 laboratory.

d. Vendors are not allowed to walk through Research areas at any time.

e. If a lab personnel needs to meet with a vendor he/she must schedule an appointment with the vendor in

the Research conference room (5A110). After completion of the meeting the research employee must escort the vendor out of the restricted laboratory area.

D. Training: Prior to accessing any BSL-3 laboratory or any lab using/storing select agents (EXEMPT OR NON-EXEMPT), all personnel must have completed the Research Laboratory Safety & Security Training. Personnel that will be working in a BSL-3 laboratory or any laboratory using/storing any amount of select agents must receive specific security/safety training from their immediate supervisor and the BSO, and their successful completion of this training must be documented.

E. Unauthorized personnel: In the event that an unauthorized individual enters the BSL-3 laboratory or any laboratory using/storing exempt and non-exempt select agents, the Police Service, the BSO and the Director of Research Operations will be notified. The individual will be removed by police and taken to their area to be questioned. Prior to the authority arriving to remove the unauthorized individual, the discovering person should stay with the unauthorized person to ensure that he/she does not have unrestricted access to any part of the laboratory area. All VAMC employees are required to wear their VA identification on their person at all times. Therefore, any individual working in the laboratory should also be wearing their identification at all time. Any individual not recognized as an authorized person in the laboratory area should be challenged and if determined not to be an authorized person for the area, removed by the previously described procedures.

F. Keys: After an employee has been authorized to work in the BSL-3 laboratory or any laboratory using/storing any amounts of select agents, he will be assigned a magnetic card as well as a security code.

(1) To enter any of these areas the employee must enter his security code first and then swipe the access card.
(2) In the event that the security card is lost or stolen, the employee will notify the Biosafety Office, the Director of Research Operations and the Police. The card will be deactivated immediately and the employee will be advised in proper storage of it if the user is back in possession of it.
(3) Employees will not share or give their personal security codes or access cards to anyone.
(4) The security code to access the BSL-3 will be deactivated by the BSO every 6 months and a new one assigned.
(5) Individuals leaving VA employment or no longer working in the VA research laboratories must follow all clearance procedures including turning in all keys/cards, these will be immediately deactivated as well as their security access code, and identification badge.
(6) In the event that an individual stops working at the VA and does not return keys/cards, these will be deactivated with the access code. Then the Administration Office will try to contact the individual, after there is enough evidence to conclude the individual will not return them the VA Police will be notified.

G. Storage: All refrigerators, freezers cabinets, and other areas where hazardous agents, including exempt and non-exempt select agents, are used or stored must be kept under lock all the time. Doors to these areas must be kept locked and should never be propped open. A Freezer Inventory Form shall be completed by each PI and/or Lab Manager with allocated freezer space at the Atlanta VAMC, and posted on each freezer's door, see Addendum e.).

H. Deliveries/Acquisition

(1) The acquisition of hazardous agents and select agents may only occur when there is an approved protocol that requires their use and storage.
(2) Prior to initiating the procurement process, the BSO, the SRS and the RDC must approve this action.
(3) The independent purchase, possession, receipt, or use of hazardous laboratory materials without appropriate authorization is prohibited. To obtain approval to purchase, a written memo/letter must be forwarded to the BSO, who in turn will approve/disapprove in writing. The memo must specify the material to be purchased, amount and expected date of use.
(4) Only laboratories holding CDC or APHIS Select Agent and Toxin Certificates of Registration may acquire

select agents or toxins. However, toxins regulated by 42 CFR 73 that meet any of the following criteria are excluded from the requirements of this part: Overlap toxins under the control of a principal investigator, treating physician or veterinarian, or commercial manufacturer or distributor, if the aggregate amount does not, at any time, exceed the following amounts: 0.5mg of Botulinum neurotoxins; 100 mg of *Clostridium perfringens* epsilon toxin; 100 mg of Shigatoxin; 5 mg of Staphylococcal enterotoxins; or 1,000mg of T–2 toxin.

(5) Transfer of select agents must comply with DOT, OSHA, NRC, CDC and USDA regulations, and can only be initiated after receiving an approved APHIS/CDC Form 2 from the CDC.

I. Package Inspection

(1) All packages entering the research containment areas are inspected immediately for any visible package integrity damage and / or leakage of the contents that could potentially pose a hazard to individuals located within the research area. Additionally, the individual(s) expecting the package should be available to receive and inspect it, or at the very least, an individual authorized to accept the package that is well versed on the package inspection procedures. If there is any possibility of the creation of aerosols during the transport of the package contents, the inspecting individual should ONLY inspect and open the package under a properly functioning biological safety cabinet (BSC) or fume hood.

(2) Conversely, a similar procedure for inspecting packages by appropriate personnel is required upon exiting from the research areas for transport.

J. Intra-facility Transfer

(1) Research laboratories that are utilizing or storing select agents or toxins are required to ensure the proper packaging and transport of these agents. The movement of these agents is strictly performed under the supervision of a VAMC individual registered with the CDC Select Agent Program under 73.8. Additionally, a chain of custody should be generated and documented by all individuals involved in the movement of the select agent or toxin. This documentation should include the individual's names involved in the movement, date and time of the movement, the select agent or toxin transported, the amount of agent moved (toxin), and the agents disposition. Both inventories sponsor and receiving laboratories should be updated accordingly.

K. Records:

(1) The PI must keep an accurate, current inventory of all hazardous agents, including select agents and exempt quantities of toxins. These records must be secured from unauthorized access, but must be available during an emergency and inspections. These inventories must be reviewed periodically to identify any discrepancies. Documentation of the periodic inventory reviews and written explanations of any inventory discrepancies must be maintained by individual laboratories and provided to the Safety Office upon request.

(2) In the case of select agents or toxins (including exempt quantities of toxins), the following information must be maintained:

a. The name, characteristics, and source data;
b. The quantity held on the date of the first inventory (toxins only);
c. The quantity acquired, the source, and the date of acquisition;
d. The quantity, volume, or mass destroyed or otherwise disposed of and the date of each such action;
e. The quantity used and dates of the use (toxins only)
f. The quantity transferred, the date of transfer, and individual to whom it was transferred (this includes transfer within / between laboratories of VAMC when the sender and receiver are registered with the same CDC Select Agents Program registration.
g. The current quantity held (toxins only)

VIII. Destruction of Select Agents and Toxins Including Exempt Quantities: These procedures do not apply if during the select agents use in the research the characteristics of a select agent or toxin are altered so that it no longer meets the criteria for a select agent, or if the select agent is destroyed or consumed during and because of the research.

A. Prior to destruction of select agents, toxins or exempt quantities of toxins, permission must be obtained from the VISN Safety Office through the Medical Center Director, BSO, ACOS for R&D, the RDC, and the SRS.

B. The destruction of select agents, toxins, exempt quantities of toxins, or highly sensitive materials must be witnessed and documented by a member of the SRS.

C. The destruction, time, date, amount and participants must be properly documented.

D. Following destruction of the material, the signed and dated documentation must be forwarded to the BSO and the RDC. If the select agent or toxin is to be destroyed, CDC requires 5 day notice prior to destruction via report to the Select Agent Program via APHIS/CDC Form 3. Therefore, notify the BSO with an official intent to destroy prior to the destruction of any select agent or toxin.

IX. References:

a. Public Law 107-188, "Public Health Security and Bioterrorism Preparedness and Response Act of 2002."
b. Title 5 CFR Parts 731 and 736.
c. Title 18 U.S.C. § 175b.
d. Title 7 CFR Part 331.
e. Title 9 CFR Part 121.
f. Title 10 CFR Parts 19 and 30, the Civil Service Reform Act of 1978, and the Whistleblower Protection Act of 1989.
g. Title 29 CFR 1910.38, 1910.120, 1910.1450 and 1960.
h. Title 42 CFR Parts 72 and 73.
i. CDC-NIH "Biosafety in Microbiological and Biomedical Laboratories" 5th edition.
j. NIH Guidelines: "Recombinant DNA and Gene Transfer," April 2002.
k. VA Directive and Handbook 0710.
l. VA Directive and Handbook 0730.
m. VA Handbook 5005.
n. VHA Handbook 1100.19.
o. VHA Handbook 1200.07.
p. VHA Handbook 1200.08.

SECTION IV

RESEARCH SERVICE
EMERGENCY PREPAREDNESS PLAN

RESEARCH SERVICE EMERGENCY PREPAREDNESS PLAN

1. **Purpose:** To provide additional clarification regarding the specific actions employees of the Research Service may have to take in support of the Atlanta VAMC response to an emergency situation. The following plan provides guidance about emergency procedures, inform laboratory personnel of potential emergencies prior to, and guide the laboratory personnel through the situation.

2. **Leadership:** The Associate Chief of Staff for Research and Development (ACOS for R&D) is responsible for directing Service response to an emergency. In the ACOS R&D absence, the following is the Service Line of Succession:

   A. ACOS for R&D: C. Michael Hart, MD, x 207632, 5A104
   B. Director of Research Operations: Antonio J. Laracuente, x 207632, 5A104, (678) 699-7444.
   C. Research Biosafety Officer: Ioana St. Amand, x 20207273 or x 201569, 5A104
   D. Science Information Officer: David Knight, x 204827, 5A104

The Research Service Line has approximately 300 employees who are available to support the Medical Center. They include consultant MDs, PhDs, research technicians, veterinarians, health science specialists, research coordinators, engineers, administrative staff and animal caretakers.

3. **Emergency Identification and Reporting Procedures:** Procedure for the Research Service Line is once an emergency is discovered, the identifying staff is to call the administrative office at x 207632 and facility Safety at 20206115 to report what the emergency is and its location. Then all personnel in the affected area(s) are to follow proper exiting procedures from the laboratory areas and gather by the floor's main elevators for instruction from emergency response personnel. If the emergency is after hours, a cascade callback maybe initiated by the medical center. Research will maintain an appropriate call back listing that is registered with the safety office.

4. **Medical Treatment:**

   A. In case of an emergency in the Research area, the Research Biosafety Officer (BSO) and the Director of Research Operations will be among the first responders to assess the situation. Research Service Line's Vulnerability Matrix and Assessment is used by the BSO and Director of Research Operations to determine the most efficient response mechanism(s) and ensure secure of the personnel and environment.
   B. If the Emergency Operations Centers (EOC) needs to be activated the Director of Research Operations will be immediately dispatched to provide the necessary information to them.
   C. In case of an emergency in any other area of the Atlanta VAMC, **t**he investigators conducting human studies research will be immediately assigned to Manpower Pool. Clinical Research coordinators and health science specialists will be available to assist with patient care as needed. Additional personnel will be made available as requested. The contact point is the Clinical Studies Center at ext. 204934.

5. Damage Assessment:

   A. Assess BSL 2.5 laboratory (room 5A151) by walkthrough and discussions with lab personnel and PI of labs.
   B. Assess Animal Facility by walk-through inspection. Discuss issues with veterinarian or veterinarian tech.
   C. Assess Research floors by walk-through inspection.
   D Assess Vulnerability Matrix and Assessment.
   E. Assess select agents lab by walk-through inspection (if such agents are in use).
   F. All areas where biological agents, toxins or chemicals listed in the VA Weapons of Mass Destruction list must be assessed immediately.

6. Evacuation:

A. The Research Service will assist in the evacuation of patients as follows: Stand ready in Manpower Pool or assist if called upon.
B. The Research Service staff, if required to evacuate their work areas, would use the following route as a primary evacuation route: Evacuate horizontally first meeting in atrium lobbies of the fourth and fifth floors. 11th and 12th floor will meet at main elevators to assess situation. If vertical evacuation is necessary, use stairs to exit building. Facility Emergency Command Personnel will meet Research staff in these areas to provide additional emergency information and procedures.
C. A pairing system will be used to ensure that each employee needing assistance to evacuate has been paired with an able-bodied employee to assist in evacuation.
D. Upon evacuation, employees of Research Service will meet outside in the refuge area of green space, adjacent to three level parking deck). Specific Research personnel will be assigned to account for all personnel that were in the areas prior to the emergency. Any unaccounted personnel will be reported to the Emergency Command Personnel to have the proper emergency responders to remove them from the building.
E. Personnel in Bldg 13 who need to evacuate will do so by moving into the general building through the north entrance. In the event the north entrance is not available , employees of Research Service will meet outside Clinical Addition building to the right of the small parking deck

7. Manpower Reserve Pool: Two employees will be immediately assigned to the Manpower Pool. If additional employees are needed for the Manpower Pool, the Service Chief will gather employees as available. These employees have the following skills: Research can offer biomedical lab personnel, engineers, MDs, PhDs, clinical research coordinators and technicians to assist. Research employees will wait for instruction from the Command Center.

8. Public Affairs: All public affairs activities will be coordinated through the Public Affairs Manager. Should an unescorted reporter enter the work area he/she will be escorted from the facility and the incident will be reported to the Public Affairs Manager.

9. Internal Disaster/Fire:

A. When the alarm sounds, each Research Section Chief and/or Supervisor and/or employee will be responsible to promptly evacuate horizontally the area shutting all doors. All personnel will meet by the main elevators of the floor on which they are and wait for first responders. Once the situation has been assessed by the first responders, research employees will be directed as to what actions they need to take.
B. If a fire originates in one of the research laboratories, remember (RACE):

R: REMOVE
A: ACTIVATE
C: CONFINE
E: EXTINGUISH/EXIT

All personnel are expected to avoid exposing themselves to unnecessary risk to save material items.

C. All laboratory employees will be responsible for stopping machinery and securing their area in a way to best contain the spread of the fire.
D. One employee will be appointed to remain with the personnel at all times and provide any necessary information. The Director of Research Operations will remain in the Research Office to be dispatched to the command center if necessary; he will be responsible for the Emergency Folder which contains information such as all employee's names, contact numbers, floor plans and emergency plans. The BSO will be among the first responders and along with the facility's Industrial Hygienist will evaluate the possibility of any hazard exposure.
E. Locations of fire alarm boxes in the Research areas are as follows:
    1. East side, near 5A101
    2. Near Service Elevators, 5th floor

3. Near Mechanical Room, 4th floor
4. Near Service Elevators, 4th floor
5. 12th floor near Service Elevator, West side (Box 2361)
6. 12th floor near Passenger Elevator, East side (Box 2362) 7. 11th floor near Passenger Elevator
8. Bldg 13- near entrance

10. Hazardous Materials:

A. Most laboratories contain chemicals and/or radioisotopes. Police, fire, and other emergency responders will be informed as to the types of biological, radioactive and chemical materials in use in each laboratory area. Additional notification information for emergency responders is referenced in item B.
B. All laboratories must have posted at all times the Hazardous Chemical Inventory List. This list must be updated every six (6) months and with the addition of any new chemicals. This list can also be obtained from the BSO, the Director of Research Operations and the facility's Industrial Hygienist.
C. Radioactive signs must be posted on the doors where radioactive material is used and stored at all times.
D. Room 5A151(A) is a containment laboratory and special precautions must be taken prior to entry.
E. The VMU is an animal holding unit and special precautions must be taken prior to entry.
F. Laboratory extinguishers are marked on walls in hallways.
G. Any major hazardous (chemical or biological) spill in the lab is to be contained by calling the Research BSO and the facility's Industrial Hygienist, shutting the lab door, and prohibiting entrance by any unauthorized personnel.
H. Fire extinguisher locations are listed under Item 8 on previous page.
I. SDS's will be made available through the web at http://vaww.ceosh.med.va.gov/ceosh/MSDS.shtml or by the lab upon request or need.

11. Utility Failure – Electrical: In the case of electrical failure, personnel in the building must monitor each laboratory for equipment failure and switch to emergency power if available. Engineering Service should be contacted immediately at ext. 206090, 206104 or 206100. If after hours, call the Director of Research Operations at (678) 699-7444. Investigators must be notified, by administration, if the power failure involves a significant timeframe. Additionally, electrical failure is covered by the Emergency Cascade Call Back protocol that requires administrative and research staff to participate by contacting appropriate personnel for notification of the emergency (electrical failure) and activation of corrective measures.
The Director of Operations, BSO, and supervisor for the animal facility (VMU) have override keys to enter the limited access areas in the case of a power failure that affects the proper operation of the Pinnacle and Edstrom access systems to access these areas and properly respond to such an emergency. This emergency procedure is practiced semi-annually for effectiveness. Details concerning the Cascade Call Back protocol are documented in the Environment of Care manual for the Atlanta VA Medical Center, chapter 7, section 3. As a final provision, the BSO ensures that all temperature controlled storage locations are monitored daily visually by Research personnel and by the off-site contractor for any alarms concerning power failures, security breaches, or temperature fluctuations. Reports from the off-site contractor are requested and reviewed quarterly by the BSO, and any abnormalities are reported immediately to the Director for Research Operations for correction.

12. Atlanta VAMC Veterinary Medical Unit: (Refer to VMU SOP 05-001)

A. Mechanical System Breakdown
   1. Mechanical breakdown or loss of air conditioning or electricity, prompts contact of Engineering Service: Ext. 206104 Monday – Friday, 8AM – 4 PM. After Hours/weekend: Ext. 206090.
   2. Explain the problem, let them know that it is an emergency and must be taken care of promptly, stress the effects on the animals in that room (move the animals to another room if necessary)
   3. Air conditioning or heating problems resulting in animal room temps above 80 degrees or below 60 degrees is an EMERGENCY.

4. Notify Jim McNeill or Dr. Michael Fallon of the situation and they will advise you as to what else needs to be done. Communication is the most important thing. Let SOMEONE know if there is a problem.
   a. Dr. Fallon: Ext. 207644 or 770-500-2191 or Cell: 404-732-5471
   b. Jim McNeill: Ext. 206162 or (H) 678-482-1246 or Pager: 404-674-9459

B. Other emergency situations would include the following: (Contact Jim McNeill as well as calling the specified extension)
   1. Water leak resulting in animal rooms/labs or offices are being flooded. (6104)
   2. Smoke or fire- DIAL 204911
   3. Medical emergency to yourself or someone in the animal facility- DIAL 204911
   4. Security problem- DIAL 204911
   5. Hazardous spill- DIAL 204911 and report the location and nature of spill (close off the area before leaving to call for help). HazMat Coordinator: x206115; Safety Officer: x 202752; or Research Biosafety Officer: x207273 or x201569.
   6. Any emergency where the health of an animal or a person is in jeopardy
   7. Automatic watering system failure resulting in animals unable to get water. (6162). In the event of a water shortage, the animal facility will maintain a backup supply of pre-filled and ultra-filtered disposable water pouches (hydroPac water pouch producing machine) to provide water to all animals within the animal facility for up to three weeks.
   8. Any veterinary emergency- Call Dr. Fallon Ext. 207644 or 770-500-2191 , Cell: 404-732-5471 or Emory weekend "on –call" veterinarian at 404-726- 6816
   9. Call or beep the animal facility management person (Jim McNeill, Sandy Meyer, or Lisa Lefebvre) that is on duty that weekend if you are unsure of what to do in a situation occurring on the weekend. Look on the calendar (near Mr. McNeill's office) in the clean side hallway to see which person is on duty that weekend. Employee contact numbers are posted on the wall in the clean side hallway (near the calendar) and Dr. Fallon's door (4A106).

C. Extended Loss of Power in Animal Facility
   1. Should there be an extended loss of power due to a storm, the primary concerns are that the animals receive food and water and be kept comfortable. You should do your very best to report to work, but DO NOT PUT YOURSELF OR OTHERS IN DANGER.
      Engineering Service: Ext. 206104 Monday – Friday, 8AM – 4 PM After Hours/weekend: Ext. 206090
   2. Check all animals to make sure they have food and water. Emergency power provided by a large generator should be on. If not, call Engineering Service at extension 206104 (Monday – Friday, 8AM – 4 PM). After Hours/weekend, call extension 206090.
   3. Open the doors to all non-animal rooms on the north side of the building to increase the amount of light available during the daytime.
   4. Dogs and pigs may be hosed down without the need for electrical power if you can see well enough to do so.
   5. Check rodent cages and change out cages that are very soiled and a threat to the health of the animals. This includes transgenic mice in sterile caging, even if the hoods are not working. Document if hoods/micro isolators not working and use appropriate PPE (gowns, gloves, and respirator).
   6. If the temperature in animal rooms is comfortable, leave all doors to animal rooms closed. If the temperature is too hot or too cold, open all the doors to animal rooms. In the event of an overheating animal facility all animals will be removed and transported down the service elevators by animal care staff and VA police and placed in front of loading dock B and an effort to make local arrangements for animal housing (if necessary due to extended over heating situation) will be initiated following removal. All BSLII animals will be removed and euthanized in the event BSLII housing cannot be obtained through local arrangements.
   7. Continue to stay with the animals until you are relieved by another person.

13. HVAC Failure: In case of a ventilation failure personnel must stop any work being performed in a chemical fume hood or a biological cabinet. If personnel were exposed to any hazard due to the failure they must report to Occupational Health immediately. The fourth and fifth floors of clinical addition A have an HVAC system

supported by redundant (three 600 kw) emergency power generators that restores power within minutes. After the HVAC is restored by these generators, the BSO and hospital safety personnel will assess the areas prior to requesting Research personnel to return. The before and after assessments will be documented and these records will be maintained in the Research Office.

14. **External Disaster:** Research personnel will contact the Research Office at x 207632. Research Service's role is local. Research office will contact the facility's command center for guidance.

15. **Terrorist Event**: In case of an internal or external terrorist event all guidelines from Chapter 4 section 5 of the Environment of Care Manual must be followed.

16. **Inclement Weather:** Employees can receive updated instructions by Direct Dial 404-327-1889 or 404-321-6111 Press 1 and extension 201889 or 800-944-9726 press 1 and extension 201889. When inclement weather conditions such as snow and ice leave roadways impassable, the medical center will provide ground transportation for mission essential employees. Employees must contact their supervisors to be placed on a prioritization listing that's maintained by management in the Emergency Operations Center EOC. During inclement weather, study coordinators will contact subjects who have scheduled appointments to cancel and reschedule as needed

    The Medical Center has assigned Emergency Response categories to employees.

    Research employees who are not administrative fall into two categories:

    Category G: Employees in the Research Service Line who are conducting time-sensitive studies that cannot be delayed, who are involved in animal care where the animals must be treated to ensure welfare, and/or staff who is involved in collection of data from subjects whose appointments cannot be rescheduled due to study requirements. These employees are considered mission essential.

    Category H: Employees in Research Service who conduct studies which can be delayed or who support outpatient research activities.

17. **Delays:** Temporary delays in activity due to inclement weather and other unplanned events shall be addressed according to each category of employees.

18. **IT:** Research data is maintained on a server that is backed up nightly. In the event that the server is not accessible and patients need to be evaluated, then paper records are maintained. Paper records will then be transferred to the electronic medical record as required or to the research data records as needed.

SECTION V

RESEARCH SERVICE
CHEMICAL HYGIENE PLAN

RESEARCH SERVICE CHEMICAL HYGIENE PLAN

1) **INTRODUCTION**
   a) **History of the OSHA Laboratory Standard:** On November 25, 1983, the Occupational Safety and Health Administration (OSHA) published the Hazard Communication Standard, which applied to certain manufacturers and in part to certain laboratories. OSHA received much comment regarding whether the procedures of the Hazard Communication Standard should apply to laboratories where the staff is usually highly educated. OSHA decided that, although 31.9% of all laboratory workers have Bachelor's degrees, 20.6% have Masters degrees, and 20.9% have Doctorates, and that "there is some question as to whether laboratory workers actually make themselves as knowledgeable as they should be, and some laboratory employees are not professionally trained" (51 FR 26664). Other unique differences for laboratories were noted, including the small amounts of chemicals used, the vast numbers of different chemicals involved, and nearly half of the laboratories in one survey could not accurately predict their chemical needs even one month in advance.
   b) OSHA decided that, "Despite the existence of the unique characteristics of laboratory work places, in actual practice incidents of acute adverse health effects resulting from exposures to toxic substances in laboratories do occur. Furthermore, some … studies have shown increased risks of certain types of diseases for laboratory workers. In addition, although laboratory workers are in general a well-educated work force, there is evidence that many laboratories do not have health and safety programs". Therefore, OSHA proposed the Occupational Exposures to Hazardous Chemicals in Laboratories rule, from which this Chemical Hygiene Plan (CHP) originates.
   c) On January 31, 1990, the Department of Labor published, in the Federal Register, an amendment to 29 CFR 1910 Subpart Z, identified as Section 1910.1450, entitled, "Occupational exposure to hazardous chemicals in the laboratory," but better known as the Laboratory Standard. The effective date of the standard is May 1, 1990. A part of that standard is the requirement to develop a chemical hygiene plan, which must be implemented by January 31, 1991.

2) **PURPOSE**: To educate research laboratory personnel in the use of safe laboratory procedures and in the hazards associated with chemicals and other hazardous materials utilized within Research Service.

3) **POLICY**: Research Service maintains a program capable of educating employees on a continuous basis, and protects them from unsafe practices and health hazards with hazardous chemicals in the laboratory. It is also designed to keep exposure limits below permissible limits and ensure compliance with pertinent federal, state, and local regulations. Protection is secured for patients, research personnel, visitors, property, and the environment.

4) **SCOPE**: To provide the necessary training to research personnel regarding safe work practices and hazardous chemicals and materials to which they may be exposed, by means of a hazard communication program, product labeling, Safety Data Sheets, training, and monitoring compliance of personnel.

   a) The biosafety standards in the following documents were considered in the development of this biosafety plan:
   b) Biosafety in Microbiological and Biomedical Laboratories (BMBL), including all appendices except Appendix F.
      i. 29 CFR part 1910.1450, Occupational Exposure to Hazardous Chemicals in Laboratories
      ii. 29 CFR part 1910.1200, Hazard Communication
      iii. NIH Guidelines for Research Involving Recombinant DNA Molecules, (NIH Guidelines).

5) **DEFINITIONS**
   a) **Hazardous Chemical-**The OSHA Laboratory Heath Standard defines a hazardous chemical as an element, chemical compound, or mixture of elements and/or compounds, which is a physical hazard or a health hazard. The standard applies to all hazardous chemicals regardless of the quantity.
      i. A chemical is a physical hazard if there is scientifically valid evidence that it is a combustible liquid, a compressed gas, an explosive, an organic peroxide, an oxidizer or pyrophoric, flammable, or reactive.

ii. A chemical is a health hazard if there is statistically significant evidence, based on at least one study conducted in accordance with established scientific principles that acute or chronic health effects may occur in exposed employees. Classes of health hazards include:
    (1) carcinogens
    (2) irritants
    (3) reproductive toxins
    (4) corrosives
    (5) sensitizers
    (6) neurotoxins
    (7) hepatotoxins
    (8) Toxic or highly toxic agents
    (9) agents that act on the hematopoietic system
    (10) agents that damage the lungs, skin, eyes, or mucus membranes
iii. A chemical is considered hazardous according to the OSHA standard, if it is listed in any of the following:
    (1) OSHA, 29 CFR 1910.1000 Table Z-1 through Z-3
    (2) Threshold Limit Values for Chemical Substances and Physical Agents in the Work Environment, ACGIH (latest edition).
    (3) The Registry of Toxic Effects of Chemical Substances, NIOSH (latest edition).
iv. A chemical is considered a carcinogen or potential carcinogen if it is listed in any of the following publications:
    (1) National Toxicology Program, Annual Report in Carcinogens (latest edition)
    (2) International Agency for Research on Cancer, Monographs (latest edition).OSHA, 29 CFR 1910.1001 to 1910.1101, Toxic and Hazardous Substances.
        (a) OSHA considers select carcinogens, reproductive toxins, and substances that have a high degree of acute toxicity to be particularly hazardous substances. Additional precautions beyond the general safety practices are required when working with particularly hazardous substances.

6) RESPONSIBILITIES

a) **Environment of Care Committee**
   i. Ensures that the established safety management system is effective in providing work and care environment of the highest quality at the medical center.
   ii. Evaluates the recommendations, actions, reports and monitoring activities of subcommittees and independent programs in the areas of safety, security, hazardous materials and waste emergency preparedness, life safety, medical equipment, utility systems and education.

b) **Associate Chief of Staff/R&D**
   i. Oversees all phases of the laboratory safety and has a responsibility and the authority to see that the Chemical Hygiene Plan (**CHP**) is written, updated, and implemented.
   ii. Appoints the Research Biosafety Officer (**BSO**) and VA Subcommittee on Research Safety (**SRS**).

c) **Research Biosafety Officer**
   i. Ensures that all work is conducted in accordance with the department Chemical Hygiene Plan.
   ii. Ensures that a current and detailed inventory of all hazardous chemicals utilized by Research Service is maintained, and provides copies to the Medical Center Safety and Health Office.
   iii. Sets up schedules for and conducts inspections of Research laboratories, at least annually, to ensure that the NIH, BMBL, CDC/USDA Select Agent, and IBC recommendations are rigorously followed.
   iv. Recruits appropriate research employees to assist in the evaluation of these laboratories as deemed necessary.
   v. Ensures that reports are forwarded on time to the **SRS** and the Medical Center Safety Committee for review.
   vi. Works in coordination with the Safety Office to ensure compliance with regulatory requirements for the **CHP**.
   vii. Thoroughly investigates incidents or unsafe conditions concerning laboratory safety and chemicals, and

ensures that prompt action is taken to prevent recurrence.

viii. Ensures development of procedures on the use, storage, spill control, and disposal of hazardous chemicals utilized in the Research Service.
ix. Serves as a member of the Subcommittee on Research Safety, The Waste Management Subcommittee, the Institutional Animal Care and Use Committee (**IACUC**), and the Infection Control Committee.
x. Will ensure that chemical waste materials are disposed of in accordance with Medical Center policy.
xi. Coordinates with the Institution's Industrial Hygienist in scheduling for hazardous waste drop-off in the Hazardous Material Storage Building for contractor disposal through the Safety Office.
xii. Trains Research Service employees with regard to safe handling and disposal of hazardous chemicals, laboratory safety, use of PPE and any other project specific safety training.
xiii. Instructs Research staff in procedures for dealing with accidents involving toxic substances.
xiv. Assist the Safety Office when necessary.
xv. Makes copies of the approved Chemical Hygiene Plan available to the Research Service program and staff.

d) **Subcommittee on Research Safety (SRS)**

i. Reviews all protocols in which biohazards or hazardous chemicals will be used. Reviews are to be conducted, and approval given, prior to initiation of the protocol; however, the Committee reserves the right to provide additional review of specific procedures (even though the protocol has already been reviewed and approved) prior to their initiation if, in the Committee's opinion, these procedures warrant it.
ii. Reviews annual laboratory inspection reports performed by the Research BSO.
iii. Assists the BSO in investigation of incidents or unsafe conditions concerning hazardous chemicals, and ensures that prompt corrective action is taken to prevent recurrence.
iv. Provides support to the BSO as needed.

e) **Principal Investigators (PI)**

i. Ensure to fill and comply with the Laboratory Annual Self-Inspection Form for each of its laboratories and projects.
ii. Ensure that less hazardous chemicals are substituted, where possible, for hazardous chemicals to minimize potential exposure and waste.
iii. Ensure that a current and detailed inventory for all hazardous chemicals used in their program(s) is maintained in their laboratory, and that a copy is provided to the BSO.
iv. Ensure that a copy of the SDS for every hazardous chemical used in the laboratory is on file and readily accessible to all employees.
v. Ensure that all personnel obtain the medical examinations and protective equipment necessary for the safe performance of their jobs.
vi. Supervises the performance of their staff to ensure that required chemical hygiene rules are adhered to in the laboratory.
vii. Obtains approval, when required, prior to using particularly hazardous or controlled substances.
viii. Ensure that any discrepancies found during inspections of their laboratory are corrected promptly.
ix. Document and maintain compliance with all local, state, and federal requirements.
x. Promptly notifies the BSO of any accidents, spills or near accidents.

f) **Employees:**

i. Read and comply with this Policy
ii. Promptly report unsafe conditions or unsafe use of hazardous chemicals to their supervisors.
iii. Report to the BSO all facts pertaining to every accident that results in exposure to toxic chemicals or biological.
iv. Remain aware of the hazards of materials used in their laboratory, and use them in a safe manner; if unsure of a hazard or safety procedure, ASK!
v. Ensure that all primary containers of chemicals are properly labeled with the identity of the chemical and its hazards.
vi. Conduct laboratory safety inspections as assigned.

vii. Understands the function and proper use of all PPE. Wears PPE when mandated/necessary.

g) **Laboratory Practices & Safety Equipment**

i. General Laboratory Safety Procedures
ii. Security
iii. Laboratory Design and Equipment
   (1) Drench Showers
   (2) Eye and Face Washes
   (3) Fire Extinguishers
   (4) First Aid Kits
   (5) Laboratory Safety Information
   (6) Door Postings and other Signs
   (7) Floor Drains and Sink Traps
   (8) Sharps Containers and Glass Only Boxes
   (9) Mechanical Pipetting Aids
   (10) Vacuum Line Filtration
   (11) Placement of Safety Equipment
   (12) Laboratory Vision Panel
   (13) Laboratory Safety Evaluations

7) GENERAL LABORATORY PROCEDURE REQUIREMENTS

a) **Access and Facility Controls:**

i. Only authorized persons are allowed to enter the laboratory working areas unrestricted.
ii. Laboratory doors should be kept closed while manipulations with potentially infectious agents are being performed.
iii. Animals not involved in experimental or laboratory procedures are not allowed in the laboratory.
iv. The facility has an insect and rodent control program and documentation of the frequency of treatment for the laboratory areas can be provided when requested.

b) **Standard Microbiological Practices**

i. Do not eat, smoke, drink, prepare food or apply cosmetics in the laboratory
ii. Do not store human foods or drinks anywhere in the laboratory working areas. This includes hallways and corridors inside the primary containment of the research corridors.
iii. Always wear appropriate clothing (e.g. pants, shirts, shoes) and personal protective equipment (e.g. safety glasses, lab coats, gloves) in the laboratory. Open sandals, clogs, crocs, and similar footwear are prohibited; shorts and skirts are not recommended.
iv. Goggles or face shields should be worn while working with chemicals, working with animals, or performing procedures that would potentially create splashes.
v. Remove personal protective equipment (PPE) before leaving the laboratory. (This includes lab coats) Do not were protective laboratory clothing outside of the laboratory. This includes administrative offices, the restroom, break room, or passage through the elevator corridor.
vi. Contact lenses should not be worn in laboratories, especially in chemistry and histology areas, unless splash-proof goggles are worn. Contact lenses, (especially soft contact lenses), will absorb certain chemicals and constitute a hazard in splashes and spills.
vii. Non-latex disposable gloves should be worn when working with hazardous chemicals. Hands should be washed after handling viable materials, after removing gloves, and before leaving laboratory technical areas.
viii. Mouth pipetting is prohibited.
ix. It is required to use a fume hood and wear face shields and/or eye protection, when handling caustics and corrosives.
x. Hair should be secured back and off the shoulders to prevent contact with hazardous chemicals and contaminated materials.
xi. Practical jokes and other behavior that might confuse, startle, or distract laboratory personnel are to be

avoided.

xii. Work areas should be kept clean and uncluttered, with chemicals and equipment properly labeled and stored; work areas are to be cleaned up on completion of a task or at the end of each day.
xiii. Glassware that is chipped or broken should be discarded in designated broken glass boxes located in laboratories.
xiv. SDS should be consulted when performing new procedures and appropriate safety procedures are in place.
xv. Delivery of chemicals should not be accepted unless an SDS is on file or accompanies the package.
xvi. Perform technical procedures in such a manner as to minimize the creation of aerosols and / or droplets. All biological work should be performed in a biological safety cabinet (BSC), and where a BSC is not available, other primary and secondary containment devises should be used (i.e. centrifuges with sealed rotors, glove box, etc.). Centrifuging *uncovered* specimens is prohibited.
xvii. All hazardous chemicals must be stored below eye level.
xviii. Inventories of chemicals stored in the laboratory should be conducted every 6 months. Old or unwanted chemicals should be disposed of in accordance with the facilities hazardous chemical waste program.
xix. All containers/tubes/flasks must to be properly labeled.
xx. Keep work areas clean and uncluttered at all times.
xxi. Any particularly hazardous substance that generates dust, vapors, or aerosols must be handled in a suitable containment device such as fume hood or glove box.
xxii. Decontaminate all work surfaces and equipment after any spill of potentially hazardous material, and at the end of your work day.
xxiii. Decontaminate all potentially contaminated materials, specimens, and cultures before disposal or cleaning for future use. Also, reference the SDS of the used hazardous material for proper decontamination methods to decontaminate the waste prior to releasing for autoclaving.
xxiv. Minimize the use of sharps whenever possible. When utilizing sharps in the laboratory, use sharps containers for proper disposal, and never place sharps in regular waste containers or biohazards waste bags. Broken glassware should not be handled directly with the hands. A mechanical means such as brush, dustpan, forceps, etc. should be used when cleaning up broken glassware, and it should be placed ONLY in the sharps disposal container.
xxv. Unauthorized individuals are prohibited from entering the laboratory.

c) **Chemical Procurement**

i. Every time an order is placed for a chemical/reagent, the individual filling out the Research Service order form must request on the order that the manufacturer provide an SDS with the chemical when it is delivered. No chemical is to be received in the laboratory without an SDS.
ii. Before a new substance that is hazardous is used, information in proper handling, storage, and disposal should be known to those who will handle it. It is the responsibility of the PI to ensure that the laboratory facilities in which the substance will be handled are adequate and that those who will handle the substance have received the proper training. All hazardous substances must be approved by the BSO prior to be used in the lab.
iii. Every effort should be made to find less hazardous substitutes for more hazardous chemicals, provided a suitable substitute is available.
iv. All chemicals should be dated and inventoried when received. Whenever a new chemical is introduced into a laboratory, it is the responsibility of the investigator to submit an updated inventory to the BSO, or every six months.
v. Labels on containers of chemicals must not be removed or defaced.
vi.

8) HEALTH AND SAFETY INFORMATION, USAGE PROCEDURES, AND STORAGE FOR CHEMICALS OF SPECIFIC HAZARD CLASS

a) **Compressed Gases -** Compressed gases are unique in that they represent both a physical and a potential chemical hazard. Gases contained in cylinders may be from any of the hazard classes described in this section (flammable, reactive, corrosive, or toxic).

i. Valve safety covers should be left on until pressure regulators are attached.
ii. Cylinders must be secured at all times so they cannot fall.
iii. Containers must be labeled clearly with name of contents and hazards.
iv. Hand trucks or dollies with a securing device must be used when moving cylinders.
v. The use of oil, grease, or lubricants on valves is prohibited.
vi. Repair of damaged cylinders and/or forcing of frozen cylinder valves should not be attempted.
vii. Carefully read the label before using or storing compressed gas.
viii. All gas cylinders should be capped and secured when stored.
ix. Do not store gas cylinders with pressure on the regulator.
x. Keep cylinders away from ignition sources and electrical outlets.
xi. Keep cylinders away from flammable substances (including waste) and incompatible and other corrosive chemicals.
xii. Keep cylinder separated from oxidizing gases.
xiii. Keep cylinders in cool and dry place (not close to sink or where water splash likely to happen) and in well ventilated area.
xiv. Store Gas cylinders so they do not interfere with exit path.

b) **Flammable Gases**

i. No more than two cylinders should be manifolded together; however, several instruments or outlets are permitted for a single cylinder.
ii. When more than one cylinder of a highly flammable gas is to be used in one room, specific approval must be obtained from the Center Director or Medical Center Safety and Health Office.
iii. Standby cylinders (full or empty) are not to be stored in the laboratory.
iv. Valves on all *flammable* gas cylinders shall be shut off when the unit is unattended.

c) **Cryogenic Liquids:**

A cryogen is an extremely cold element or compound. Cryogens are liquefied gases that have boiling points below –238ºF. Common cryogens used include nitrogen and possibly argon and helium. One volume of liquid nitrogen at atmospheric pressure expands to 694 volumes of nitrogen gas at 68ºF.

Background of Hazards Associated with Cryogenic Liquids:

* At room temperature, and under normal conditions, cryogens will rapidly begin to boil and convert from a liquid to a gas.
* The critical point is the highest temperature at which a material changes from a gas to a liquid regardless of atmospheric pressure. The temperature at which this takes place is called the critical temperature.
* Liquid cryogens warmed above their critical temperature will generate high pressure, which can cause a confining vessel to rupture or even explode. Fully containing a cryogenic fluid as a liquid at room temperature is usually not feasible -- e.g. the pressure required to maintain liquid nitrogen at room temperature is 43,000 psi.
* Cryogenic fluids with a boiling point below that of liquid oxygen may condense oxygen from the air if exposed to the atmosphere.
* Cryogens with BPs lower than liquid O_2, are Ar, N_2, H_2, & He.
* Because oxygen does not evaporate as rapidly as liquid nitrogen, it will accumulate and may cause violent reactions with incompatible materials in the system.
* Burns to the skin can result from: a) Direct contact, b) Un-insulated piping, c) Equipment containing a cryogen,
* Burns to the eyes can result from: eye contact from a splash.
* Keep containers (Dewars or tanks) containing liquid nitrogen in cool and out of exposure to sun.

Follow the following practices of "Safe Dewar Handling":

(1) No cross contamination.
(2) Label Properly.
(3) Keep upright.
(4) Do not bump, drop or roll.
(5) Remove jewelry or keep it covered.
(6) Perform tasks slowly.
(7) Do not permit liquid oxygen or oxygen enriched air to come into contact with materials or flammable/combustible substances (e.g. oil, grease, asphalt, kerosene, cloth, tar).
(8) While pouring cryogenic liquids: Use cryogenic PPE (Tongs, Apron, Full face shield or safety goggles, Insulated gloves, High-top shoes, Cover all skin).
(9) Position pressure relief valve away from personnel.
(11) After completion of filling of Dewar(s), if pressure valve is hard to close due to freezing while filling Dewar(s) than wrap a towel around the valve for couple of minutes to allow it to be slightly warmed up and try closing it again.
(12) Do not walk away without ensuring closing of the valve. If the valve resists closing properly, report it to Research BSO.
(10) Keep fill & vent ports closed.
(13) Periodically inspect pressure relief valves for ice.

d) **Corrosive Chemicals**

(1) The major classes of corrosive chemicals are strong acids and bases, dehydrating agents, and oxidizing agents. These chemicals can erode the skin and the respiratory epithelium and are particularly damaging to the eyes.
(a) The primary routes of entry are the skin and the eyes.
(b) If large quantities of acids or alkaline are being used, a shield or barrier of some sort must be used so that breaks and spills can be controlled.
(c) Aprons, non-latex gloves, and eye protections should be worn, as recommended on SDS, when handling highly corrosive materials.
(d) Care should be taken not to inhale vapors. Whenever there is a possibility of vapors and splashing, use chemicals in the fume hood.
(e) Mouth pipetting is prohibited!
(f) Dilution: great care must be taken and reagents should be added SLOWLY. Always add acid to water. Allow acid to run down the side of the container and mix slowly by gentle rotation. Avoid overheating.
(g) Heavy plastic bottles must be used when transporting.
(h) Perchloric acid:
i. Use of goggles or other protective eyewear is mandatory.
ii. Acid must always be transferred over a secondary container to catch any spills.
iii. Heating of Perchloric acid is NOT allowed at the Atlanta VAMC due to lack of an appropriate hood.
iv. Perchloric acid must be checked monthly for discoloration; if discoloration is noted, acid should be discarded following methods in SDS.
v. No organic materials containing Perchloric acid should be stored in the hood.
vi. Do not allow Perchloric acid to come in contact with strong dehydrating agents.
(i) Dehydrating agents:
i. Mixing of these agents should always be done by adding the agent to water, and not the reverse, to avoid violent reaction and spattering.
ii. These substances cause severe burns on contact with skin because of their affinity for water. Affected areas should be washed promptly with large volumes of water.
iii. To handle these substances the following PPE must be worn: face shield, goggles, and impervious apron.
(j) Store corrosives in cabinets or under the hood in a secondary container, away from flammables. Keep

containers not in use in storage areas and off bench tops.

9) Highly Reactive Chemicals & High energy oxidizers

a) Highly reactive chemicals include those which are inherently unstable and susceptible to rapid decomposition as well as chemicals which, under specific conditions, can react alone, or with other substances in a violent uncontrolled manner, liberating heat, toxic gases, or leading to an explosion.
   i. Peroxide formers: These can form peroxides during storage and especially after exposure to the air (once opened). Peroxide forming substances include:
      (1) Aldehydes
      (2) Ethers
      (3) Compounds containing benzylic hydrogen atoms
      (4) Compounds containing the allylic structure
      (5) Vinyl and vinylidene compounds

b) Excessive amounts of highly reactive compounds should not be purchased, synthesized, or stored in the laboratories.

c) Perform all manipulations of highly reactive oxidizers in a chemical fume hood.

d) Handle shock sensitive substances gently, avoiding friction, grinding, and all forms of impact.

e) When working with highly reactive compounds and high-energy oxidizers, always wear the following protective equipment: lab coat, non-latex gloves, and protective glasses.

f) Oxidable compounds (Reference: Emergency Technical Services Corp., Schaumberg, IL)
   i. All peroxidizable compounds should be stored away from heat and light. Sunlight is an especially good promoter of peroxidation.
   ii. Protection from physical damage and ignition sources during storage is also essential. Particular care should be given to ensure tight closure of storage containers. Loose or leaky closures may permit evaporation of storage material, leaving a hazardous concentration of peroxides in the container.
   iii. Most common container materials – such as steel, stainless steel, copper, nickel, aluminum, backed phenolic linings, and ceramics – are suitable for containers; however, they must be clean and free from metal oxides because oxides of iron or copper may actually promote peroxide formation.
   iv. The use of oxidation inhibitors is especially important in the safe handling of peroxidizable materials. Hydroquinone, alkyl phenols, aromatic amines, or similar materials are recommended by the manufacturer as effective in preventing peroxide formation during storage. The proper inhibitor must be selected to avoid possible conflict with use or purity requirements of the compound.
   v. Compounds suspected of having very high peroxide levels – because of visual observation, unusual viscosity, crystal formation, or age – should be considered extremely dangerous.
   vi. The precautions taken for disposal of these materials should be the same as for any material that can be detonated by friction or shock. IT IS OF THE UTMOST IMPORTANCE THAT THE CONTAINER NOT BE OPENED! THE ACT OF OPENING THE CONTAINER COULD DETONATE PEROXIDE CRYSTALS under the container cap or other closure. Peroxidation in a chemical process may not only be a serious hazard, because of the explosion potential, but may also affect lower yield and unwanted impurities.

10) Chemicals of High Acute & Chronic Toxicity: Substances that possess the characteristics of high chronic toxicity cause damage after repeated exposure or exposure over extended periods of time. Health effects often do not become evident until after a long latency period. Specific acute and chronic toxicity information on the substances used in your laboratory can be found on these substances in the SDS. Lab personnel of childbearing age should be informed of any known male and female reproductive toxins used in the laboratory.

a) **Solvents**
   i. The primary routes of entry are through inhalation and skin absorption.
   ii. Toxic effects of some solvents (plus flammable properties) must be considered. Generally, solvents are used in a fume hood.
   iii. If used outside a fume hood, the permissible exposure limits (PEL) and the need for respiratory protection must be evaluated. Contact the BSO for more information.
   iv. Non-latex gloves must be worn; evaluate the solvent's permeation rate to determine the type of gloves

required.

v. Appropriate eye protection (goggles, face shield) must be used.
vi. The date of receipt and date of opening must be recorded on containers of solvents that could present a long-term storage hazard, such as peroxide-forming materials.
vii. Special procedures may be required for certain extremely hazardous chemicals (e.g., phenol) and OSHA substance-specific chemicals (such as benzene and formaldehyde) (see below).

b) **Formaldehyde**

i. Exposure to any formaldehyde solution, gas, or mixture composed of >0.1% formaldehyde is considered a potential carcinogen. Any employee that will be working with formaldehyde must inform the BSO.
ii. The OSHA PEL (Airborne Concentration) is not to exceed 0.75 ppm calculated as an 8-hr time-weighted average (TWA). OSHA action level 0.5 ppm 8TWA (per 29 CFR 1910.1048); OSHA short-term exposure limit (STEL) is 2.0 ppm per 15 min.
iii. The employer must ensure that no employee is exposed to an airborne concentration exceeding one part formaldehyde per million parts air as an 8-hr TWA. This is to be accomplished by:
(1) mechanical controls – e.g., Fume hoods, etc., and
(2) respiratory protection.
iv. Employees at risk of potential overexposure to formaldehyde will be monitored per requirements of 29 CFR 1910.1048.
v. The Safety and Health Office will forward copies of the results for review by the Research BSO, the appropriate PI, and the VA Safety Officer.
vi. In case of overexposure, the PI must notify the employee within 15 days of results of dosimetry.
vii. All detectable results must be shared with the affected employee and the Occupational Health Physician. If results are above the listed safety range, the employee will be scheduled for a baseline examination. The Occupational Health Service will issue, then a letter to the PI and employee with recommendations.
viii. Each PI is responsible for implementing plans to reduce exposure.
ix. Areas identified as exceeding permissible exposure limits must be identified with the following warning:
(1) **DANGER: IRRITANT AND POSSIBLE CANCER HAZARD FORMALDEHYDE – AUTHORIZED PERSONNEL ONLY**
x. The Research BSO and PI are responsible for coordination of the monitoring with the VA Safety and Health Office.

c) **Xylene**

i. Exposure to xylene is not to exceed 100 ppm calculated as an 8-hr TWA. This is the action level per standard 29 CFR 1910.1000.
ii. Exposure is not to exceed 150 ppm per 15 min STEL.
iii. Measured levels exceeding recommended exposure require medical surveillance.
iv. Employees at risk of overexposure will be monitored per standard 29 CFR 1910.1000.
v. The Safety and Health Office will forward copies of the results for review by the Research BSO, the appropriate PI, and the VA Safety Officer.
vi. In case of overexposure, the Principal Investigator must notify the employee within 15 days of results of dosimetry.
vii. Plans must be implemented to reduce exposure.

d) **Carcinogens**

i. *Definitions*: Many chemical substances may generate malignant tumors in test animals under severe, prolonged, or combined conditions. The term "carcinogenic" has different meanings when used in scientific vs. regulatory contexts:
(1) The National Institute of Occupational Safety and Health (NIOSH) classify a chemical compound as a carcinogen when a controlled scientific study identifies a statistically significant increase in the incidence of malignant tumors solely related to the administration of the test substance. The compound is listed as a neo plastinogen when the tumors are benign or when they cannot be clearly classified as benign or malignant. The compound listed is an equivocal tumorigenic agent if rigorous

scientific proof of carcinogenicity or neo plastinogenicity is lacking. The classification system is published in the Registry of Toxic Effects of Chemical Substances, which is updated quarterly.

(2) OSHA has codified the employer's requirements for containing the hazards for the following substances:
   (a) 4-nitrobiphenyl
   (b) 3,3'-dichlorobenzidine
   (c) b-naphthylamine
   (d) 4-aminodiphenyl
   (e) b-propiolactone
   (f) 4-dimethylaminoazobenzene
   (g) vinyl chloride
   (h) a-naphthylamine
   (i) methyl chloromethyl ether
   (j) benzidine
   (k) ethylenimine
   (l) 2-acetylaminofluorine
   (m) n-nitroso dimethylamine
   (n) Benzene
   (o) 4,4'-methylene bis (2-chloroaniline)

ii. *General*: Any laboratory using an OSHA-regulated chemical carcinogen must consult the relevant Department of Labor regulations (29CFR 1910.1001-1045). The following pertains to all chemical compounds that may be scientifically rather than officially designated as carcinogenic or potentially carcinogenic. Each laboratory must survey the reagent chemicals stocked and used with regard to current concepts of tumorigenicity.

(1) The Principal Investigator has the responsibility to:
   (a) Acquire the knowledge and information regarding the tumorigenicity of these chemicals
   (b) Define laboratory procedures that minimize the hazards inherent in these chemicals
   (c) Inform the employee using these chemicals of the significant risks.
   (d) Arrange for immediate medical attention in case of accident involving ingestion, inhalation, or inoculation of any of these risks.
   (e) Inform the BSO of any suspected over exposure.

(2) The employees in these laboratories have the responsibility to:
   (a) Comply with safety policies.
   (b) Report unsafe working conditions.
   (c) Report any accident involving any of these chemicals.

iii. *Requirements:*

(1) Use of protective apparel is required; on leaving a designated area, remove protective apparel and thoroughly wash hands and skin surfaces.
   (a) Appropriate clothing may include jumpsuits, laboratory coats, aprons, dust masks or respirators, and gloves; clothing and equipment should be laundered or discarded after each use or contact.
   (b) Appropriate eye protective devices should be available and used in the work area; such devices may include close-fitting goggles and/or face shield.

(2) Personnel should wash hands and forearms after completing any procedures in which chemical carcinogens are used. Following gross contact with carcinogenic material, thorough showering and clothes change is mandatory.

(3) Carcinogenic chemicals should be segregated from other materials; a list of such chemicals should be posted on the door of the cabinet where they are stored.

(4) All work, including transfers, should be performed in controlled areas or restricted access, such as hoods, glove boxes, or portions of a laboratory specifically designated for that purpose.
   (a) Glove boxes should be kept at negative pressure with a minimum of two air changes per hour.
   (b) If positive-pressure glove boxes are used, they must be tested for tightness prior to each use.
   (c) Glove boxes should be vented into a hood equipped with a HEPA filter and an appropriate scrubber for vapors.

(5) Access to chemical carcinogens should be limited to knowledgeable individuals; the work area should be designated so as to preclude casual contact by others.
(6) Work surfaces should be covered by dry absorbent plastic-backed paper, which should be disposed of after each procedure in proper antineoplastic waste containers; alternatively, the work surface should be constructed of impervious material and thoroughly decontaminated after each procedure.
(7) Working quantities should be maintained at a minimum. In all cases where known carcinogens are in use, serious attempts should be made to change the procedures, substituting chemicals with less inherent hazard.
(8) Accurate records should be kept of the amounts of substances stored and used, along with the names of persons using them and the dates used.
(9) Labeling of the chemicals and the work area is mandatory when carcinogenic risk is significant. The recommended precautionary label should include the following warning;
  (a) CAUTION CANCER-SUSPECT AGENT (Additional precautions may be specified regarding flammability, radioactivity, etc.)
  (b) Contingency plans, equipment, and materials must be available in case of accidents or spills.
(10) Limitations: Medical Center laboratories may not be able to meet all the requirements for compliance with federal regulations. As a bare minimum, it is recommended that:
  (a) An inventory of reagents and materials must be taken and update every six months.
  (b) Substances identified as carcinogenic must be set aside in a special area for proper labeling and controlled access.
  (c) The use of these reagents be reviewed and limited to critical procedures as ordered by the Principal Investigator.
(11) All materials that come in contact with the carcinogen agent should be disposed of properly in properly labeled and color coded containers
(12) For work with antineoplastic agents and animals please see the animal facility SOP to work with carcinogens.

e) **Flammables:** Flammable liquids are among the most common of the hazardous materials found in laboratories. They are usually highly volatile and their vapors, mixed with air at the appropriate ratio, can ignite and burn.
  i. While working with flammable liquids you should wear non-latex gloves, protective glasses, and long sleeved lab coats.
  ii. Reagents in one gallon or larger glass containers (for purity) must be placed in bottle carriers when transported from one area to another to reduce the danger of breakage.
  iii. Small quantities (working amounts) may be stored in the laboratory. These quantities are to be kept to a minimum, and containers must be clearly labeled. Bulk storage must be in an approved flammable storage cabinet refrigerators and freezers specifically designed for flammable storage or in a designated room.
  iv. Never store glass containers of flammable liquids on the floor.
  v. Hoods are NOT storage areas.
  vi. Ether must be stored in a closed area such as a refrigerator, nor kept in storage for more than 1 year unless it contains inhibitors known to prevent the formation of peroxides. Opened containers of ether should be discarded within six (6) months of the date first opened. Thus, cans should be dated when received and again when opened. Ether is not to be discarded via the drains (see section on Hazardous Waste Disposal of this Research Chemical Hygiene Plan). Empty containers are to be placed in a fume hood with the cap off overnight before discarding.
  vii. Electrical bonding should precede the transfer of flammables from one metal container to another in order to avoid a static spark that may result from pouring the solvent.
  viii. Flammable liquids are not to be stored in a refrigerator unless it is approved for flammable storage in accordance with NFPA standards 45 and 46. Refrigerators approved for flammable storage shall be labeled as such.
  ix. When using flammables in the laboratory all sources of ignition should be turned off.

f) **Incompatible Chemicals:** Certain hazardous chemicals should not be mixed or stored with other chemicals

because a severe reaction can take place or an extremely toxic reaction product can result. The label and SDS will contain information of incompatibilities. The following table contains examples of incompatible chemicals:

Chemical	**Incompatible Substances (**keep out of contact with:)
Acetic acid	Chromic acid, nitric acid, hydroxyl-containing compounds, ethylene glycol, Perchloric acid, peroxides and permanganates
Acetone	Concentrated nitric and sulfuric acid mixtures
Acetylene	Copper (tubing), fluorine, bromine, chlorine, iodine, silver, mercury and their compounds
Alkali metals (calcium)	Water, carbon dioxide, carbon tetrachloride, other chlorinated hydrocarbons and halogens
Ammonia (anhydrous)	Mercury, halogens, calcium, hypochlorite, hydrogen, fluoride, chlorine, iodine
Ammonium nitrate	Acids, metal powders, flammable liquids, chlorate, nitrites, sulfur, and finely divided organics or combustibles
Chemical	**Incompatible Substances:**
Aniline	Nitric acid, hydrogen peroxide
Arsenical materials	Any reducing agent
Azides	Acids
Bromine	Ammonia, acetylene, butadiene, butane, benzene, hydrogen, methane, propane, sodium carbide, turpentine, and finely divided metals
Calcium Oxide	Water
Carbon (activated)	Calcium hypochlorite, all oxidizing agents
Carbon tetrachloride	Sodium
Chlorates	Ammonium salts, acids, metal powders, sulfur, finely divided organics or combustibles, carbon
Chromic Acid	Acetic acid, naphthalene, camphor, glycerin, turpentine, alcohol, flammable liquids in general
Chlorine	Ammonia, acetylene, butadiene, butane, methane, propane, hydrogen, sodium carbide, turpentine, benzene, and finely divided metals
Chlorine Dioxide	Ammonia, methane, phosphine, hydrogen sulfide
Copper	Acetylene, hydrogen peroxide
Cyanides	Acids
Flammable liquids	Ammonium nitrate, chromic acid, hydrogen peroxide, nitric acid, sodium peroxide,

	halogens
Hydrocarbons, general	Nitric acid, oxidizing gases
Hydrocyanic Acid	Nitric acid, alkali
Hydrofluoric Acid	Ammonia, aqueous or anhydrous
Hydrogen peroxide	Copper, chromium, iron, most metals or their respective salts, flammables, alcohols, acetone, organic materials, aniline, oxidizing agents and nitromethane
Hydrogen Sulfide	Fuming nitric acid, oxidizing gases, acetylene, ammonia, hydrogen
Hypochlorite	Acids, activated carbon
Iodine	Acetylene, ammonia, and hydrogen
Mercury	Acetylene, fulminic acid, ammonia
Nitrates	Sulfuric acid
Nitric acid	Acetic, chromic, and hydrocyanic acids; aniline, carbon, hydrogen sulfide, flammables, readily nitrated substances
Nitrites	Acids
Oxalic acid	Silver, mercury
Chemical	**Incompatible Substances:**
Oxygen	Oils, grease, hydrogen, flammables
Perchloric acid	Acetic anhydride, bismuth and its alloys alcohol, paper, wood and other organics
Phosphorous pentoxide	Water
Potassium	Carbon tetrachloride, carbon dioxide, water
Potassium Chlorate	Sulfuric and other acids
Potassium permanganate	Glycerin, ethylene, glycol, benzaldehyde, sulfuric acid
Silver	Acetylene, oxalic acid, ammonium compounds
Sodium	Carbon tetrachloride, carbon dioxide, water
Sodium Peroxide	Ethyl or methyl alcohol, glacial acetic acid, acetic anhydride, benzaldehyde, carbon disulfide, glycerin, ethylene glycol, ethyl acetate, methyl acetate
Sulfuric acid	Chlorates, perchlorates, permanganates

g) **Laboratory Procedures Involving Radioactivity**

i. Coats or other protective clothing are to be worn at all times in areas where radioactive materials are used.

Film badges are to be worn when working with sources of radiation, as designated by the Facility Radiation Safety Officer.

ii. Disposable gloves must be worn at all times.

iii. In case of a spill, hands and clothing must be monitored for contamination before leaving the area; clean-up procedures established by the Radiation Safety Office must be followed.

iv. Nonporous absorbent lab mats are to be used on all work benches, trays, and other work surfaces where radioactive materials are handled; these mats will be replaced daily in areas that are used regularly.

v. Solid and liquid radioactive waste must be disposed of as instructed by the Radiation Safety Office. Some waste may be hazardous according to the EPA.

vi. Radioactive solutions must be confined in covered containers or shielded containers, plainly identified and labeled with name of compound, radionuclide, date, activity, and radiation level if applicable.

vii. The amount of radioisotopes stored at any one time in any laboratory must not exceed the possession limit for the authorized user.

viii. A weekly wipe test (or a monthly test when no radioactive material has been used), will be done by laboratory personnel to monitor radioactive material in the area.

ix. A permanent record of the weekly survey results will be kept by the laboratory and reviewed periodically by the Radiation Safety Office.

11) HOUSEKEEPING, MAINTENANCE, AND INSPECTIONS

a) **Housekeeping**

i. Environmental Management Service (EMS) is responsible for routinely cleaning all floors within the Research Service, (except in the Veterinary Medical Unit, VMU, laboratories. Hallways within the VMU will be cleaned as needed).

ii. All research laboratory personnel are responsible for daily cleaning of all bench tops and other work areas, such as fume hoods and laminar flow hoods.

iii. **All telephones within the research laboratories should be routinely disinfected.**

iv. Special arrangements must be made with EMS to have floors waxed.

b) **Maintenance**

i. All laminar flow hoods will be inspected, cleaned, and certified on a yearly basis. Staff will not use hoods lacking certification or where certification has expired.

ii. Fume hoods will be inspected and necessary maintenance performed by Engineering Service on an annual basis.

iii. Eye wash fountains

(1) Engineering Service will inspect all eye wash fountains on weekly and monthly basis.

(2) Any problems will be recorded on the inspection report when it is submitted to the Research Office so that Engineering Service can be notified to take corrective action.

iv. Emergency drench-type showers: Engineering Service will inspect all emergency showers at periodic intervals.

v. Fire extinguishers: Medical Center Safety and Health Office will inspect all Research Service fire extinguishers on a monthly basis.

c) **Inspections**

i. Quarterly inspections of research areas will be carried out by appropriate Research Service Personnel. The Research BSO will inspect annually areas where hazards are in use. (This does not include radioisotopes, since areas using them are routinely inspected by the Radiation Safety Office.)

d) **Passageways**

i. Stairwells and hallways should not be used as storage areas.

ii. Access to emergency exits, emergency equipment, and utilities controls should never be blocked.

iii. Emergency exit routes should be posted.

12) MEDICAL PROGRAM

a) **Routine Surveillance**

i. The Occupational Health Office administers the surveillance program, as outlined by OSHA regulations, for all VA employees who handle or are exposed to hazardous materials. The following are monitored by Occupational Health on an as-needed basis:
   (1) Formaldehyde
   (2) Asbestos
   (3) Anticholinesterases/insecticides
   (4) Chemotherapeutic agents
   (5) Ethylene oxide
   (6) Nitrous oxide
   (7) Noise
   (8) Ionizing radiation
   (9) Blood-borne disease agents
   (10) Xylene
   (11) Animal Dandruff

ii. See Medical Center Memorandum 05-3 for a description of the facility's Occupational Health Program.

b) **Emergency First Aid Procedures**

i. In case of chemical splash to the eyes, ask coworkers to help you wash the eyes thoroughly; lift eyelids to avoid pooling of chemicals under eyelids. Flush with water for 15 minutes.
   (1) Consult Occupational Health immediately.
   (2) Report accident to immediate supervisor and BSO.
   (3) Submit form CA-1/CA-2 electronically.

ii. Cuts, punctures, needle sticks
   (1) If the injuries are clean cuts punctures, and needle sticks: clean the affected area immediately with surgical soap, then flood or soak affected area in antiseptic fluid. Bandage to prevent infection. Report to Occupational Health.
   (2) If the injuries are dirty cuts, punctures, or needle sticks (e.g., those contaminated with patient blood or body fluids or bacterial agents): proceed as above if no object that caused the wound is left in the wound. Report to Occupational Health
   (3) If the object causing the injury is not easily removed, do not attempt to cleanse the area; doing so may cause further damage. Report to the emergency department immediately.
   (4) If the object that caused the injury is contaminated with patient specimens, identify the specimen with the patient's name for further evaluation and investigation. Thoroughly cleanse the wound. Report to Occupational Health immediately.
   (5) Report ALL incidents of any degree to the Supervisor and BSO. Consult Occupational Health. The supervisor or PI has to submit a Form 2162 "Report of Accident" through ASIST to Hospital's Safety Officer and CA-1 to the Research BSO.
   (6) Chemical Burns
      (a) Corrosives can cause second- and third-degree burns. These chemicals include alkalis such as sodium hydroxide, and common acids such as hydrochloric, sulfuric, and nitric
      (b) Chemicals should be diluted and washed off with copious amounts of water. Minor splashes and spills can be flooded in a sink. Larger spills and splashes require the use of the emergency drench-type shower. Enlist the help of co-workers. Some chemical powders should be brushed off the skin before flooding with water, to avoid further skin and tissue damage. Always consult the chemical manufacturer's SDS for emergency first-aid procedures BEFORE working with any chemical.
      (c) When a burn of any degree occurs, report to the emergency department immediately.

13) PROTECTIVE APPAREL AND EQUIPMENT

a) Personnel Protective Equipment (PPE) includes gloves, goggles, face shields, aprons, fluid impervious gowns, masks, and respirators. Although the use of such equipment is generally the least desirable way to control workplace hazards, because it places the burden of protection on the worker, the equipment must be available for situations when an unexpected exposure to chemical substances, physical agents, or biological materials could have serious consequences. Before the purchase or use of any personal protective equipment, the Research Biosafety Officer or the VAMC Safety and Health Office should be consulted to determine whether the equipment is acceptable.
b) Employees should always wear long legged clothing and avoid short-sleeved shirts. A laboratory coat should always be worn over street clothes and be laundered weekly in the Medical Center laundry. Dirty laboratory coats must be brought down to the laundry on Fridays after 1:00 pm. Solid shoes should be worn in the laboratory at all times. Sandals and perforated shoes are prohibited in the laboratories.
c) The types of personal protection equipment are listed below:

i. **Eye wear**:
(1) Chemical splash goggles and/or face shields, rather than safety glasses, should be used when pouring hazardous chemicals or hazardous waste, as they provide the best protection against splashes.
(2) Protective eyewear must be available in all areas where hazardous substances are used.
(3) Protective eyewear should be easy to clean and disinfect.
(4) For those employees who wear glasses, goggles must fit over glasses.
(5) When handling highly reactive substances or large quantities of hazardous chemicals, corrosives, poisons, and hot chemicals, goggles with face shield have to be worn.

ii. **Gloves**:
(1) Employees must wear appropriate protective gloves (latex or alternatives) when handling all patient specimens.
(2) Acid-resistant gloves will be used in all areas utilizing acids.
(3) Appropriate protective gloves should be used whenever hand contact with formaldehyde is possible; latex gloves are not acceptable while handling formaldehyde because they are too fragile.
(4) Chemical resistant gloves should be worn whenever the potential for contact with corrosive, toxic, hazardous substances and substances of unknown toxicity exists.
(5) Before each use, gloves should be checked for integrity.

iii. **Respirators:**
(1) The Research Department at Atlanta VA Medical Center has adopted a written plan for using respirators. This plan outlines organizational responsibilities for the following respirator program components: exposure assessment, respirator selection, medical approval and surveillance, fit testing, user training, and storage. Each of these program components is required by OSHA's respiratory protection standard (29 CFR 1910.134) in all situations where respirators are used. If you are using a respirator and are not included in the respirator protection program, or have questions concerning the use of respirators, contact the Research BSO (x207273 or x 201569).

iv. **Other personal protective equipment**:
(1) Rubber, acid-resistant aprons should be used when pouring concentrated chemicals.
(2) Disposable jumpsuits (Tyvek) (if there is a need to completely cover clothing) are available from the Supervisor, Veterinary Medical Unit.

v. For more information on PPE, please refer to the PPE Program and Respiratory Protection Program included in this manual, Section V.

14) RECORDKEEPING

a) **Accident Reporting**
i. Supervisors will accompany injured employees experiencing an occupational injury/illness to the Occupational Health Clinic and they will electronically file the appropriate report in ASISTS. (MCM 00-

11).

ii. Accident reports will also be investigated by the BSO and reviewed by the Subcommittee on Research Safety at its next meeting.
iii. **Any accidents that caused an injury, including cuts, contusions, falls etc.**
iv. **Any potential incidents that could lead to exposures, including spills, needle sticks, bites.**
v. **Any near-misses that could have resulted in an accident or exposure but did not.**
vi. Any unexplained illnesses that present the signs and symptoms of exposure

b) **Medical Record keeping**

i. Medical records will be retained in accordance with OSHA's medical records rule (29CFR 1910.20), state and federal regulations.
ii. Individuals may obtain copies of their reports by making a request in writing to the Occupational Health Service.

c) **Spill Reporting and Emergency Spill Procedures**

i. Chemical spills must be reported immediately by dialing extension 204911 and reporting the material spilled and the location of the spill to the Operator. Spill area must be blocked and restricted to unauthorized personnel walking through the area. Research personnel should use the spill kit to initiate clean-up until help arrives.

ii. Report all spills, accidents, and potential exposures to the laboratory supervisor and the BSO immediately. Also, maintain a written record of the accident in the laboratory.

d) **Chemical Inventory** (Ref.: VAC Memo, Hazardous Materials and Waste Management)

i. A complete inventory of all chemicals used in each research laboratory/program will be maintained by the PI in each laboratory, also will be available on the intranet.
ii. An updated copy of the inventory will also be posted on each laboratory main door.
iii. A copy of the complete chemical inventory will be sent electronically to the Research BSO every time it is updated.
iv. An inventory of hazardous wastes will be kept in the Administrative Officer's office.
v. Inventories must be updated every time a new chemical is received in the laboratory and every 6 months. Each chemical listed must have a corresponding SDS, readily accessible to affected employees.
vi. Safety Data Sheets (SDS) can be found online at https://vaww.ceosh.med.va.gov/ceosh/SDS.shtml.

15) SIGNS AND LABELS

a) Prominent signs and labels of the following types should be posted:
   i. Telephone numbers of emergency personnel, supervisors, and laboratory workers
   ii. Location signs for safety showers, eye wash stations, other safety and first-aid plans
   iii. Location of emergency kits
   iv. Location of SDS: https://vaww.ceosh.med.va.gov/ceosh/MSDS.shtml.
   v. Warnings at areas of unusual hazards; i.e., radioactive materials, x-ray equipment, etc.

Note: The main door to the lab must be free of posters, pictures or other information that is not the Chemical Inventory List, and the Radio safety and Biosafety decals.

b) Each chemical must be labeled with the following information:
   i. Chemical identity
   ii. Appropriate hazard (e.g., caustic, corrosive, poison, irritant, flammable, carcinogenic, etc.)
   iii. Date received
   iv. Date opened
   v. Expiration date, if any
   vi. Storage requirements
c) Torn or illegible labels should be replaced immediately. Existing labels on new containers of hazardous chemicals should never be removed, except when empty.

d) All chemical solutions of 1% or greater must bear the same hazard warning label as the concentrated chemical(s).

16) SPILLS AND ACCIDENTS

a) **Chemical Spills** (Reference: VAMC Fire and Disaster Plan)

i. ALL spills must be reported to the BSO (x207273 or 1569).

ii. Spill control kits are located in rooms 5A118, 4A150, 12C189, and 11C120.

iii. The Research BSO and/or the Radiation Safety Manager (at the supervisor's request) should instruct laboratory personnel in proper use of spill kits on an annual basis. *Chemical spills should only be cleaned up by knowledgeable and experienced personnel. The BSO, X207273 or 1569 and Industrial Hygienist, X206115 should be contacted in the event of a major chemical spill.*

iv. "Incidental" chemical spills (Usually small and not immediately life threatening):

(1) Attend to anyone who may have been contaminated.
(2) Notify all personnel in the immediate area of the spill.
(3) If the spill is flammable, turn off ignition and heat sources.
(4) Leave on or establish exhaust ventilation if it is safe to do so.
(5) Obtain spill kit materials and proceed with cleanup, following the package directions and wearing appropriate personal protective equipment.

b) **Mercury spills**:

i. Evacuate everyone from the area and control access.

ii. Immediately notify the Research BSO and the facility's Industrial Hygienist.

iii. For cleanup after normal working hours, page the Environmental Management Supervisor on duty.

iv. Mercury is prohibited on the campus of the Atlanta VAMC. Therefore, any mercury found/observed in any of the laboratories should be reported to the BSO, X207273 or 1569, and Industrial Hygienist, X206115, for proper disposal.

c) **Emergency spill situations** (Usually large or spills with harmful fumes):

i. DO NOT ATTEMPT CLEANUP YOURSELF!

ii. Attend to anyone who may have been overcome by fumes, chemicals spilled or splashed on the body, or otherwise contaminated.

iii. Notify and evacuate all personnel in the immediate area of the spill/release. Control access to the area by shutting doors.

iv. If the spilled material is flammable, turn off ignition and heat sources.

v. Leave on or establish exhaust ventilation if it is safe to do so.

vi. Immediately notify your supervisor as well as the Research BSO, and the Security and Safety Officers.

Close doors and secure the affected area; if available, also place damp cloths or towels along the base of doors to prevent escape of vapors from the room. Chemical spills must be reported immediately by dialing extension 204911 and reporting the material spilled and the location of the spill to the Operator.

d) **Biological Spills**

i. Large spills with significant aerosol formation: evacuate the area at once and notify the Safety and Health Office immediately.

ii. Small spills with aerosol formation:

(1) Spray affected area with 5% sodium hypochlorite or 85% ethanol.
(2) Place paper towels over spill and wait until they absorb spilled material about 10 minutes.
(3) Wear appropriate PPE to pick up contaminated materials; dispose in biohazard bags.
(4) Clean affected area with soap and water. Dispose of PPE appropriately.

iii. Spill Evaluation

(1) All spills and near-spills will be carefully analyzed by the BSO the Radiation Safety Manager, and Medical Center Safety Committee. Following analysis, results will be given to all personnel to prevent further incidents.

NOTE: If clothing is damaged, scrubs are available in the Animal Research Facility.

17) EMPLOYEE INFORMATION AND TRAINING

a) All employees exposed, or **potentially** exposed, to hazardous chemicals while performing their laboratory duties will receive information and training regarding the standard, the chemical hygiene plan and laboratory safety. The Research Service CHP will be readily available to all employees and students. A copy of the plan will be available in each laboratory as well as in the Research Office. Prior to beginning work assignments, Research personnel are trained in the laboratory practices by the PI and must take Laboratory Biosafety online at http://www.citiprogram.org/. Annually, thereafter, Laboratory Biosafety Refreshers are to be done online at http://www.citiprogram.org/. Research personnel will receive annual training in the following areas by the Research BSO:

i. Methods and observations utilized to detect the presence and release of hazardous chemicals.
ii. Physical and health hazards of chemicals in the laboratory.
iii. Measures employees can take to protect themselves from chemical exposure hazards, including emergency procedures and personal protection equipment.
iv. Spill cleanup procedures.
v. Signs and symptoms associated with exposure to hazardous chemicals used in the laboratory.
vi. Safe handling and disposal of hazardous chemicals.
vii. SDS.
viii. Security procedures
ix. HAZMAT procedures
x. Emergency procedures
xi. Reporting procedures

b) Employees will be provided with information, on an annual basis, regarding infection control guidelines and the emergency preparedness plan.

c) When an employee is to perform a non-routine task presenting hazards for which he or she has not already been trained, the employee's supervisor (PI) will be responsible for discussing with the employee the hazards of the task and any special measures. This will include any pre-screening necessary with occupational health and appropriate PPE for the associated risks of the non-routine task. Additionally, specific laboratory protocol training and competencies of laboratory personnel are the responsibility of the PI. Documentation of this initial training and competency should be maintained by the PI or laboratory manager.

18) HAZARDOUS WASTE DISPOSAL: Consult SDS for the manufacturer's recommended disposal methods.

a) **Sewer Disposal**

i. Liquid waste:
(1) Some liquids may be flushed into the sewer system with copious amounts of water, provided the chemical volume is minimal (less than 1 ml) and the pH is ~7.4.
(2) Biomedical waste solutions containing active cells (tissue) must be properly deactivated prior to disposal into the sewer system.
(3) Disposal through the sewer system must comply with all federal, state, and local regulations and ordinances.
(4) The BSO and Health Office should be consulted when in doubt whether a chemical can be disposed of via the sewer system.

ii. **Contracted Disposal**
(1) Research personnel will not store hazardous waste beyond a 7-day period unless approved by the facility's industrial hygienist. Approved containers, flammable storage cabinets or designated vaults will be used for temporary storage.
(2) Hazardous chemicals stored for disposal will be in compatible groups, in appropriate containers of proper size, labeled clearly to indicate hazard warnings, and will comply with applicable fire and safety warnings.
(3) Research personnel will complete the hazardous waste label and attach to each container before

turning them in to the Hazardous Materials Building for disposal. The hazardous waste label can be found in Research's I: drive under the Biosafety Folder, titled Chemical Waste Label.

(4) Each individual container must have one form and label.

(5) Move materials to the Hazardous Material Storage Building located between Parking Decks E & F.

(6) The building is open each Wednesday from 2:00pm to 3:00pm or by appointment calling the Research BSO (x207273 or 1569).

(7The service elevators located in the Clinical Addition, or Main Tower should be use as primary route to reach the service court. Due to the present construction taking place in the Service Court, the safest route to this location would be to use the Service Elevators (S-1 or S-2) located in Section A (Clinical Addition) or Service Elevator (S-7) located in Section B. Either of these elevators can be used to the Ground Floor. Research personnel should follow the corridor to the Atrium in Section A then exit the building through the automatic doors. If using a cart, all personnel should follow the wheelchair ramp to the sidewalk and then follow it further to the HAZMAT building.

(8) Transport all hazardous materials in their original containers if available. If the original container is not available, adequate compatible containers must be used. Improper, damaged, or unsealed containers **will not** be accepted at the building. All hazardous materials must be transported using carts which are safe and sturdy. Spill kits are required when transporting liquid solvents and corrosives. (9) The Waste contractor will make regular pickups.

(10) The Safety office will be provided with the complete inventory and a copy of the Waste Manifest of all hazardous waste picked up by a contractor.

(11) ***Recycling and Waste Minimization*** – To reduce the amount of waste generated, it is imperative that you are conservative with your chemical orders. Only order what you need. If chemicals you would like to dispose have not expired, another lab or facility may be able to use them. Contact your Chemical Hygiene Officer or the IH, who may be able to find someone that can use them.

19) SAFETY RECOMMENDATIONS

a) The following practices are those that are directed primarily toward prevention of physical injury rather than toward prevention of toxic exposure. However, failure to take precautions against injury will often have the secondary effect of causing toxic exposure. Therefore, the following have been added to this Chemical Hygiene Plan.

i. Electrical Safety

(1) Grounding: All instruments must be grounded and periodically checked by the Biomedical Engineers.

(2) Shocks: All shocks of any magnitude must be reported to the Research Service immediately so that the equipment can be checked. Do not attempt to use an instrument that is causing shock. Small shocks often precede major shocks.

(3) Repairs: Repairs on the electrical system by other than Engineering personnel are prohibited. Any work performed on switches, outlets, circuit boxes, or equipment must be done by Engineering Service personnel. Notify Research Service so that it can request assistance from appropriate Engineering personnel.

(4) Extension cord usage: The use of 3-to-2 wire adapters (cheater plugs, multiple outlet plugs) and extension cords are prohibited on all equipment. Modifications to electrical distribution systems shall be accomplished where their use seems indicated; excessively long lines are to be avoided.

(5) Adapters are to be avoided wherever possible. If they must be used to allow equipment fitted with distinctive plugs to be used with conventional grounded outlets, they shall be inspected by Engineering Service monthly to assure continuity of all conductors.

(6) Any personal electric device, (i.e. toasters, microwave ovens, radios, etc.) brought into the institution by any employee must be approved and tagged by the facility's safety officer x 204257)

ii. Fire Safety

(1) Procedures to follow in case of fire, Remember (RACE):

R: **Remove** employees/patients/visitors/others to a safe area, if possible
A: **Activate** nearest manual fire alarm box and/or dial 204911 to report exact location
C: **Confine** fire by closing doors and windows
E: **Extinguish** fire and evacuate patients and visitors if necessary.

(2) Prevention
(a) Be aware of ignition sources (e.g., open flames, heating elements, spark gaps).
(b) Do not use flammable liquids in the presence of ignition sources.
(c) Flammable liquids give off vapors that may also ignite or explode. Be sure that flammable liquids (other than small, "workable" quantities) are properly stored in approved flame cabinets or in a designated area.
(d) Do not store materials so they block or hinder the action of the building fire suppression systems.

(3) Control of fires:
(a) Evaluation:
(i) Evaluate the type and extent of the fire; if it seems large, get out. Control measures should only be taken for small fires.
(ii) If the fire is small, evaluate the type of material burning (wood, flammable liquids, electrical, gases) and take action as indicated below.
(b) Action (for small fires only):
(i) Solid combustibles:
1. Handle small objects with heat-resistant gloves and extinguish with water or CO_2.
2. CO_2 or dry chemical extinguishers may be needed for larger objects
(ii) Flammable liquids: Dry chemical extinguishers are usually needed for safe and effective control of burning liquids. Do not use water; it enhances the fire's spread.
(iii) Electrical equipment:
1. Do not use water unless the circuit has been shut down; shut down the circuit if possible.
2. CO_2 is most suitable to prevent further damage to computer equipment, but dry chemical extinguishers are also safe and effective.
(iv) Gas:
1. Shut off source if possible.
2. Extinguish flame when CO_2 has been shut off.
3. Keep flames away from gas cylinders.

(4) Fire safety equipment:
(a) Use sand or absorbent material to contain spread of liquids that have not ignited.
(b) Fire extinguishers are of the CO_2 chemical type, and may be used on any type of fire.
(c) Heat-resistant gloves may be used to move or handle small burning objects, to handle hot vessels, to turn off hot valves or handles, etc.

20) References:

a) OSHA Standard 29 CFR 1910.1450, "Occupational Exposure to Hazardous Chemicals in the laboratory".
b) OSHA standard 29 Subpart Z.
c) VHA Handbook 1200.08

SECTION VI

RESEARCH SERVICE PERSONAL PROTECTIVE EQUIPMENT PROGRAM

RESEARCH SERVICE PERSONAL PROTECTIVE EQUIPMENT PROGRAM

1) PURPOSE

a) To establish policy and procedures for the proper use and maintenance of personal protective safety apparel and/or equipment in the Research Service area protecting employees from the risk of injury by creating a barrier against workplace hazards. Personal protective equipment (PPE) is not a substitute for good engineering or administrative controls or good work practices, but should be used in conjunction with these controls to ensure the safety and health of employees.

2) POLICY: Performance of certain duties requires specialized clothing and/or equipment. This policy is designed to promote an awareness of procedures to be utilized in obtaining the necessary items to assure the safety of our employees. Employees are required to observe all precautions for personal safety, posted rules, signs, written or verbal safety instructions and to use protective clothing and/or equipment, as required by their assigned duties.

a) Personal protective equipment is justified only when the job hazard cannot be eliminated by other means.
b) This equipment will be provided by the VA at no expense to the employee if justified by the supervisor as a protection from occupational hazards and not merely as a convenience or comfort to the individual.
c) All personal protective equipment purchased by this Medical Center remains the property of the Department of Veterans Affairs.
d) Any personal protective equipment that shows evidence of being misused will be replaced at the employee's expense.
e) Each employee, regardless of job title or assignment, who performs a duty considered hazardous, will use adequate personal protective devices.
f) Visitors to hazardous areas, which are readily identified, will be provided the necessary safety equipment to afford them the same personal protection as that provided to other personnel.
g) Employees are authorized to wear only issued, non-interchangeable, personal protective equipment during work only and not after duty hour or for personal work or activities. Misuse of personal protective equipment violates Public Law 722 (18 U.S.C. 641).

3) REFERENCES:

a) American National Standards Institute (ANSI) standards for Personal Protective Equipment (PPE)
b) Occupational Safety and Health Administration (OSHA) primary PPE standards, Title 29 CFR 1910.132 through 1910.138

4) DEFINITIONS:

a) ***Non-interchangeable safety Equipment***- those items of personal equipment i.e., gloves, safety glasses, respirators, etc., which should not be reconditioned for reissue.
b) ***Interchangeable Safety Equipment***- those items of personal equipment which can/should be reconditioned for reissue, i.e., goggles, face shields, etc.

5) RESPONSIBILITIES:

a) **Research Biosafety Officer**
   i. Provide training and technical assistance to supervisors/personnel on the proper use, care and cleaning of approved PPE.
   ii. Conduct periodic inspections of usage of PPE issued by supervisors throughout the Research Service Area.
   iii. Provide guidance to the PI for the selection and purchase of approved PPE.
   iv. Review, update and evaluate the overall effectiveness of the PPE Program.

b) **Occupational Health Office**
   i. Will be responsible for the development and maintenance of an effective Medical Surveillance Program as required for certain users of PPE such as respirators. (For more information, see Research Respiratory Protection Program.)

c) **Associate Chief of Staff**

i. Ensure that personnel in his area of responsibility are not exposed to potential occupational safety and health hazards, by procuring only PPE, which is recommended for the intended use and meets the regulatory requirements for that protection.
ii. Ensure that each principal investigator (PI) conducts a Risk Assessment Survey/Personal Protective Equipment (PPE) Selection Survey for every position under his supervision to determine that each employee is receiving the proper PPE and in-service training in the use and care of that equipment. All requests for any kind of PPE will be submitted for approval by the Research BSO before ordering.

d) **Principal Investigator/Supervisor**

i. Responsible for providing PPE to employees at no charge adequate for the associated risks in the laboratory
ii. Conduct periodic inspection of personal protective equipment to assure effectiveness and proper sanitation.
iii. Ensure employees are trained on the proper use, care, and cleaning of PPE.
iv. Maintain records on PPE assignment and training.
v. Supervise staff to ensure that the PPE Program elements are followed and that employees properly use and care for PPE.
vi. Initiate action for repair/replacement of equipment by submitting a written memorandum stating the justification for repair/replacement along with the item to their service line chief.
vii. Ensure that interchangeable equipment is retrieved from separating employees or those reassigned to positions not requiring items of safety equipment.

e) **Employee**

i. To follow the requirement of the PPE Program by wearing the PPE as required, attending required training sessions, and caring, cleaning, and maintaining PPE as required.
ii. Maintain equipment in good condition**.**
iii. Request replacement/repair through his/her supervisor.
iv. Turn in all issued interchangeable personal protective equipment upon request.

6) PROCEDURES:

a) **Safety Glasses**

i. Suitable eye protection shall be used when employees are exposed to hazards from acids or caustic liquids, chemical liquids, gases, or vapors, bio-aerosols, or biological hazards.
ii. Wearers of contact lenses must also wear appropriate eye and face protection devices in a hazardous environment.
iii. Goggles and face shields shall be used when there is a hazard from any of the following:
(1) when working with chemicals
(2) working with animals
(3) performing procedures that would potentially create splashes.
(4) procedures with a high potential for creating aerosols
(5) necropsy of infected animals, harvesting of tissues or fluids from infected animals
(6) manipulation of high concentrations of infectious materials.
iv. Emergency eyewash facilities are available in all Research areas where the eyes of any employee may be exposed to corrosive materials or chemicals.

b) **Laboratory coats/gowns**

i. Laboratory coats or gowns must be worn while working in any BSL2 laboratory.
ii. Laboratory coats can be obtained from the Laundry Service, located on the ground floor, Friday's after

1:00 pm.

c) **Hand Protection**
   i. Suitable gloves (latex or alternatives) shall be worn when hazards from chemicals, cuts, lacerations, abrasions, punctures, burns, biological and harmful temperature extremes are present.
   ii. Glove selection shall be based on performance characteristics of the gloves, conditions, duration of use, and hazards present (BMBL, 5th Ed., Appendix I).

d) **Respirators**- (Please see Research Service Respiratory Protection Program, section VII.)

7) REFERENCES:

a) Public Law 91-596, Para 19, dated December 29, 1970.

b) PSHA Safety and Health Standard, 29 CFR 1910.

c) Office of Health and Safety, Center for Disease Control and Prevention, dated January 2, 1997.

d) VA Medical Center, Safety Manual, Chapter 1 section 6, latest revised edition.

SECTION VII

RESEARCH SERVICE RESPIRATORY PROTECTION PROGRAM

RESEARCH SERVICE RESPIRATORY PROTECTION PROGRAM

1) **PURPOSE:** To establish a respiratory protection program that will provide effective protection for all Atlanta VA Medical Center Research service employees occupationally exposed to chemicals, gases, airborne pathogens and particulates, and other contaminants. Our primary objective is to control and prevent harmful exposure of contaminants by accepted engineering controls and administrative measures. When effective controls and measures are not feasible, or while they are being instituted, appropriate respiratory protection will be required.

2) **POLICY:** The VA Medical Center actively promotes and requires the use of respiratory protection when the atmosphere is susceptible to known and unknown contaminants.

3) **STANDARDS:**
   a) American National Standards Institute (ANSI) established standards for PPE equipment
   b) Occupational Safety and Health Administration (OSHA) primary PPE standards, Title 29 CFR 1910.134

4) **DESIGNATIONS:**
   a) **The Research Biosafety Officer** (BSO) in conjunction with the facility's industrial hygienist is responsible for the following:
      i. Establishing and implementing a respiratory protection program.
      ii. Provide annual training and maintaining training documentation for all users of respirators regarding specific respirators issued, and information on the hazards of gases, chemicals and known contaminants to include an appraisal of what may happen if the respirator is not used or improperly used.
      iii. Informing the employee why the respiratory protection to be used was chosen and its capabilities and limitations.
      iv. Conducting regularly scheduled inspections of the respiratory protection used by the Research service personnel.
      v. Successfully completing a respiratory protection-training course sponsored by the Occupational Safety and Health Administration (OSHA), National Institute for Occupational Safety and Health (NIOSH), or any other similarly accredited training institution.
      vi. Documenting testing frequency and the technique used for testing each respirator.

   b) **The Associate Chief of Staff for Research is responsible for the following**:
      i. Consult the BSO to determine which personnel under their supervision will need respiratory protection, and the type of respiratory protection required.
      ii. Scheduling personnel under their supervision for an annual medical evaluation by the Occupational Health Physician prior to fitting and using the respiratory protection. In addition, any new employees required to use respiratory protection would receive a medical evaluation prior to being fitted.
      iii. Ensuring that the respiratory protection is available as required.
      iv. Ensuring that employees wear the protection as required.
      v. Ensuring that Research Service personnel attend mandatory periodically scheduled respiratory protection program training classes scheduled by the BSO.
      vi. Providing adequate space to store the respiratory protection when not in use.
      vii. Ensuring compliance with all procedures listed in paragraph 4 below.

   c) **Research Service employees** who are required to wear respiratory protection are responsible for:
      i. To comply with all requirements and procedures listed in this respiratory protection program and any supplemental requirements.
      ii. Using the respiratory protection supplied to him/her in accordance with instructions, training and manufacturer's recommendations.

iii. Inspecting and having necessary repairs made through their supervisors prior to each use.
iv. Cleaning, disinfecting, inspecting and properly storing respirators after each use.

d) **The Office of Employee Health**:
i. To establish medical evaluation and surveillance procedures of Research area employees required to wear respiratory equipment.
ii. To review the health status of these employees annually and/or in the completion of their assigned tasks.

e) **Others**:
i. Personnel, such as employees, inspectors, and visitors, who must enter an area where the use of respiratory protective equipment is required, even when their stay time in the area may be 15 minutes or less, shall be provided with and use appropriate equipment, including instructions regarding use and limitations. Personnel shall be fit tested and medically qualified to wear the respirator being issued prior to entry to the site.

5) PROCEDURES: In accordance with VA policy and OSHA regulations, the following guidelines and procedures will be followed.

a) General procedures involving all known contaminants, including asbestos and TB, will be as follows:
i. Applicability- Respiratory protection shall be provided to all VA Medical Center employees exposed to or subject to exposure of toxic vapors, dust, mists, fumes, gases or TB.
(1) Respiratory protection is considered an acceptable method of protecting personnel when it has been determined that no feasible engineering or work practice controls can be used to adequately control the hazard.
(2) During the interim periods when engineering controls are being designed and installed.
(3) During emergencies.

NOTE: Respirators for use in areas where biohazards are used or stored must be selected based on a review of the laboratory procedures, protocols, biohazard agents proposed for use and engineering controls. The investigator and BSO will evaluate the associated risks for the personnel to make this determination.

ii. Selection or Respiratory Protection- The correct NIOSH approved respiratory protection for each job will be specified based on industrial hygiene evaluations or the requirements specified by Federal Law or VA policy.
iii. Health Screening- Personnel assigned tasks or jobs requiring the use of respirators must be medically evaluated prior to fitting and annually thereafter. The Employee Health Practitioner shall determine what health and physical conditions are pertinent. The medical status of each employee required to use a respirator shall be documented and reviewed annually while he/she is employed by the Department of Veterans Affairs.
iv. Assignment- Respiratory protection shall be assigned to individual workers for their exclusive use when practical.
v. Fitting of Respiratory Protection-
(1) Annual fittings will be provided to employees issued general purpose respiratory protection and will be performed in accordance with OSHA's 29 CFR 1910.134.
(2) Employees will not be fitted for respiratory protection under the following conditions that could prevent good face seal; a growth of beard, sideburns, a skull cap that projects under the face piece, or temple pieces on glasses; also, the absence of one or both dentures which seriously affect the fit of a face piece.
(3) No contacts are to be worn with respiratory protection, since they can hold irritant or toxic chemicals.
vi. Training- all users of respiratory protection shall satisfactorily complete a respiratory protection training course. The content of this training shall be in accordance with American National Standards Institute

(ANSI) No. Z88.2. Additional training procedures with which to comply are as follows:

(1) Every respiratory protection user shall receive instructions, including demonstrations and practice in how the respiratory protection should be worn, how to adjust it, and how to determine if it fits properly. The manufacturer's face piece fitting instructions shall be strictly adhered to each time VA personnel use respiratory protection. To assure proper protection, the face piece fit shall be checked by the user prior to every use.

(2) Each respiratory protection user shall receive instructions in the nature and degree of the hazards and a preliminary appraisal of what may happen if the respiratory protection is improperly used or not used at all. The user shall also be informed as to why the respiratory protection used was chosen, capabilities, and limitations of the respiratory protection.

(3) The instructor of all respiratory protection training courses must have successfully completed a respiratory protection training course sponsored by OSHA, NIOSH, or any similarly accredited training institution.

(4) The BSO is responsible for training Research personnel that are fit-tested and issued respirators. The training must include, but is not limited to inspection, donning, use, checking seals, and maintenance and storage of the issued respirator. Annual refresher respirator trainings will be performed on http://www.citiprogram.org/.

vii. Maintenance and Repair- A program for maintenance and repair shall include the following basic services:

viii. Inspection for Defects- prior to use of the respiratory protection, each user will perform an inspection to identify defects.

ix. Repair- Any defect must be repaired prior to re-use. Any repairs that may affect the respiratory fit will require fit testing prior to re-use, or if cannot be repaired to form a complete seal, the respirator must be replaced.

x. Storage- Respiratory protection shall be stored to protect against dust, sunlight, heat, extreme cold, excessive moisture, damaging chemicals or mechanical injury. Storage in a plastic bag or other closed container is required.

xi. Cleaning and Disinfecting- The following procedures are required for cleaning and disinfecting respiratory protection:

(1) Remove any filters, cartridges of canister.
(2) Thoroughly clean face piece and breathing tube with an adequate cleaner-disinfectant solution.
(3) Rinse completely in clean, warm water.
(4) Air dry in a clean area.
(5) Clean other respiratory protection parts as recommended by the manufacturer.
(6) Inspect valves, head strips and other parts. Repair or replace any defective parts.
(7) Replace filters or insert new filters if expired or loaded to the recommended capacity.
(8) Place in a plastic bag or other closed container for storage.
(9) Cleaner-disinfectant solution may be commercially prepared. An alternate method is to wash respirator parts in a liquid detergent solution, rinse and air dry. Several acceptable solutions are listed below.
   (a) Hypochlorite solution (50ppm chlorine) for two minutes.
   (b) Aqueous iodine solution (50ppm iodine) for two minutes.
   (c) Quaternary ammonium solution (200ppm of quaternary ammonium compound in water with less than 500 ppm for the total harness) for two minutes.

NOTE: Prolonged immersion in hypochlorite and iodine solutions can damage respirator parts by degrading the rubber and corroding metal parts. Quaternary ammonium compounds can cause dermatitis if not completely rinsed from the respirator. Vigorous mechanical agitation should not be used.

xii. Record Keeping- The following records will be maintained by the listed personnel. Hard copy records are required for the period of employment. Microfilm records may be used thereafter.

xiii. Medical Records- The medical records that establish the employee's ability to use a particular respiratory protection must be provided and maintained by the Employee Health Professional.

xiv. Air Sampling Records- all air sampling data must be preserved. This information shall be used to establish that the respirator chosen for a particular task will provide adequate worker protection. This data must be recorded on VA Form 10-0018 by the Facility Manager Service Chief.

xv. Training Records- Documentation of the training received by each user of a respirator must be kept by the Research Biosafety Officer.

xvi. Fit Testing Records- Testing frequency and the techniques used for fit testing each respirator must be kept by the Research BSO.

xvii. NEO Respirator User Permit- Documentation of the specific user's fit-tested / issued respirator must be maintained by the Research BSO on an annual basis.

xviii. **Affected employees will comply with the requirements of this respiratory protection program's procedures, guidelines and responsibilities for their own safety and protection.** Failure to comply may result in appropriate disciplinary action in accordance with Department of Veterans Affairs Manual of Procedures- 5, Part I, Chapter 752 and Medical Center Policy 05-23, "Discipline and Adverse Actions- Title 5 Employee."

6) References:

a) OSHA's Standard 29 CFR 1910.134.

b) Manual of Procedures- 5, Part I, Chapter 752.

c) Medical Center Policy 05-23, "Discipline and Adverse Actions- Title 5 Employee"

d) ANSI Z88.2, Practices for Respiratory Use.

SECTION VIII

INFECTION CONTROL POLICY

INFECTION CONTROL POLICY

1) **PURPOSE/MISSION:**
   a) To establish guidelines and define the policy for use by the Research & Development Service (R&D Service) which will prevent or minimize the transmission of infections to patients, staff, and visitors. The purpose of this exposure control plan is to develop a strategy for the prevention or minimization of occupational exposures to potentially infectious materials in employees and others working in VA Research laboratory, research animal, or other biomedical facilities. Copies of the written plan have been distributed to all major organizational segments and are available to individual employees and to local, state and federal authorities. The plan incorporates the following principles and establishes the practices, safety equipment, and facilities recommended for biosafety level 2 and animal biosafety level 2 as the basic and minimal standards for laboratory activities involving the use of any known or potentially infectious material.

2) Adoption of a concept of "standard precautions" which assumes that all blood and body fluids, tissues, secretions and excretion from all persons are potentially infectious.
   i) Minimizing or preventing overt exposures to potentially infectious materials by training employees in hazard recognition, use of safe laboratory practices (work practice controls), appropriate barrier precautions, and immunization.
   ii) Mandatory reporting of all occupational exposure, injuries and accidents to the PI, Supervisor, and BSO.
   iii) Provide medical evaluation, follow-up including appropriate treatment, and surveillance for all occupational exposures to potentially infectious materials.
   iv) Maintain employee medical and training records for the period specified in the standard.

3) POLICY
   a) It shall be the policy of the R&D Service and its employees to function in accordance with the Medical Center's infection control guidelines, to include Standard Precaution, Occupational Safety, and Health Administration's infection-related standards, and other regulatory and professional standards as approved by the Infection Prevention & Control Committee. Since medical history and physical examination cannot reliably identify all persons infected with blood borne or other pathogens, the concept of "standard precautions" ("universal precautions") will be used in the collection and handling of all blood, body fluids, tissues, cultures, or other potentially infectious materials from all persons. "Other potentially infectious materials" includes tissue cultures, organ cultures, and culture media as well as blood, organs, or other tissues from research animals infected with agents that are or may be transmissible to humans.

   b) VA Research Service will provide for all employees a safe and healthful work environment reasonably free of identified physical, chemical, infectious, and other occupational hazards. The OSHA blood borne disease standard (29 CFR Part 1910.1030) will serve as the principal reference in developing an exposure control plan to prevent or minimize occupational infections in staff and others with HBV, human immunodeficiency virus (HIV), and other infectious agents that may be handled or encountered in VA Research laboratories and animal facilities. The concept of "standard precautions" that all blood, body fluids, tissues, and cultures are potentially infectious – and such other national consensus recommendations and standards as applicable, will be incorporated into the exposure control plan to meet the stated policy objective.

   c) The VA advocates – in accordance with applicable Federal laws, regulations, and rules – the safe handling, use, storage, and disposal of potentially infectious materials used in laboratories, research animals, and other biomedical facilities.

   d) VA Research, through Office of the EOSH, will establish uniform guidelines and plans:
      i) To ensure the detection, evaluation, surveillance, and control of hazards associated with the use of potentially infectious agents or materials used in laboratories, research animal, and other biomedical facilities.

ii) To ensure the identification of potentially infectious materials with hazard warning signs, color coding, or other hazard warning information.
iii) To provide employees, on-site contractors, and others with information on infectious materials that may be present in VA Research facilities.
iv) To develop a plan and identify resources for responding to spills of potentially infectious materials or other emergencies in facilities where infectious materials are handled or stored.
v) To assist Principal Investigators (PIs) and other supervisors in the development of a training program for personnel in accordance with the proposed standard.
vi) To implement the use of safer sharp devices and practices when employee is considered at risk of exposure to body fluids.

4) DESIGNATIONS

a) The ACOS R&D and the Director of Research Operations are responsible for assuring that employees comply with infection control policies.

b) Employees and research personnel are responsible for being knowledgeable about the risk of transmission of infection, modes of transmission, implementation of infection control guidelines, and for maintaining personal health and hygiene.

c) The Biosafety Officer (BSO) will develop and distribute a model exposure control plan and will provide technical assistance in interpretation and application of OSHA's requirements. PIs and Supervisors are responsible for assuring that the required safety practices and procedures are carried out and for the operational management of the infection control plan in their areas of responsibility. Employees who work with blood or other potentially infectious materials are responsible for following the requirements of the written plan and established safety practices, and for promptly reporting exposures, accidents, and unsafe practices to their respective supervisors.

d) A member of the Infection Prevention & Control Program serves as a member of the sub-committee of Research Safety (Biosafety Committee).

5) PROCEDURES

a) Education and Training: All new employees will take the Infection Control Training found in the Healthcare Education Program prior to performance of hazardous activities. Continuing employees are required to attend any designated mandatory infection control training and/or an annual (or more frequent, if needed) educational program specific to prevention and control of infection. Training in the recognition and prevention of occupational infection hazards will be provided to all current and new employees by the PI or Supervisor in collaboration with the Medical Center Biosafety Committee. Training materials will be updated as indicated and training will be repeated annually for all employees. Training records – including dates of training sessions, content of training materials, name(s) of trainers, and names/social security numbers of employees attending training – will be maintained for 5 years in accordance with the provisions of the Blood borne Disease standard (20 CFR 1910.1020 (h) (1-4). Essential components of the training program include:
i) The blood borne diseases standard
ii) Epidemiology and occupational hazards associated with blood borne and other pathogens
iii) The written exposure control plan
iv) Engineering controls
v) Work practice controls
vi) Personal protective clothes and devices
vii) Pre-exposure immunization
viii) Post-exposure procedures
ix) Emergency actions
x) Medical surveillance

xi) Additional training may be required for individuals working in areas that pose specific infectious hazards.

b) Employee Risk Assessment

i) Each employee is to be assessed for risk of infection as requested by the Infection Prevention & Control Committee to include "Blood borne Pathogen Exposure Determination" and "Tuberculosis". Other assessments may be required in collaboration with employee health records of epidemiological investigations.

ii) Individual risk assessments for all laboratory personnel are completed annually and can be submitted for BSO review up to 180 days (6 months) prior to the LASIF submission. The risk assessments include all associated risks that the individuals potentially may come in contact with in the Research areas. These risk assessments are required annually as part of each laboratory Principal Investigator's (PI) Laboratory Self-Inspection Form (LASIF). These are reviewed by the BSO and SRS Committee annually, and upon any major modifications.

iii) Without regard to the use of personal protective devices, the PI or Supervisor will compile a list of job classifications as well as tasks, procedures, or activities where occupational exposure (i.e., reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or other potentially infectious materials) may occur and list personnel who are regularly or occasionally involved in these activities. This combination of a list of tasks and personnel will constitute a registry of personnel at occupational risk of infection. The registry will be amended as activities, tasks, and personnel change.

iv) A copy of the registry will be maintained by the PI or Supervisor, and a copy will be forwarded to the occupational healthcare provider to serve as a reference and guide for immunizations and surveillance.

v) Exposure determinations as outlined above will be completed by PIs or Supervisors.

c) Staffing

i) The R&D Service is staffed to minimize transmission of infections and includes the following employees:
- **(1)** Principal Investigator
- **(2)** Biological Lab Technicians in BSL2 facility
- **(3)** PI and Research Nurses for HIV Center
- **(4)** PI and Biological Lab Technicians in Animal Facility

d) Traffic Control

i) Laboratory, research animal, or other biomedical facilities where work with infectious agents is being conducted at biosafety level 2. When the infectious agent(s) are in use in biosafety level 2 laboratories or research animal facilities special provisions for entry (e.g., immunization) are required; the PI or Supervisor will post a hazard warning sign which will incorporate: the universal biohazard warning symbol, the name of the agent(s) being handled, and the name and telephone number of the PI or Supervisor.

ii) HIV and HBV Research laboratories and production facilities, and biosafety level 3 laboratory activities. The PI or Supervisor will post hazard-warning signs on entry doors of laboratories and research animal facilities where HIV or HBV research, production, or other biosafety level 3 activities are being conducted. The sign will incorporate: the universal biohazard warning symbol and the legend BIOHAZARD, the name of the infectious agent(s) being handled, the name and telephone number of the PI or Supervisor, and specific requirements for entry.

iii) Source of signs and labels. Hazard warning signs and labels specified in this Infection Control Plan are available from the Biosafety Office (room 4A107).

e) Hand Hygiene

i) Hand washing is required before and after working on any laboratory experiment. Hand washing facilities are located in each laboratory where such experiments are conducted.

ii) Instant hand sanitizer is available in the Human Research unit and all interview rooms. This is to be used on room entry and exit.

f) Standard Precautions

i) Personal protective equipment: When there is a potential for occupational exposure to infectious agents, the PI or Supervisor will provide and assure that employees use personal protective equipment and devices appropriate for the assessed risk of the planned activity. Protective equipment or devices may include non-latex gloves, gowns, fluid proof aprons or sleeves, coveralls, laboratory coats, head and foot coverings, face shields, surgical-type masks and goggles, and such other devices that may be necessary to prevent overt exposures to employees. The use of gloves will vary according to the procedure being conducted. In general, gloves will be worn when employees have the potential for direct or indirect contact with blood or other potentially infectious materials that may be present in or on clinical specimens, cultures, experimental animals, or environmental surfaces. This includes any contact of patients and decontamination procedures. Full-face shields or surgical-type masks and goggles will be worn whenever there is a likelihood of eye, nose, or mouth contamination with or exposure to blood or other potentially infectious materials.

(1) Laboratory coats or other appropriate protective clothing will be worn by employees engaged in laboratory activities involving blood, body fluids, cultures, research animals, or other potentially infectious materials.

(2) If the volume of materials being handled or used is likely to result in soaking of permeable coats, gowns, or uniforms, then fluid-resistant coats, gowns, sleeves, aprons, or other protective clothing will be worn.

(3) Surgical caps and shoe covers will be worn if there is a potential for contamination of the head or shoes of the employee.

(4) Potentially contaminated protective clothing, gloves, shoe covers, etc., will be removed and appropriately discarded before leaving the laboratory or research animal area.

ii) Engineering control measures: The ACOS/R&D will assure the facility heating, ventilation, air conditioning, lighting, electrical service, plumbing, chemical fume hoods, and other operational and safety support systems shall be regularly examined and maintained to assure that they meet with and function according to design or other applicable standards.

iii) Primary containment equipment:

(1) Chemical fume hoods will be evaluated periodically by the Engineering Service to ensure adequate capture and face velocities of 75-125 linear feet per minute (lfm) for fume hoods used for iodination) with the sash in the normal operating position in accordance with Section VI C 1 of the Research Chemical Hygiene Plan.

(2) Class I or Class II biological safety cabinets will be certified in accordance with the National Sanitation Foundation's Standard 49 (Class II, laminar flow) Biohazard Cabinetry or other applicable standards:

(a) When the cabinet is initially installed in the laboratory

(b) When the cabinet is physically moved or relocated

(c) At least annually thereafter

(3) Open-fronted vertical or horizontal laminar flow "clean benches" will not be used for procedures or manipulations of potentially infectious, sensitizing, or toxic materials.

iv) Special precaution guidelines: Laboratories engaged in research and production activities with HIV and HBV with quantities or concentrations of agents greater than those typically used in the isolation and identification of isolates from patients will utilize biosafety level 3 practices, for all activities conducted within the laboratory.

g) Environmental Requirements

i) Work and other environmental surfaces will be cleaned and disinfected after completion of procedures, when overly contaminated, immediately after the spill of any potentially infectious material, and at the end

of the work shift.

ii) Potentially infectious **biomedical wastes** will be segregated, at a point of origin, from non-contaminated wastes; otherwise, all wastes will be assumed to be biomedical and suitably decontaminated before disposal by Environmental Management Services personnel. Laboratory personnel will properly identify biomedical waste as those items of biological sources and not hazardous chemicals. The use of color-coded (red) bags for disposal of non-biomedical materials is extremely costly.

iii) Containers for potentially infectious laboratory wastes will be labeled with biohazard sign, leak proof, and closeable.

iv) Reusable containers will be decontaminated before washing and reuse.

v) The use of chemical disinfectants will be restricted to those compounds classified as "hospital disinfectants" (tuberculocidal) and include laundry bleach (1:100 dilution in tap water), phenolics, and other compounds of demonstrated efficacy against the target organism or virus being handled in the laboratory. Chemical disinfectants will be prepared and used in accordance with the instructions on the label or the Safety Data Sheet (SDS).

h) Equipment/Supplies: The PI or Supervisor will assure that hazard-warning labels are affixed to: containers for BMW, refrigerators, incubators, freezers, or other equipment used to process potentially infectious materials, and containers used for storage or transportation of potentially infectious materials. Labels used for this purpose will incorporate the universal biohazard symbol and the legend BIOHAZARD. In keeping with the concept of universal precautions, it is not the intent of this Exposure Control Plan to affix hazard-warning labels or otherwise identify individual specimen containers, blood tubes, petri dishes, culture tubes or flasks, or other discrete individual containers as "infectious" or "potentially infectious". Hazard warning signs and labels specified in this Infection Control Plan are available from the Biosafety Office. Safer sharps are used in accordance with the Medical Center's infection control guidelines. Exceptions are approved by the Infection Control Committee.

i) Quality Improvement Monitoring: Quality improvement will be monitored by means of planned Ad Hoc inspections of procedures, techniques, and compliance to this document by the BSO or ACOS/AO for Research.

j) Employee Health

i) All new employees (including persons who are employed Without Compensation) are required to be processed through Occupational Health.

ii) The PI or Supervisor will conduct occupational exposure determinations, evaluate the need for and make arrangements for, or require verification of immunization and appropriate surveillance of staff and others against vaccine-preventable diseases to which they may be exposed in the VA Research work environment. Vaccination against hepatitis B virus and other vaccine preventable diseases will be offered without cost to employees determined to be at occupational risk of infection to those specific agents.

iii) Employees who elect not to be immunized against HBV must sign a copy of the Hepatitis B Vaccine Declination form. A copy must be kept in the employee's folder.

iv) Additionally, employees who may have occupational exposures to hepatitis B virus or other potentially infectious agents will be provided with appropriate medical evaluation, surveillance, counseling, laboratory testing, prophylaxis, and treatment by or under the supervision of a licensed physician and according to accepted medical standards. All laboratory tests will be performed by a laboratory accredited by a national or state accrediting organization.

v) Employees must report exposure or potential exposure incidents to the PI or Supervisor who will arrange for appropriate medical evaluation and follow by the Employee Health Unit.

k) Waste Management

i) All biomedical wastes, as defined by the Georgia Department of Natural Resources Environmental Protection Division, will be handled, packaged, labeled or color-coded, transported, and decontaminated in

accordance with the requirements of this agency's biomedical waste rule (Georgia Code Chapter 391-3-4.15). Currently, approved methods of decontamination of BMW include autoclaving and incineration. BMW that have been autoclaved may be discarded as non-regulated solid waste. Blood, urine, feces, and other body fluids, secretions, excretions, and suctioning may be discarded by carefully decanting into the sanitary sewer, by autoclaving, or by incineration. Generators who choose to decontaminate BMW by autoclaving on-site must use the following procedures to document that autoclave chamber temperatures of at least 121ºC (250ºF) have been achieved and maintained for 30 minutes or longer for each load of BMW treated.

ii) Weekly biological indicators (e.g., Bacillus subtilis spore strips or suspensions) will be used to verify heat inactivation of BMW. Biological verification of inactivation may be conducted by the PI/Supervisor using commercially available biological indicator.

l) Work Practices: Those work practices and barrier precautions which are recommended for biosafety level 2 and animal biosafety level 2 (see Appendix A) activities will represent the basic and minimal conditions under which blood and other potentially infectious materials are handled in VA Research laboratory, research animal, and other biomedical facilities. These practices include:

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

ii) Employees will wash their hands with soap and water immediately after any contact with potentially infectious materials or research animals, and after removal of protective gloves.

iii) All used needles and other sharps will be placed directly into an appropriately labeled puncture-resistant container immediately after use. Used needles will not be shared, bent, broken, or removed from disposable syringes or recapped by hand.

iv) Eating, drinking, smoking, applying cosmetics or lip balm, handling contact lenses, storage or preparation of food or drink are prohibited in laboratories, research animal rooms, or other potentially contaminated areas.

v) All manipulations and procedures involving the use of blood or other potentially infectious materials will be performed in such a way as to minimize splashing, spraying, generation of aerosols, or spills.

vi) All personal protective equipment and devices (e.g., gloves, masks, coats) will be removed immediately upon leaving the laboratory, research animal room, or other work area, or as soon as possible if overtly contaminated and placed in a designated container for storage prior to washing, decontamination, or disposal.

vii) Class I or Class II biological safety cabinets or other primary containment equipment or devices will be used for all procedures which may produce aerosols (e.g., blending, sonic disruption, harvesting infectious tissues from eggs or animals, high speed centrifugation) and for all manipulations and procedures involving the use of cell cultures or other concentrations of human retroviruses (HTLV III, LAV, HIV 1 and HIV 2). Biological safety cabinets will be certified as indicated in V.B2b of this plan.

viii) When activities with blood and other potentially infectious materials are conducted concurrently in the same laboratory with materials not covered by the standard, the practices specified in the standard will apply to all activities.

m) Disinfection and Sterilization

i) The PI or Supervisor will assure that the worksite is maintained in a clean and sanitary condition, and will establish procedures and schedules for cleaning and methods for appropriate disinfection of potentially contaminated surfaces and items.

ii) Work and other environmental surfaces will be cleaned and disinfected after completion of procedures, when overtly contaminated, immediately after the spill of any potentially infectious material, and at the end of the work shift.

iii) Potentially infectious biomedical wastes will be segregated, at the point of origin, from non-contaminated wastes; otherwise, all wastes will be assumed to be biomedical and suitably decontaminated before disposal by Environmental Management Services personnel. Laboratory personnel will make every effort to properly identify biomedical waste as those items of biological sources and not hazardous chemicals.

The use of color-coded (red) bags for disposal of non-biomedical materials is extremely costly.

n) Laboratory Waste Decontamination

i) **Liquid waste** (i.e. media, supernatant, buffers)-decontaminate chemically (e.g. dilute bleach) or by autoclaving waste.
ii) **Sharps**. Needles, syringes, slides, unbroken glass bottles should be placed in proper sharps containers.
iii) **Solid waste**. Soiled gloves, plastics, and contaminated paper should be placed in red biohazard bags.
iv) The following are autoclaved:
v) Contaminated waste from laboratories autoclaved
vi) Contaminated PPE and experimental animals autoclaved
vii) Animal cages and bedding autoclaved. Animal cages are cleaned in the cage washer after being autoclaved.
viii) Containers for potentially infectious laboratory wastes will be labeled and color-coded, leak proof, and closeable.
ix) Reusable containers will be decontaminated before washing and reuse.
x) The use of chemical disinfectants will be restricted to those compounds classified as "hospital disinfectants" (tuberculocidal) and include laundry bleach (1:100 dilution in tap water), phenolics, and other compounds of demonstrated efficacy against the target organism or virus being handled in the laboratory. Chemical disinfectants will be prepared and used in accordance with the instructions on the label or the Safety Data Sheet (SDS).

o) **Recommended Resources**

i) A complete copy of the recommended resources is available in the library, labeled the Infection Control Policy Resource Book.
ii) Incident reporting: Employees who experience on-the-job injuries, accidents, or exposures to potentially infectious materials or agents must prepare a brief narrative report of the incident and forward, through their PI or Supervisor, to the Biosafety Officer. Injured or exposed employees will also complete a copy of the Treatment Report of Employee on-the-job Injury at the time of examination in Employee Health. Supervisors will subsequently receive a copy of the Supervisor's Report, which is to be completed and returned to Personnel Services and Medical Center Safety Engineer.
iii) Medical Records: Medical records required by the blood borne disease standard shall be kept and maintained by the medical care provider for the duration of employment plus 30 years, in accordance with OSHA 39 CFR Part 1910.20
iv) Emergency procedures: It is not possible to develop a single plan of action that would be applicable to all situations involving spills or accidental release of known or potentially infectious materials. As part of operational planning, the PI or Supervisor should anticipate potential spills or releases, and develop an appropriate procedure for decontamination, including the selection of a suitable chemical disinfectant. Appendix B describes a plan of action for decontamination of a spill or accidental release of blood, body fluids, or other materials in an open laboratory where activities are being conducted at biosafety level 2. If a spill or release of materials requires biosafety level 3 practices, containment equipment, and facilities – all personnel should leave the spill site, close exit doors, and immediately notify the VA BSO.

BIOSAFETY PROCEDURES AND PRACTICES SPECIFIC TO THE BSL-2

The CDC/NIH biosafety levels are used to describe and refer to laboratory types that are used to contain the infectious agents. These levels are used to designate laboratories according to their design features, construction and containment facilities. Biosafety level 1 (**BSL-1**) and Biosafety level 2 (BSL-2) labs are basic teaching labs and Biosafety level 3 (**BSL-3**) labs are called a containment lab. In the Atlanta VA Medical Center Research Service all laboratories are designated BSL-2.

Human immunodeficiency virus (HIV and hepatitis B virus) HBV have been assigned to Biosafety Level 2 (BSL-2) by CDC/NIH. However, when producing research laboratory-scale amounts of HIV, BSL-3 procedures must be followed. Biosafety Level 2 (BSL-2) is suitable for work involving agents of moderate potential hazard to personnel and the environment. It requires that: (1) laboratory personnel have specific training in handling pathogenic agents and be directed by competent scientists; (2) access to the laboratory is controlled when work is being conducted; and (3) procedures during which infectious aerosols may be created be conducted in biological safety cabinets or other physical containment equipment.

The following standard and special practices, safety equipment, and facility characteristics apply to agents assigned to BSL-2:

A. Standard Microbiological Practices:

1. Access to the laboratories is limited or restricted by the laboratory director.
2. Eating, drinking, smoking, and applying cosmetics are *strictly prohibited* in the laboratories and breezeway.
3. All procedures are performed carefully to prevent spills or the creation of aerosols.
4. Mechanical pipetting devices are used; mouth pipetting is *strictly prohibited.*
5. Work surfaces are decontaminated with 70% ethanol (or an appropriate disinfectant) before and after work and after any spill
6. All infectious wastes (liquid and solid) are decontaminated with Wescodyne (or an appropriate disinfectant) before disposal.
7. Use of needles or any sharp instrument is *prohibited* in these laboratories. Use of glassware is strongly discouraged. Pasteur pipettes must be enclosed in a sturdy puncture-proof container. Every effort will be made to use plastic ware whenever possible.
8. Hands are washed after handling infectious materials and when leaving the laboratories.
9. Standard Operating Procedures (SOPs) are established for any activity that must be performed in a BSL2 laboratory. Personnel will not deviate from these established SOPs. All new procedures must be submitted to the laboratory director for review and approval for safety in handling.
10. When the infectious materials including organisms containing recombinant DNA molecules in use in the laboratory require special provisions for entry (e.g.. vaccination), a hazard warning sign incorporating the universal biosafety symbol is posted on the access door to the laboratory work area. The hazard warning sign identifies the agent, and indicates the special requirement(s) for entering the laboratory.

B. Laboratory Access:

The laboratory director limits access to the laboratories and has the final responsibility for assessing each circumstance and determining who may enter or work in the laboratories. Those persons permitted access to the BSL2 laboratories have their names posted on the access door to the laboratory work area. Those persons whose names are not on that list but wish to conduct work in one of these laboratories must discuss it with the laboratory director and submit a SOP. This SOP will include the appropriate disinfectant to be used to inactivate the infectious agent and any other special precautions not listed in this manual which will be taken.

1. Only laboratory personnel specifically trained in handling pathogenic agents and who have read, signed, and dated the Laboratory Biosafety Manual, will be allowed access.
2. Only laboratory personnel who have received the full complement of vaccines for HBV will be allowed access to laboratories working with it.
3. Persons at increased risk of acquiring infection are not allowed in the laboratories.

4. Housekeeping and Engineering personnel are not routinely allowed entry to the laboratories. However, should the need for cleaning or maintenance arise, the laboratory director will be informed, all potentially infectious materials will be safely contained, and all work surfaces will be decontaminated with 70% ethanol (or an appropriate disinfectant). A person trained in handling pathogens will be present during the entire process.
5. Baseline serum samples for all personnel working in the HIV/BSL2 laboratories are collected and stored prior to admittance to the laboratories. Thereafter, serum samples will be collected and stored at 6-month intervals. Personnel are also bled upon termination of their appointment.

C. Laboratory Identification:

A biohazard warning sign, incorporating the universal biohazard symbol and a restricted access sign are posted on the access door to the laboratory work area. The biohazard warning sign identifies the infectious agent and indicates the special requirement(s) for entering the laboratory. A list with the name and telephone number of the laboratory director and other responsible personnel is also posted on the access door to the laboratory work area.

D. Laboratory Facilities:

1. The laboratories are separate from areas that are open to unrestricted traffic flow within the building. Passage through two sets of doors is the basic requirement for entry into the laboratories from access corridors or other continuous areas.
2. Accesses into the Research laboratories are self-closing and will remain closed at all times.
3. The interior surfaces of walls, floors, and ceilings of the BSL-3 laboratory are water-resistant so that they can be easily cleaned.
4. The laboratories are designed so that they can be easily cleaned. Spaces between benches, cabinets, and equipment are accessible for cleaning.
5. Laboratory furniture is sturdy.
6. Bench tops are impervious to water and resistant to acids, alkalis, organic solvents, and moderate heat.
7. Each laboratory contains a sink for hand washing.
8. A sterilizer for decontaminating infectious wastes is available to all BSL-2 laboratories.
9. All freezers containing infectious materials are locked at the end of the day; keys are located for easy access.
10. An insect and rodent control program is in effect.

E. Personal Protective Equipment:

1. Laboratory coats or gowns are worn while working in the BSL-2 laboratory. Personnel with access to both laboratories need two gowns. Before leaving a laboratory for any reason, this protective gown is removed and left in that laboratory. These gowns are autoclaved before being laundered.
2. Special care is taken to avoid skin contamination with infectious materials. The double-glove technique is required when working with such agents. When leaving the biological safety hood, the outer pair of gloves is removed and discarded in the doubled biohazard bag that is inside the hood.
3. Goggles, masks, booties, and surgical scrubs are also available.
4. Adhesive bandages are also available to protect any minor cuts or scrapes.

F. Containment Equipment:

1. The HEPA-filtered exhaust air from the Class 2A biological safety hoods is discharged directly to the outside (NuAire) or through the building exhaust system (Baker). Exhaust air may be re-circulated within the laboratories if the hood is tested and certified at least every 12 months. Since the HEPA-filtered exhaust air

from the Class 2A biological safety hoods is to be discharged to the outside through the building exhaust air system, it is connected to the system in a manner that avoids any interference with the air balance of the hoods or the exhaust system.

2. Any potentially infectious materials are centrifuged in buckets sealed with safety lids. These buckets are opened only in the biological safety hoods.

G. Procedures which must be conducted in Biological Safety Hoods:

1. All procedures that might create infectious aerosols are discouraged. If such procedures are necessary, they must be conducted inside a biological safety hood. This includes grinding, blending, aspirating, vigorous shaking, or opening containers of infectious materials whose internal pressure may be different from ambient pressures. Sonic disruption in open containers is *strictly prohibited*.

H. Procedures to follow during the use of Biological Safety Hoods

1. When using either the Baker or the NuAire biological safety cabinets, the fluorescent light and outlet switches are turned on during work. These switches are turned off after work in the hood and the UV light should only be turned on for about 20 minutes a day. A good practice is to turn the UV light early in the morning leave the room and come back in 20 minutes and turn it off.
2. Blowers to both hoods are left on at all times, except for weekends and holidays.
3. For the Baker biological safety hood, the front protective shield is lifted to the 8-inch mark before work and closed down after work.
4. The entire interior of the hood is sprayed with 70% ethanol (or an appropriate disinfectant) and wiped down before and after work in the hood.
5. The interior is kept uncluttered.
6. All items are kept off the front and back air vents.
7. If plastic-backed absorbent paper is laid down on the interior work surface of the hood; this paper is removed and discarded into the doubled biohazard bag inside the hood when work is finished at the end of the day or if a spill occurs (see item L, Procedures for Handling Spills or Accidents).
8. Doubled biohazard bags are placed inside the hood for disposal of infectious waste. These bags are removed from the hood at the end of the day or when two-thirds full (see item I, Disposal of Infectious Materials).
9. A polypropylene beaker with ~500 ml of Wescodyne is placed inside the hood. Wescodyne is transferred to polypropylene bottles with lids and sterilized at the end of the week or when two-thirds full (see item I, Disposal of Infectious Materials).
10. Items moved into and out of the hood are sprayed thoroughly with 70% ethanol (or an appropriate disinfectant).

I. Disposal of Infectious Materials:

1. Double biohazard bags:
   a. Pipettes and pipette tips that have been used with infectious materials are disinfected by drawing up Wescodyne from the beaker and then releasing it back into the beaker. These items are then placed into the bag and *not* ejected back into the beaker.
   b. Infectious liquids contained in tubes or flasks are disinfected by diluting half with Wescodyne from the beaker. Tighten the lids and place inside the bag.
   c. Other waste materials may include plastic ware, gloves, paper towels, and any other material that has not come into direct contact with infectious material but was used while work was conducted with infectious material.
   d. When work is completed inside the hood, a sterilizer deodorant is placed inside the bag. The inner biohazard bag is folded down and the outer biohazard bag is sealed with a rubber band. The outer bag is sprayed thoroughly with 70% ethanol before being removed from the hood. A piece of sterilizer indicator tape is placed on the outer biohazard bag.

e. Biohazard bags are sterilized in the liquid cycle of the Consolidated Direct Steam Heated Sterilizer, model SR-24-DMC, in the BSL-2 laboratory; this cycle runs for 45 min at 250ºF and 22 psi.
f. After sterilizing, biohazard bags are placed in the trash receptacle in the breezeway.
g. Doubled biohazard bags must be used to dispose of infectious or potentially infectious materials. General noninfectious waste may be disposed of in single biohazard bags before sterilizing.

2. Polypropylene beakers and bottles:
   a. When work is completed at the end of the week, or sooner if necessary, the Wescodyne in the beaker is transferred to a polypropylene bottle by carefully pouring. This is done over plastic-backed absorbent paper. The interior of the beaker is sprayed with 70% ethanol and allowed to drain into the bottle. The beaker is left in the hood for continued use.
   b. Polypropylene bottles are sterilized in the liquid cycle of the Consolidated Direct Steam Heated Sterilizer; model SR-24-DMC, in the BSL2 laboratory. This cycle runs for 45 min at 250ºF and 22 psi.
   c. If the polypropylene beakers begin to yellow from continued use with Wescodyne and from the UV lights, they are discarded into a doubled biohazard bag. Beakers are sterilized according to the procedure for sterilizing biohazard bags.
   d. After sterilizing, the liquid waste may be disposed of by pouring down the sink of the BSL3 laboratory with abundant running water. Polypropylene bottles may be reused if appropriate.

J. Control measures for verifying sterilization process:

1. Biological monitors: a live spore test utilizing *B. stearothermophilus* is the most reliable form of biological monitoring. The Castle Biosign indicator is used for this purpose at the HIV lab and the common autoclaves. This indicator is specifically designed to routinely monitor all steam sterilization cycles except the 270ºF (132ºC) gravity displacement steam sterilization cycle.

   a. Two indicators from the same lot are labeled with the date, technician's initials, and room number; one is labeled **control** and the other **test**.
   b. The test indicator is placed in an autoclave bag, and sterilizer tape is used to seal it closed.
   c. The bag is placed on the bottom shelf near the door and over the drain.
   d. The sterilizer is run on the dry cycle. It is not necessary for the sterilizer to be empty in order for the test to be run.
   e. After sterilizing, the bag and control, are taken to the Biosafety Office.
   f. After 48 hr, the results are read by the BSO and noted in the logbook.
   g. Testing is performed at least once a week.
   h. If the test indicator is positive, the laboratory director is notified immediately. A service technician is then contacted. The biohazard sterilizer located in the Animal Facility on the 4_{th} floor of the Clinical Addition is used until the repaired sterilizer has passed a biological test.

2. Chemical controls: Sterilizer tape is used to secure packages; it serves only as an index of exposure to the sterilant system.

K. Transportation of infectious materials:

1. Transportation within BSL2 laboratories:
   a. All potentially infectious materials are enclosed in durable, sealed containers (flasks, centrifuge tubes, freezer vials, etc.), which are appropriate for the expected use.
   b. When moving a flask from the incubator, the lid is closed tightly while the flask is still in the incubator and is then transported.
   c. A cart is used whenever transporting more than one infectious item.
   d. A secondary container should be used to prevent any spills.

2. Transportation within the VAMC:
    a. This is done during a time when fewer people are present; i.e., before 8 a.m. or after 6 p.m. on weekdays, but preferably on the weekend.
    b. All potentially infectious materials are enclosed in durable sealed containers (flasks, centrifuge tubes, freezer vials, etc.), which are appropriate for the expected use. Before transferring, these containers are capped tightly and sprayed thoroughly with 70% ethanol. These containers are then placed in plastic biohazard bags, which are also sealed with a rubber band.
    c. These bags are placed in sturdy cardboard or Styrofoam boxes with appropriate padding (paper towels, absorbent paper, etc.) to minimize breakage.
    d. The exterior of the box is clearly labeled BIOHAZARD.
    e. These boxes are placed on a cart for transportation within the VAMC.
    f. Only laboratory personnel specifically trained in handling pathogenic agents will transport these materials. At least two laboratory personnel must accompany the transported material. Personnel will also take along spray bottles of 70% ethanol, 10% bleach (or an appropriate disinfectant), absorbent paper, doubled biohazard bags, and appropriate personal protective equipment for use in case of an accident.
    g. Service elevators are used for transportation between floors; a map may be drawn showing the expected route through the VAMC.
    h. The infection Control Practitioner at x 207676 will be notified if appropriate.

L. Procedures for handling spills or accidents:

Biological spills outside of biological safety hoods will generate aerosols that can be dispersed in the air throughout the laboratory. These spills are very serious if they involve microorganisms that can transmit disease by infectious aerosols.

To reduce the risk of inhalation exposure in such an incident, occupants should hold their breath and leave the laboratory immediately. The laboratory should not be re-entered for at least 30 min to decontaminate the spill. During this time, the aerosol will be diluted or removed from the laboratory by the exhaust air ventilation system.

1. Laboratories:
    a. Personnel in the immediate area are alerted of the spill.
    b. ALL the appropriate personal protective equipment necessary is worn; this includes a gown impervious to liquids, doubled disposable gloves, disposable booties, safety goggles, and a mask when appropriate.
    c. Small spills are confined with absorbent paper. The absorbent paper is then dampened by spraying the entire contaminated area with 70% ethanol, 10% bleach, or an appropriate disinfectant. Avoid splashing. The contaminated absorbent paper is removed directly to double biohazard bags for sterilization. The entire contaminated area is again sprayed with 70% ethanol, 10% bleach, or an appropriate disinfectant. The liquid is then cleaned up carefully with absorbent paper. This procedure is repeated to ensure that the area has been disinfected. Finally, the area is sprayed with 70% ethanol and allowed to evaporate.
    d. If assistance is required for a larger spill, the laboratory director and/or other laboratory personnel trained in handling pathogenic agents are contacted. The situation is assessed and appropriate decontamination procedures are employed.
    e. Any medical conditions are treated immediately.
    f. In all cases, the laboratory director is notified immediately; a written account is provided to the laboratory director within 24 hr and kept on record.
    g. Those laboratory personnel involved are required to fill out VA incident forms and report to employee health. Medical evaluation, surveillance, and treatment are provided as appropriate. If necessary exposed personnel will be bled immediately following the incident, 6 weeks later and again 3 months later. Emergency phone numbers are clearly posted next to all telephones.

2. Spills or accidents outside BSL-2 laboratories:

a. Laboratory personnel accompanying transported materials will always take along appropriate equipment for cleanup (see K, Transportation of Infectious Materials). All spills are cleaned up by those laboratory personnel responsible and/or other personnel trained in handling pathogenic agents.
b. If possible, one person should remove all nonessential personnel to a safe area.
c. The VAMC Safety Officer, The Research BSO, and the laboratory director are notified immediately.
d. While using all the appropriate personal protective equipment necessary, the spill is confined with absorbent paper. The absorbent paper is then dampened by spraying the entire contaminated area with 70% ethanol, 10% bleach, or an appropriate disinfectant. The contaminated absorbent paper is removed directly to double biohazard bags for sterilization.
e. The entire contaminated area is again sprayed with 70% ethanol, 10% bleach, or an appropriate disinfectant. The liquid is then cleaned up carefully with absorbent paper. This procedure is repeated to ensure that the area has been disinfected. Finally, the area is sprayed with 70% ethanol and allowed to evaporate.
f. If assistance is required for a larger spill, the laboratory director, the Research Biosafety Officer and/or other laboratory personnel trained in handling pathogenic agents are contacted. The situation is assessed and appropriate decontamination procedures are employed.
g. Any medical conditions are treated immediately.
h. A written account is provided to the laboratory director within 24 hr and kept on record.
i. Those laboratory personnel involved are required to fill out VA incident forms and report to employee health. Medical evaluation, surveillance, and treatment are provided as appropriate. If necessary, exposed personnel will provide a blood sample immediately following the incident, 6 weeks later and again 3 months later.

OCCUPATIONAL HEALTH SAFETY PROGRAM:

1) **Purpose:** This document provides guidelines to facilitate the risk assessment medical evaluation of personnel working in Research laboratories and the VMU.

2) **Background:** Exposure to environmental hazards in Research should be maintained in order to assist personnel with medical needs as required.

3) **Responsibility of Medical Center Director:** The Medical Center Director is responsible for providing access to the Occupational Health Program for all Research personnel.

4) **Research Personnel:** In compliance with the VHA Handbook 1200.07, all persons who come in contact with laboratory animals at Atlanta VA Medical Center must enroll in the Preventative Medicine Program (PMP). The options of this are the following. All personnel meeting the criteria in subparagraph 10c(1) of the Handbook must either participate in the preventative medicine program (PMP), be a participant in a similar PMP of an affiliate facility, or sign a waiver opting out of the program. This includes personnel that handle animals or unfixed animal tissues, and also personnel exposed to aerosolized animal allergens on more than one occasion. The Atlanta VA Medical Center health care professionals and IACUC decide the level of PMP necessary. This is determined by reviewing the individual's risk assessments at least on an annual basis and upon the addition of any significant changes. Additionally, all laboratory personnel caring for or handling experimental animals are required to complete a health evaluation questionnaire annually. This document is reviewed by the facility BSO, SRS, and OHS personnel for changes in annual modifications and associated risks. If the opt-out option is chosen, this does not exclude any personnel from taking mandated immunizations or tests put into place by the Director or Chief of Staff for the hospital. Additionally, testing necessary for the health and well-being of laboratory animals (e.g., TB for personnel contacting primates) is a requirement that may not be waived.

5) **Basic Program Content**

a) Pre-Employment Medical Evaluation
   i. A pre-employment physical exam is required for all Research personnel that will have any contact with experimental animals or performing work in any of the animal laboratories in the Atlanta VA Medical Center's VMU. These exams provide assessments on the prospective employee's capabilities to perform the physical demands of the job responsibilities and if any pre-existing conditions would potentially put the employees or others at any risk. These pre-employment evaluations are performed by health care professionals in OHS and documented results of these exams are maintained in the OHS office for patient confidentiality.
   ii. Additionally, Research employees that will be working with experimental animals and in laboratories utilizing chemicals in the lyophilized state will be given the option to be enrolled in the Atlanta VAMC's respirator program. This procedure involves medical evaluation by the VA medical staff to ensure that the staff is physically able to wear a negative pressure respirator. Upon approval by medical staff the Research employees are fit tested with an OSHA approved respirator. The annual risk assessment required by all Research laboratory staff is utilized to assess if anything involved in the employee's job responsibilities either includes or excludes an employee from being part of the Atlanta VAMC Research respirator program. The BSO and medical staff are responsible for reviewing these risk assessments.

b) Medical Follow-up –
   i. Annually after employment begins, an occupational health and safety physician, or other qualified medical professional, reviews Research personnel's medical history, concentrating on immunizations necessary for the prevention and development of the employee's allergies while in contact with experimental animals. This review is performed by the responses on OHS's questionnaire and or physical exam, and the employee's risk assessments completed annually.

c) Annual Risk Assessment Review –
   i. It is a requirement of the Research Service Line that all Principal Investigators submit an electronic Laboratory Self Inspection Form (LASIF) annually detailing all approved research being performed under their supervision. A key component of the LASIF is that all associated risk assessments for all personnel working in all laboratories, including animal laboratories in the VMU, are provided and updated. The Biological Safety Officer (BSO) and Subcommittee for Research Safety (SRS) reviews these for primary and secondary protective equipment and enhanced Biosafety practices necessary to adequately protect the personnel depending on their associated risks. If any significant changes are introduced/discovered by these reviewers, the personnel will be referred to facility OHS for annual evaluation by a proper health care professional. The evaluation will be performed to ensure that the personnel will be capable of performing his / her modified job responsibilities without increasing health risks associated to the modification(s). The documented results of these exams are maintained in the OHS office for patient confidentiality.

d) Access to Animals and IACUC Approvals –
   i. Atlanta VA Medical Center is mandated to provide a safe workplace to Research employees. Therefore, as a requirement of VHA 1200.07, subparagraph 4a(1), all Research employees must provide documentation to the facility IACUC that they have enrolled in the PMP prior to entering the VMU and beginning any work with experimental animals. This documentation must be received and reviewed prior to approvals and issuance of unique means of access to the VMU.

e) Occupational Safety Training –
   i. Appropriate and documented training for all Research personnel that will have any contact with experimental animals with which they handle is required. The training provided to personnel includes appropriate PPE, any special handling practices and techniques, and hygiene practices. Research personnel are taught to reduce unnecessary risk while manipulating experimental animals.

f) Illness and Injury Reporting –
   1. Injuries occurring in the VMU are required to be reported immediately to the employee's supervisor. Examples of these injuries are bites, scratches and cuts obtained while manipulating experimental animals. Once reported by the employee, an accident report is completed on VA Form 2162, Report of Accident, and the employee is referred to Occupational Health for evaluation and treatment if necessary. Additionally, any illnesses that present the signs and symptoms of animal exposure should be handled in the same manner.

6) Occupational Health and Safety (OHS) Program for Non-Research Personnel Entering VMU and Laboratory Animal Housing Areas

This program concerns non-research parties entering VMU and Laboratory Animal Housing Areas at the Atlanta VA. All non-VA parties and non-research VA personnel such as, but not limited to 3rd party contractors, vendors, VA Housekeeping, Engineering and Police staff must read and acknowledge the Occupational Health and Safety information about the potential hazards, risks and exposure prior to entering this area. A printable version of this program can be found here or can be obtained by contacting the Biosafety Office.

7) References

a) The following regulations, guidelines, and documents are references utilized in the development of the Occupational Health and Safety Program.
   i. Animal Welfare Act, Public Law 89-544 as amended; codified at 7 U.S.C. 2131-2159.
   ii. USDA Animal Welfare Act Regulations and Standards, 9 CFR Parts 1, 2, 3, and 4.

iii. The Health Research Extension Act of 1985, Public Law 99-158, as amended, "Animals in Research," codified at 42 U.S.C. Section 289d.

iv. PHS Policy on Humane Care and Use of Laboratory Animals. NIH, Office of the Director. Revised September 1986, and reprinted October, 2000.

v. U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training. Prepared by the U.S. Interagency Research Animal Committee, and originally published Federal Register, May 20, 1985, Vol. 50, No. 97, by the Office of Science and Technology Policy.

vi. Guide for the Care and Use of Laboratory Animals. National Research Council Eight Edition,2011 (or most recent edition).

vii. Report of the AVMA Panel on Euthanasia. Journal of the American Veterinary Medical Association, Volume 218(5): 671-696, 2001.

viii. Biosafety in Microbiological and Biomedical Laboratories. CDC and NIH. 5th edition (or most recent revision)

ix. NIH Guidelines for Research Involving Recombinant DNA Molecules. NIH, 1994, and as subsequently amended.

x. CDC, Title 42 Code of Federal Regulations (CFR) 73, Possession, Use, and Transfer of Select Agents and Toxins.

xi. AALAC, International. "Rules of Accreditation," revised January 2001.

xii. Nuremberg Code of 1947.

xiii. VHA Handbook 1108.1, Controlled Substances

xiv. VA Handbook 0730, Security and Law Enforcement.

xv. Title 38 United States Code, Part V**,** Chapter 73, Section 3707, Functions of Veterans Health Administration: Research Programs.

xvi. National Research Council. National Need and Priorities for Veterinarians in Biomedical Research. 2004.

xvii. Potkay S, NL Garnett, JG Miller, CL Pond, DJ Doyle. "Frequently Asked Questions about the Public Health Service Policy on Humane Care and Use of Laboratory Animals," Laboratory Animal 24:24-26, 1995.

xviii. USDA Animal and Plant Health Inspection Service, Animal Care Section. Animal Care Policy Manual, Policy #10: Licensing and Registration of Producers of Antibodies, Sera and/or Other Animal Parts and Pregnant Mare Urine (PMU). April 14, 1997.

xix. Potkay S, NL Garnett, JG Miller, CL Pond, DJ Doyle. "Frequently Asked Questions about the Public Health Service Policy on Humane Care and Use of Laboratory Animals," Contemporary Topics 36:47-50, 1997.

xx. Baker DG. "Natural Pathogens of Laboratory Mice, Rats, and Rabbits and Their Effects on Research," Clinical Microbiology Reviews. 11: 231-266. 1998.

xxi. VHA Handbook 1108.2, Inspection of Controlled Substances.

xxii. M-2, Part VII, Pharmacy Services.

xxiii. VA Handbook 5005, Staffing, Part II, Appendix F32.

xxiv. VHA Handbook 1200.06, Control of Hazardous Agents in VA Research Laboratories.

xxv. VHA Handbook 1200.08, Safety of Personnel Engaged in Research.

xxvi. VHA Directive 1105.1, Procedures for Management of Radioactive Materials.

ADDENDUMS

EXAMPLES OF RESPONSES FOR SECTION 4E (COMPLIANCE QUESTIONS) OF RISK ASSESSMENT SECTION:

This information is guidance for everybody for compliance and safety reasons since many responses provided by employees are too short or vague. The next full page shows examples of responses to each question from 4E.1 to 4E.5.

Following is a review of background and requirements for each of the questions for this section.

4E.1 What are the steps to be taken in the event of a spill?
This question applies as part of OSHA's Hazard Communication under 29CFR 1910.1200. That is, under hazard communication, all those who enter a research area and prior to the job assignment have a "right to know" about the hazards involved and should be able to use the knowledge learned in Biosafety Training and from the PI about how to take care of a spill without panicking and/or inadvertently causing injury or exposure to rescuing person(s). Generally, the scenario of a spill is possible either by direct involvement or due to a spill in the area by somebody else working within the vicinity.

In most cases it has been noted that answers provided are too short such as "call for help" and/or "Call biosafety officer" does not indicate enough understanding of this question.

Following are basic issues that must be acknowledged about a spill in the research lab.

a) Understanding of type of spill: chemical, biological, radioactive materials
b) Understanding of extent of spill: minor or large
c) Alert people immediately in the area and must be aware of the contact phone numbers of the Research BSO as well as the Safety Office.

4E.2 Can you give one example of a flammable chemical in your work area?
This question is described as a part of the Hazard Communication section of this manual. Persons working in research areas must have a good understanding of how to handle flammable chemicals and be able to answer examples of flammables stored in the laboratory. Alcohol (every lab usually has some amount of alcohol), Acetone, Benzene are few to that are commonly kept in laboratories. You should be able to describe the flammable chemicals stored in your laboratory and the safe handling practices for them.

4E.3 Please provide specific directions to locate the SDS for one reagent?
This part of the Hazard Communication applies to any workplace that uses chemicals. An individual must be able to provide information about **how** to access the SDS for any chemical found in the laboratory. Safety Data Sheets (SDS) online at https://vaww.ceosh.med.va.gov/ceosh/MSDS.shtml. This link should be made available as an icon on the desktop of all laboratory computers. This information is also consolidated in the "Helpful Information" attached as a last page of chemical inventory for each lab.

4E.4 Describe the precautions required for the disposal of any used sharp?
This question pertains to sharps which may be anything with sharp edges. This includes pipettes, needles, blades, or any type of glass materials. A glass material can shatter if accidently dropped on the floor and then each shattered piece of glass is a sharp material.

4E.5 What steps are to be taken in the event of a contamination with a pathogen?
This question deals with special case of a spill or exposure to biologically hazardous agents. Employees at least should be aware of the contact phone numbers of the Research BSO as well as the Safety Office and reporting requirements of the incident to PI as well as Research BSO.

EXAMPLES OF POSSIBLE ANSWERS – Every lab will be different based on the Hazards involved

4E. Compliance Questions

4E.1 What are the steps to be taken in the event of a spill?

First, determine nature of hazardous material, extent of spill (small or large), and means to contain. If it is a chemical spill, alert people around the area, turn off heat and ignition source (electrical). Use proper PPE that includes gloves (chemical resistant), mask, safety goggles etc. Contain the flow (if liquid) by placing absorbent paper around the spill. If the spill is a toxic material or is large, call the Research Biosafety Officer (x207273) and safety office (X202752 or 205159) for a proper cleaning kit and additional help as needed. Also call HazMAT coordinator (X206115 or 201569). If the spilled material is a biological hazard, alert people around also call Research Biosafety Officer (X207273). Leave the area for 30 minutes so that any aerosol containing any live organism is settled and/or diluted. Use appropriate PPE (lab gown, gloves, face mask, and appropriately safety goggles) and use large number of absorbent papers to contain the spread of spill. Spray all the infected material with 70% ethanol and 10% bleach. Use biohazard bags to discard all the infected material. Once all the material is discarded, clean the area with 70% ethanol. For Radioactive material spill – Call RSO at X202543. Scan area with GM counter for extent of spill, use proper PPE, holding a tong use absorbent towels until cleaned area shows no detectable radioactivity with the scanner. Discard all waste into container marked for radioactive waste. Make sure Inform PI and Research Biosafety Officer.

4E.2 Can you give one example of a flammable chemical in your work area?

Such as Alcohol, Acetone, and/or Benzene

4E.3 Please provide specific directions to locate the SDS for one reagent?

Master SDSs are available at Rooms: 4A125 (Office of animal lab supervisor-for animal Lab Section only), 4A150, In hallways across Room 5A109A, 11C120, and 12C190. Hard copies of SDSs are placed alphabetically in a yellow binder labeled "SDS". Locate the labeled tab in the binder associated with the material you are seeking information on any chemical. The Web site for SDSs and chemical information is: http://vaww.ceosh.med.va.gov/ceosh/MSDS.shtm

4E.4 Describe the precautions required for the disposal of any used sharp?

Discard sharps (such as pipettes, needles, blades) only in specific Red Sharps containers.

If sharp is glass material which breaks/shatters when accidently dropped on the floor then do not try to pick up with bare hands for disposal. A dust pan and brush/mop will be used to collect the broken glass and placed into a Red Sharps container.

4E.5 What steps are to be taken in the event of a contamination with a pathogen?

Use appropriate disinfectant to clean the area and use substantial number of absorbent papers to contain which also work to isolate the contamination. For example, pathogen such as HIV-1 contamination in a specific area can be cleaned (using gloves & mask) with 70% ethanol followed by wipe with 10% bleach. All absorbent material should be discarded in the biohazard bags and autoclaved before disposal. If contamination is in cell culture, entire incubator should be sterilized. All the contaminated plastic ware should be discarded in biohazard bags and properly sterilized. The shelves of incubator should first be cleaned with 10% bleach and then sterilized by autoclaving. Any medium suspected of contamination should also be autoclaved and properly discarded. Make sure to inform the PI and Research Biosafety Officer in the event of contamination with a pathogen.

In case of spill on your body, immediately wash and scrub (EZ scrub) the affected area for 15 minutes with soap and water. If broken skin is exposed, then seek medical help. Make sure to notify your supervisor and the Research Biosafety Officer (x207273) to complete an incident report.

VAMC ATLANTA
RESEARCH PERSONNEL SCOPE OF PRACTICE
FOR NON-HUMAN STUDIES RESEARCH

NAME: _____

PRINCIPAL INVESTIGATOR: _____
The Research Scope of Practice is specific to the duties and responsibilities of each individual working with a Principal Investigators on an approved research study(ies). The purpose of developing the Scope of Practice is to define the parameters and functions of individuals participating in research activities, including human studies, animal studies, bench studies, and research development studies.

PROCEDURES:
An individual working in Research Service may be authorized to perform the following duties/procedures on a regular and ongoing basis. Duties listed below are provided as a template to the individual and Principal Investigator. The final list should reflect the duties assigned to each individual. The individual should initial in the appropriate space provided. For each duty granted the Principal Investigator should initial and date in the appropriate space. Those duties granted must be based the individual's education, training, and experience.

ANIMAL RESEARCH STUDIES
For animal studies, the investigator delegates to the employee the ability to perform such functions as detailed in the VA approved animal protocol and may include: handling, caring and humanely treating animals. Administering euthanasia, analgesics, injections and test substances as dictated in the ACORP. Identifying humane endpoints for animals. Performing surgery according to approved protocol.

_____ _____
Requested Granted
(Employee initials) (Supervisor initials)

LABORATORY STUDIES:

For laboratory studies, the investigator delegates to the employee the authority to perform experiments as approved by the R&D Committee utilizing procedures approved by the Subcommittee on Research Safety. This also includes maintaining laboratory areas and equipment, calibration, and cleanliness and ensuring a safe working environment.

_____ _____
Requested Granted
(Employee initials) (Supervisor initials)

OTHER DUTIES:

If other duties are assigned that are not within the above scope, the investigator delegates to the employee the following miscellaneous duties (if applicable should be completed separately by each PI):

_____
_____
_____
_____
_____
_____
_____
_____

_____ _____
Requested Granted
(Employee initials) (Supervisor initials)

PRINCIPAL INVESTIGATOR'S STATEMENT

_____'s Research Scope of Practice was reviewed and discussed with him/her on the date documented on the last page of this form. After reviewing the individual's education, training, experience, qualifications, and individual skills, I certify that the individual possesses the skills to safely perform the aforementioned duties and procedures. The individual agrees to abide by the parameters of the Research Scope of Practice and all applicable medical center policies and regulations.

This Research Scope of Practice will be reviewed annually and or amended as necessary to reflect the individual duties and responsibilities.

_____
EMPLOYEE NAME (print)

_____ _____
EMPLOYEE SIGNATURE DATE
-

_____ _____
PRINCIPAL INVESTIGATOR DATE
SIGNATURE

_____ _____
ACOS FOR R&D DATE
SIGNATURE

VA MEDICAL CENTER (ATLANTA)
DECATUR, GEORGIA

CREDENTIALING PROCESS FOR PERSONNEL ENGAGED IN NON-HUMAN RESEARCH ACTIVITES

1. **PURPOSE**: To outline the credentialing process for personnel working with in research projects within laboratories. To detail the duties and responsibilities, through the completion of a Research Scope of Practice, of personnel who have are not engaged human subjects research and working in a laboratory or other research setting.

2. **POLICY:**

a. Principal Investigators (PI) and other research personnel, who are part of a research team engaged in research, must be credentialed by either Research Service participate in research activities. This applies to all personnel regardless of the source of compensation (Emory, VA, AREF, GSU or other entity) or type of appointment (VA paid or Without Compensation).

b. The PI must complete a Research Scope of Practice outlining the specific research-related duties that will be delegated to research personnel. The Research Scope of Practice will be maintained as part of the credentialing documents.

c. This process is not intended to replace the current medical center credentialing process for physicians, residents, nurses and other clinical staff. Personnel who have undergone another VA medical center credentialing process will only undergo a Research Scope of Practice.

3. **DEFINITIONS:**

a. **The Research Scope of Practice**:
   i. A Research Scope of Practice is documentation of duties requested by personnel and granted by the PI.

4. **PROCEDURES:**

a. Credentialing and Research Scope of Practice
   i. The following documents must be completed prior to engaging in human research activities:
      (1) Dated Curriculum Vitae or dated resume
      (2) Completed Education Verification Form
      (3) Research Scope of Practice

   ii. The documents will be pre-reviewed and verified for accuracy and completeness.

   iii. For personnel who do not require credentialing by the Credentialing Office, the Research Office will create and maintain a research credentialing file.

   iv. The Research Scope of Practice is reviewed and approved by the Associate Chief of Staff for Research.

   v. The PI and the employee will be notified by the research office when the research credentialing request is approved.

vi. Employees can engage in research only after credentialing, scoping (if needed) and appropriate amendments to R&D and IRB are completed.

b. Periodic Review

i. The Research Scope of Practice must be reviewed annually by the ACOS for Research. Whenever there is a change in the research personnel's duties, or begins work on a new project for a different PI that has different duties a new scope will be required.

5. **RESPONSIBILITY:**

a. The Associate Chief of Staff for Research is responsible for assuring that the process is upheld and reviewing all Research Scopes of Practice annually.
b. The Research Office is responsible for implementing the process.
c. The PI is responsible for ensuring that his/her research staff obtains appropriate credentialing and provides an appropriate scope of practice when necessary.
d. Non-compliance with these policies and procedures may result in discontinuation research approval conducted at the Atlanta VA Medical Center.

Standard Operating Procedures

Atlanta VAMC Institutional Biosafety Committee

INTRODUCTION

The *NIH Guidelines* outline procedures involving the use of recombinant DNA (rDNA) and describe the roles, responsibilities, and relationships among the principal investigator (PI), the Institutional Biosafety Committee (IBC), and the National Institutes of Health (NIH)/Office of Biotechnology Activities (OBA). It is the intention of the Atlanta VA Medical Center (AVAMC) to abide by these guidelines. The manner in which experiments are classified in the *Guidelines* determines the required review procedures. This document is a summary of the review procedures for those planning to initiate any type of rDNA research at the AVAMC, regardless of funding source.

In that the AVAMC does not have containment level III or higher facilities, no research deemed to require greater than Level II containment will be approved.

No human gene transfer experiments will be approved.

No research involving plants will be approved.

ROLES AND RESPONSIBILITIES

Institution
The IBC and Research Office must submit through the Medical Center Director an annual report to the NIH including a roster of all members and their biographical sketches. The chair and contact person must be clearly indicated.

Any changes or significant new information regarding the guidelines or the functioning of the Committee will be communicated to all investigators via email.

The Research and Development Committee (R&DC)
The R&DC is responsible for the review and approval of all research at the AVAMC. Procedures for submission of projects and details of the approval process are outlined in MCM 151-1. The Subcommittee on Research Safety (SRS) ensures compliance with applicable biosafety requirements and has delegated the authority for review of research involving rDNA to the Atlanta IBC. If a project involves non-exempt rDNA experiments, it must be reviewed and approved by the Atlanta IBC prior to initiation.

The Atlanta IBC.
1. Membership

   a. The Atlanta IBC will have at least 5 voting members who collectively have experience and expertise in recombinant DNA technology and the capability to assess the safety of recombinant DNA research and to identify any potential risk to public health or the environment. At least 2 of these individuals must be non-affiliated with the institution.

   b Members will be appointed by the Medical Center Director for terms not to exceed 3 years. Consecutive terms are permitted.

   c. The Chairperson will be appointed by the Medical Center Director from among the voting members.

2. The IBC will review all rDNA research to be conducted at the Atlanta VAMC for compliance with *NIH Guidelines* and approve those research projects that are in conformity. However, no voting member may be involved in the review or approval of a project in which (s)he has been or expects to be engaged or has a direct financial interest. This review shall include:

a. An independent assessment of the containment levels required by the *Guidelines* for the proposed research.

b. An assessment of the facilities, procedures, practices, and training and expertise of personnel involved in rDNA research.

c. Ensuring compliance with all surveillance, data reporting, and adverse event reporting as required by the *Guidelines*.

3. All reviews shall take place at a convened meeting where a quorum (>50% of voting members) is present. Email exchanges cannot fulfill this expectation. Each member will be provided with all relevant information. If changes to a protocol are required, the Chair or a designated reviewer may review these changes prior to granting final approval providing no member objects. If any member objects to the use of a designated reviewer, the protocol must be returned to the convened committee. If the approval requires specific conditions then the chair of designee must verify that those conditions have been met and this must be reported at the next convened meeting.

4 Other responsibilities include:

a. Report the results of committee reviews to the Biosafety/Biosecurity Committee in writing.

b. Set containment levels for certain specified experiments.

c. Review periodically rDNA research being conducted at the AVAMC to ensure compliance with the *Guidelines*.

d. Adopt emergency plans covering accidental spills and personnel contamination resulting from such research.

e. Report within 5 days to the Research Compliance Officer, to the NIH, and to ORO any significant problems with or violations of the *Guidelines* and any significant research-related accidents or illnesses.

f. Prohibit initiation of experiments not explicitly covered by the *Guidelines* until NIH establishes the required containment.

g. Perform such other functions as may be delegated to the committee by the *Guidelines*.

5. Minutes:

Minutes of the Atlanta IBC will be written and submitted to SRS Committee and to the R&DC for approval. Since minutes are a primary means of communication with upper management, they will be sufficiently detailed to provide a clear understanding of the operation of the committee. Minutes will be forwarded to VA Central Office upon request.

Principal investigators conducting rDNA research

Principal Investigators are responsible for full compliance of the *Guidelines.* These responsibilities are outlined in Section IV-B-7 of the *Guidelines*.

General requirements state that the investigator shall:

a. Initiate or modify rDNA research subject to the *Guidelines* only after that research or the proposed modification thereof, has been fully approved and has met all other requirements of the *Guidelines*.

b. Determine the classification of the experiment and follow appropriate procedures.

c. Report immediately to the Research Office all problems with and violations of the *Guidelines* and all research-related accidents and illnesses. Significant problems must be reported to the NIH and ORO within 5 days.

d. Report new information bearing on the *Guidelines* to the Research Office.

e. Be adequately trained in good microbiological techniques.

f. Adhere to approved emergency plans for dealing with accidental spills and personnel contamination.

g. Comply with shipping requirements for rDNA molecules (Appendix H of the *Guidelines*).

In submissions to the Atlanta IBC, the PI shall:

a. Make an initial determination of the required levels of physical and biological containment in accordance with the *Guidelines*.

b. Select appropriate microbiological practices and laboratory techniques to be used for the research.

c. Submit the initial research protocol and any subsequent changes to the Committee for review and approval or disapproval.

d. Remain in communication with the Committee throughout the conduct of the project.

Prior to initiating the research, the PI shall:

a. Make available to all lab staff the protocols that describe the potential biohazards and the precautions to be taken.

b. Instruct and train lab staff in:

(1) Practices and techniques required to ensure safety, and

(2) Procedures for dealing with accidents.

c. Inform the lab staff of the reasons and provisions for any precautionary medical practices advised or requested (e.g., vaccinations or serum collection).

During the conduct of the research, the PI shall:

a. Supervise the safety performance of the laboratory staff to ensure that the required safety practices and techniques are employed.

b. Investigate and report any significant problems pertaining to the operation and implementation of containment practices and procedures in writing to the RCO, the Committee, and other appropriate authorities, if applicable.

c. Correct work errors and conditions that may result in the release of rDNA materials.

d. Ensure the integrity of the physical containment (biological safety cabinets) and the biological containment (purity, genotypic and phenotypic characteristics).

CONTAINMENT GUIDELINES

Experiments involving recombinant DNA are divided into six classes (Nomenclature based on guidelines). This committee will **not** approve protocols involving Classes III-A, III-B, or III-C experiments or experiments involving Risk Group 3 or higher agents.

Class III-D experiments
These experiments require approval and submission of an rDNA Registration Document prior to initiation. These experiments involve:

1. The introduction of rDNA into Risk Group 2 agents shall be conducted at Biosafety Level (BSL) 2 containment. Experiments with such agents shall be conducted with whole animals at BSL2 or Animal BSL (ABSL) 2 containment.

2. Experiments in which DNA from Risk Group 2 agents is transferred into nonpathogenic prokaryotes or lower eukaryotes may be performed under BSL2 containment. The Committee may approve the specific lowering of containment for particular experiments to BSL1. Many experiments in this category are exempt from the *Guidelines* (see Section III-F). Experiments involving the formation of rDNA for certain genes coding for molecules toxic for vertebrates require NIH/OBA approval (see Section III-B-1 of the *Guidelines*) or shall be conducted under NIH specified conditions as described in Appendix F of the *Guidelines.*

3. The use of infectious DNA or RNA viruses or defective DNA or RNA viruses in the presence of helper virus in tissue culture systems.

a. Experiments involving the use of infectious or defective Risk Group 2 animal viruses in the presence of helper virus may be conducted at BSL2.

b. Experiments involving the use of infectious or defective restricted poxviruses in the presence of helper virus shall be determined on a case-by-case basis following NIH/OBA review.

c. Experiments involving the use of infectious or defective viruses in the presence of helper virus which are not covered in Sections III-D-3-a through III-D-3-d may be conducted at BSL1.

4. Whole animals.

a. Recombinant DNA, or DNA or RNA molecules derived therefrom, from any source except for greater than two-thirds of eukaryotic viral genome may be transferred to any non-human vertebrate or any invertebrate organism and propagated under conditions of physical containment comparable to BSL1 or ABSL1 and appropriate to the organism under study.

b. Animals that contain sequences from viral vectors, which do not lead to transmissible infection either directly or indirectly as a result of complementation or recombination in animals, may be propagated under conditions of physical containment comparable to BSL1 or ABSL1 and appropriate to the organism under study.

c. For experiments involving rDNA, or DNA or RNA derived therefrom, involving whole animals, including transgenic animals, and not covered by Sections III-D-1 or III-D-4-a, the appropriate containment shall be determined by the Committee

d. Exceptions under Section III-D-4, *Experiments Involving Whole Animals*

1) Experiments involving the generation of transgenic rodents that require BSL1 containment are described under Section III-E-3.

2) The purchase or transfer of transgenic rodents is exempt from the *Guidelines* under Section III-F, *Exempt Experiments* (see Appendix C-VI, *The Purchase or Transfer of Transgenic Rodents*).

5. More than 10 liters of culture.

Class III-E experiments
These experiments require Committee notification and submission of an rDNA Registration Document simultaneously with initiation. Those experiments not included under Classes A, B, C, D or F are considered in this class. For example, experiments in which all components are derived from non-pathogenic prokaryotes and non-pathogenic lower eukaryotes are included in this class and can be carried out at BSL1 containment. Creation of transgenic and knockout animals, or other projects which involve modification of the genome, that may be housed at ABSL1 containment, are also classified under III-E. Additional rDNA experiments include:

1. Experiments involving the formation of rDNA molecules containing no more than two-thirds of the genome of any eukaryotic virus (all viruses from a single Family being considered identical). These experiments may be propagated and maintained in cells in tissue culture using BSL1 containment. For such experiments, it must be demonstrated that the cells lack helper virus for the specific Families of defective viruses being used. If helper virus is present, procedures specified under Section III-D-3 should be used. The DNA may contain fragments of the genome of viruses from more than one Family but each fragment shall be less than two-thirds of a genome.

2. Experiments involving the generation of rodents in which the animal's genome has been altered by stable introduction of rDNA, or DNA derived therefrom, into the germ-line (transgenic rodents). Breeding of rodents which results in modification of the genome is also covered under this section (crossing 2 transgenics or crossing onto another background). Only experiments that require BSL1 containment are covered under this section; experiments that require BSL2, BSL3, or BSL4 containment are covered under Section III-D-4.

Class III-F experiments
These experiments are exempt from the *Guidelines* and no registration is required. These experiments include:

1. Those that are not in organisms or viruses.

2. Those that consist entirely of DNA segments from a single non-chromosomal or viral DNA source, though one or more of the segments may be a synthetic equivalent.

3. Those that consist entirely of DNA from a prokaryotic host, including its indigenous plasmids or viruses, when propagated only in that host (or a closely related strain of the same species) or when transferred to another host by well-established physiological means.

4. Those that consist entirely of DNA from a eukaryotic host including its chloroplasts, mitochondria, or plasmids (but excluding viruses) when propagated only in that host (or a closely related strain of the same species).

5. Those that consist entirely of DNA segments from different species that exchange DNA by known physiological processes, though one or more of the segments may be a synthetic equivalent.

6. Those that do not present a significant risk to health or the environment (see Section IV-C-1-b -(1)-(c)) as determined by the NIH Director, with the advice of the RAC, and following appropriate notice and opportunity for public comment. See also Appendix C of the *Guidelines*.

REVIEW PROCEDURES
1. All projects must be reviewed and approved by the R&DC and all applicable subcommittees before research commences. Refer to the" Atlanta VAMC Investigator's Handbook" for details.

2. For all rDNA experiments which are not exempted from the *Guidelines*, and are therefore defined as subject to the *Guidelines* (See Section III), PIs are required to submit an rDNA Registration Document to the

Research Office along with the SRS project review form. The rDNA Registration Document must be reviewed and approved prior to the initiation of the research, except for Section III-E experiments which require submission that is concomitant with the initiation of the project.

3. PIs will receive formal notification when their rDNA Registration Document is approved.

CONTENTS OF rDNA REGISTRATION DOCUMENT

Description.
This should include the name and department of the principal investigator and Co-investigator(s), when appropriate. Be succinct and explicit enough so that additional explanatory materials are not needed. Description will include:

1 A brief overview of the project

2 The hosts and vectors to be used

3 Experimental design

4 The expression of proteins or regulatory RNAs

5 Whether it will involve gene transfer to humans or animals

6 Whether it will involve the generation of transgenic or knockout animals

7 Whether other laboratories or core facilities will be involved in the project and whether materials will be shipped.

8 A risk assessment including section(s) of the NIH Guidelines which apply to the proposed research activities.

Assessment of containment.
The PI must assess the physical and biological containment levels needed to carry out the experiment. When proposed facilities are under construction or in renovation at the time the rDNA Registration Document is reviewed, the PI must include an assurance that rDNA experimentation will not occur until the Committee has surveyed the completed facility and found it to be in compliance with the *Guidelines*.

Information on health surveillance
If applicable (see Section IV-B-1-i of the *Guidelines*), information on health surveillance of personnel and the nature of the program and procedures that will be initiated should be submitted with the application.

Training
The PI must provide information on the relevant experience he/she and all applicable personnel have in relation to the proposal (work with organisms, viruses, BSL2 work, etc.) or, if applicable, describe the training the PI and/or personnel will receive.

Shipment
The PI will agree to comply with the shipment requirements for rDNA as indicated in Appendix H of the *Guidelines*.

Signature and Date
The PI must accept responsibility for compliance with the *Guidelines* as well as compliance with the items noted above and attest to the accuracy of the information submitted for review.

COMMITTEE FOLLOW-THROUGH MEASURES

A. The Committee will certify that the project has been reviewed and found to be in (non-) compliance with the *Guidelines* and other specific instructions. The date of the review will be specified.

B. The Committee will verify the PI's assessment of physical and biological containment levels.

C. The Committee will be responsible for annual review of the status of the research subject to the *Guidelines.*

NOTIFICATION OF MAJOR CHANGES

The PI is responsible for notifying the Research Office of any significant changes in the rDNA component of all approved projects. Examples of such are: (a) a change in hosts or vectors; (b) a change in the donor species or nature of the DNA segments; (c) a change in the physical location of the experiments; and (d) a change of the responsible investigator. The changes should be submitted on a "Request for Modification" form. Modifications should not be initiated until approval is obtained.**VA MEDICAL CENTER (ATLANTA)**

DECATUR, GEORGIA

FREEZER & REFRIGERATOR FORM

Instructions:

a. Download e-fillable PDF form here.
b. Complete form and post a hard copy on each freezer located in Research, at the Atlanta VAMC.
c. Email an electronic copy to the BSO.