

SAFETY OF PERSONNEL AND SECURITY OF LABORATORIES INVOLVED IN VA RESEARCH

1. REASON FOR ISSUE: This Veterans Health Administration (VHA) directive establishes mandatory standards for safeguarding the safety of personnel regarding hazards associated with the conduct of research and establishes organizational controls for the security of VA research facilities to protect public health, the environment, and national security.

2. SUMMARY OF CHANGES: This directive combines two previous VHA handbooks. It clarifies responsibilities for implementing and evaluating plans for research safety/biosafety, security, chemical hygiene and emergency management (formerly VHA Handbook 1200.08, Safety of Personnel Engaged in Research, dated March 6, 2009), and addresses the security of both VHA facilities in which research is conducted and agents used in that research (formerly VHA Handbook 1200.06, Control of Hazardous Agents in VA Research Laboratories, dated October 21, 2005). It incorporates new Federal regulations established since those handbooks were published.

3. RELATED ISSUES: VHA Directive 1200, Research and Development Program, dated May 13, 2016; other 1200 series directives and handbooks; and Office of Research and Development Program Guides.

4. RESPONSIBLE OFFICE: The VHA Office of Research and Development (ORD, 10X2) is responsible for the contents of this VHA directive. Questions may be referred to 202-443-5600.

5. RESCISSION: VHA Handbook 1200.08, Safety of Personnel Engaged in Research, dated March 6, 2009; VHA Directive 2005-003, Requirements for Submittal and Approval of Biosafety Level-3 (BSL-3) Research Laboratory Construction and Renovation, dated January 19, 2005; and VHA Handbook 1200.06, Control of Hazardous Agents in VA Research Laboratories, dated October 21, 2005, are rescinded.

6. RECERTIFICATION: This VHA directive is scheduled for recertification on or before the last working day of April 2024. This VHA directive will continue to serve as national VHA policy until it is recertified or rescinded.

April 24, 2019

VHA DIRECTIVE 1200.08

CERTIFIED BY:

**BY DIRECTION OF THE UNDER
SECRETARY FOR HEALTH:**

/s/ Carolyn M. Clancy, M.D.
Deputy Under Secretary for Health for
Discovery, Education, and Affiliate Networks

/s/ Carolyn M. Clancy
Deputy Under Secretary for Health for
Discovery, Education, and Affiliate Networks

NOTE: *All references herein to VA and VHA documents incorporate by reference subsequent VA and VHA documents on the same or similar subject matter.*

DISTRIBUTION: Emailed to the VHA Publication Distribution List on April 26, 2019.

CONTENTS

SAFETY OF PERSONNEL AND SECURITY OF LABORATORIES INVOLVED IN VA RESEARCH

1. PURPOSE..... 1

2. BACKGROUND..... 1

3. DEFINITIONS 2

4. POLICY 5

5. RESPONSIBILITIES 5

6. SUBCOMMITTEE ON RESEARCH SAFETY 16

7. INSTITUTIONAL BIOSAFETY COMMITTEE 22

8. VA RESEARCH LABORATORY ACCESS AND PHYSICAL SECURITY 24

9. INSPECTIONS OF VA RESEARCH AREAS 24

10. TRAINING REQUIREMENTS 24

11. RECORDS MANAGEMENT..... 25

12. REFERENCES..... 25

SAFETY OF PERSONNEL AND SECURITY OF LABORATORIES INVOLVED IN VA RESEARCH

1. PURPOSE

This Veterans Health Administration (VHA) directive establishes mandatory standards addressing safety and security related to the involvement of hazards including biohazards, chemical hazards, hazardous materials and physical hazards in VHA research. This includes the safety of personnel with potential exposure to these hazards and the security of both the facilities in which the research is conducted and the agents used in the research. This directive applies to all VA research conducted in VA research laboratories. **NOTE:** *This directive specifically addresses the management of safety and security in VA research laboratories. It is not intended to replace general occupational safety and health policy applicable to all VA employees, regardless of their roles, security policies applicable to all VA medical facilities, or to replace specific regulatory programs mandated by law.* **AUTHORITY:** Title 38 United States Code (U.S.C.) 7303 and Title 38 U.S.C 8117b.

2. BACKGROUND

a. Medical and Prosthetics Research and Development (R&D) in VHA is an intramural program administered by the VHA Office of Research and Development (ORD) in support of research conducted at VA facilities, in space occupied by VA under a legal agreement and in approved off-site space.

b. VA research is designed to yield knowledge, information, products, and technologies that advance the understanding of health and disease, and the development of treatments that improve the wellbeing of Veterans. Such research can involve physical hazards and require the use of chemicals, gases, radioactive materials, radioactive sources, and human pathogens and their products. Because some of these materials pose health and safety risks to research personnel, other individuals, and the environment, VA needs policies aimed at controlling these risks.

c. The VA R&D program requires VA research to comply with all applicable Federal policies, statutes, regulations, and guidelines, including those issued by the Occupational Safety and Health Administration (OSHA), Environmental Protection Agency (EPA), Nuclear Regulatory Commission (NRC), Centers for Disease Control and Prevention (CDC), United States Department of Agriculture (USDA), and National Institutes of Health (NIH), as applicable. **NOTE:** *No research requiring Biosafety Level 4 (BSL-4) containment is permitted in VA.*

d. Failure to conform to the requirements and standards of this directive may result in immediate withdrawal of VA research funding, suspension of the local research program, or both. Individuals who knowingly fail to follow the provisions of this directive are subject to disciplinary action proportionate to the severity of the violation, including termination of VA employment or termination of a contract. Failure to comply with Federal regulations may also result in criminal or civil penalties.

3. DEFINITIONS

a. **Biohazards.** Biohazards are biological agents or conditions that are a threat to humans, animals, or the environment. Biohazards include, but are not limited to, the following:

(1) Pathogens, human and animal blood, body secretions, tissues, and cell lines corresponding to Biosafety Levels (BSL) 1-4.

(2) Microbial toxins produced by micro-organisms including bacteria and fungi.

(3) Poisonous, toxic, parasitic, and venomous animals or plants.

(4) Recombinant and synthetic nucleic acid molecules:

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

(b) Nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules (i.e., synthetic nucleic acids).

(5) Select agents, as specified in 42 Code of Federal Regulations (CFR) 73, 7 CFR 331, and 9 CFR 121.

b. **Chemical Hazards.** Chemical hazards include any substance or mixture of substances with properties capable of producing adverse effects on the health and safety of humans. Chemical hazard categories include, but are not limited to, the following:

(1) Corrosives.

(2) Toxic substances (poisons, irritants, asphyxiates).

(3) Sensitizers.

(4) Carcinogens, mutagens, and teratogens.

(5) Flammables.

(6) Explosives.

(7) Any chemical which can cause a physical or a health hazard, as defined by the Hazard Communication Standard (29 CFR 1910.1200).

c. **Dual Use Research of Concern.** Dual Use Research of Concern (DURC) is life sciences research that, based on current understanding, can reasonably be anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public

health and safety, agricultural crops and other plants, animals, the environment, or national security. Further information on DURC is available at <https://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf>. **NOTE:** *This linked document is outside of VA control and may not be conformant with Section 508 of the Rehabilitation Act of 1973.*

d. **Hazardous Materials.** A hazardous material is any item or agent (biological, chemical, radiological, and/or physical), which has the potential to cause harm to humans, animals, or the environment, either by itself or through interaction with other factors. Hazardous materials include, but are not limited to, the following:

(1) USDA Animal and Plant Health Inspection Service (APHIS) biological agents (7 CFR 331, 9 CFR 121) and their products (toxins).

(2) Gases that are easily disseminated or transmitted and have a potential for high mortality rates and major public health impact, have the potential for causing public panic and social disruption, or are risks for public health preparedness.

(3) Radioactive material and/or radioactive sources.

(4) Other agents with the potential for being used as weapons by terrorists.

e. **Physical Hazards.** Physical hazards are a type of environmental hazard that can cause harm with or without contact. Physical hazards include, but are not limited to, the following:

(1) Ionizing and non-ionizing radiation.

(2) Noise.

(3) Vibration.

(4) Extremes of temperature and pressure.

(5) Explosive hazards.

(6) Electrical hazards.

(7) Mechanical hazards.

f. **Research Safety and Security Program.** The Research Safety and Security Program (RSSP) is the research specific program (as defined in this directive) to provide for the safety of personnel and security of VA research laboratories, that defines the roles and responsibilities of the research service in the context of that program. Components of an RSSP vary depending in part, on the type of research being conducted and the level of activity in research laboratories. General components of an RSSP required for all research laboratories are listed below:

- (1) Safety;
- (2) Security;
- (3) Inventory Control;
- (4) Inspections;
- (5) Emergency Management;
- (6) Training; and
- (7) Record Keeping.

g. **Select Agents and Toxins.** Pursuant to 42 U.S.C. 262a and 7 U.S.C. 8401, select agents and toxins are a subset of biological agents and toxins that the Department of Health and Human Services (HHS) and USDA have determined to have the potential to pose a severe threat to public health and safety, to animal or plant health, or to animal or plant products. Current lists of select agents and toxins can be found at 42 CFR 73.3 and 73.4, 9 CFR 121.3 and 121.4, 7 CFR 331.3, and at: <http://www.selectagents.gov/SelectAgentsandToxinsList.html>.

(1) Excluded select agents and toxins are attenuated strains of select agents or toxins that have been modified to be less toxic or potent, and therefore have been determined not to pose a severe threat to public health and safety. Once excluded, the agent or toxin is not covered by the select agents and toxins regulations found in 42 CFR 73 and 9 CFR 121. A list of attenuated strains may be found at <https://www.selectagents.gov/SelectAgentsandToxinsExclusions.html>. Information regarding the process to request exclusion of an attenuated strain or modified toxin may be found at <https://www.selectagents.gov/egd-requests.html>.

(2) Permissible toxin amounts are the amount of select toxins that an investigator can store or use that are not subject to regulations found in 42 CFR 73. The specific toxins and the permissible toxin amounts of toxins may be found at <https://www.selectagents.gov/PermissibleToxinAmounts.html>.

h. **VA Research.** VA research is research that is conducted by VA investigators (serving on compensated, without compensation (WOC), or Intergovernmental Personnel Act (IPA) appointments) while on VA time or VA property. The research may be funded by VA, by other sponsors, or be unfunded. VA research must have R&D Committee approval.

i. **VA Research Laboratories.** VA research laboratories are research laboratories under the control of VA and/or used for VA research within VA facilities or a space occupied by VA under a legal agreement (e.g., lease). **NOTE:** *Laboratories within the VA facility in space leased to a non-VA entity should have in the leasing agreement requirements for managing safety and security.*

4. POLICY

It is VHA policy that each VA medical facility conducting research must safeguard the safety of personnel, the public and the environment, and the security of research laboratories and other applicable research space in compliance with all applicable VA policies, Federal statutes and regulations from OSHA, EPA, NRC, NIH and CDC guidelines, and State and local requirements. This is to be accomplished by establishing and implementing a RSSP that enforces organizational controls set forth in this directive.

5. RESPONSIBILITIES

a. **Under Secretary for Health.** The Under Secretary for Health is responsible for:

(1) Ensuring overall VHA compliance with this directive.

(2) Approving only the construction of new BSL-3 laboratories, major revisions to existing BSL-3 laboratories, or the re-activation of inactive BSL-3 laboratories, if it is feasible for VA to maintain appropriate security for such facilities. **NOTE:** *Permission to reactivate a BSL-3 laboratory is required if the laboratory has been out of use as a BSL-3 facility for 12 months or longer.*

b. **Deputy Under Secretary for Health for Operations and Management.** The Deputy Under Secretary for Health for Operations and Management is responsible for:

(1) Communicating the contents of this directive to each of the Veterans Integrated Services Networks (VISNs).

(2) Ensuring that each VISN Director has the sufficient resources to fulfill the terms of this directive in all VA medical facilities that conduct research within that VISN.

(3) Providing oversight of VISNs to assure compliance with this directive, relevant standards, and applicable regulations.

c. **Chief Research and Development Officer, Office of Research and Development.** The Chief Research and Development Officer (CRADO) is responsible for:

(1) Approving requests for new BSL-3 laboratories, deactivation or major renovation of existing BSL-3 laboratories, or the reactivation of inactive BSL-3 laboratories.

(2) Approving requests for a waiver of the requirements for a SRS.

d. **Executive Director, Office of Research Oversight.** The Executive Director, Office of Research Oversight (ORO), is responsible advising the Under Secretary for Health on matters of compliance and assurance related to human subject protections, laboratory animal welfare, research safety, research laboratory security, and research

information security, as well as on matters of research misconduct, and other research improprieties.

e. **Veterans Integrated Services Network Director.** Each VISN Director is responsible for:

(1) Ensuring that the VA research programs at facilities within the VISN comply with current policies and guidelines relating to safety.

(2) Ensuring that the VA research programs at facilities within the VISN comply with current policies and guidelines relating to the prevention of terrorist events, and the security of VA research laboratories.

f. **VA Medical Facility Director.** Each VA medical facility Director is responsible for:

(1) Ensuring the establishment and implementation of the RSSP.

(2) Ensuring the availability of adequate staffing and resources to cover key functions of the RSSP such as Facility Safety Officer functions, Chemical Hygiene Officer functions, as well as appropriate expertise in research safety, biosafety, radiation safety, and facility security.

(3) Ensuring that the research areas are included in all facility-wide safety, security, and emergency management plans as appropriate.

(4) Ensuring that Facility Safety program coordinates with Occupational/Personnel Health, VA Police, Research Safety, Engineering and all other relevant parties to insure overall safety of Research Personnel, and such coordination is consistent with relevant Federal, VA, and applicable regulations.

(5) Ensuring the physical security of VA research laboratories and other specialized research areas, including animal care facilities, regardless of their BSL of containment.

(6) Appointing, in writing, members to serve on the Subcommittee on Research Safety (SRS) for terms up to 3 years, with unlimited renewal at the discretion of the Director. For responsibilities of the SRS, see paragraph 5.i.

(7) Appointing, in writing, the SRS Chair for the term of up to three years, which may be renewed.

(8) Appointing, in writing, at least one qualified VHA employee to be a voting member, and at least one other qualified VHA employee to serve as an alternate voting member of any external SRS. These employees must have at least 5/8-VA-compensated appointments.

(9) Ensuring that the approval of the VISN Director, the CRADO, and the Under Secretary for Health have been secured before allowing construction of a new BSL-3

laboratory, or major renovation of an existing BSL-3 laboratory, or the reactivation of an inactive BSL-3 laboratory.

(10) Ensuring that access to BSL-3 laboratories is authorized only for individuals who meet the requirements for maintaining appropriate security. This responsibility may be delegated to the Associate Chief of Staff for R&D (ACOS/R&D).

g. **Associate Chief of Staff for Research & Development.** The ACOS/R&D (or Coordinator for R&D in small facilities) is responsible for:

(1) Overseeing the implementation of all requirements set forth in this directive.

(2) Ensuring creation and update of the facility RSSP that appropriately addresses research safety, and laboratory security, at the facility and in space occupied by VA under a legal agreement. For VA research conducted in laboratories located in approved off-site facilities such as affiliate universities, the ACOS/R&D must ensure that a process is in place to review research safety and security, and if necessary provide feedback to the responsible party for the off-site facility on any deficiencies.

(3) Coordinating efforts and communication among all relevant officials, committees and individuals to ensure the successful implementation of the RSSP.

(4) Putting mechanisms in place to ensure that access to VA research areas is monitored and evaluated regularly to prevent unauthorized persons from gaining access.

(5) Ensuring that research service provides the facility police service with the information and the support necessary to meet police responsibilities for research security. This includes:

(a) Ensuring that all research areas are included in the routine assessment of the vulnerability of the facility to security breaches conducted by the police service. **NOTE:** *This does not include off-site facilities that are not under a fully executed VA lease.*

(b) Supporting the performance of the routine security and incident response drills or exercises required by the Emergency Management Program or Safety Office.

(c) Informing the facility police service of any changes in research affecting the facility's security needs.

(6) Notifying ORD and ORO when construction of any new BSL-3 research laboratory, renovation of any existing BSL-3 research laboratory, or reactivation of any inactive BSL-3 laboratory is planned.

(7) Notifying ORD and ORO when a BSL-3 laboratory will be inactivated or closed.

(8) Ensuring that there is a process by which the SRS is notified whenever space is decommissioned, or when the identification and disposal or decontamination of hazardous materials and/or equipment is required between uses.

(9) Establishing mechanisms to ensure that all personnel conducting VA research (including VA contractors, students, and visiting fellows, as well as those with VA appointments), comply with all VA standards for safety and security described in this directive and all other applicable ORD guidelines (<https://www.research.va.gov/resources/policies/default.cfm>).

(10) Ensuring that safety-related communications from ORD or other VA offices are distributed to appropriate local personnel, in a timely manner, upon receipt.

(11) Working with the SRS as needed to ensure that research activities stop when the SRS imposes either a safety hold or suspension until the hold or suspension is rescinded.

(12) Meeting the responsibilities assigned to the ACOS/R&D in the RSSP.

(13) Identifying an individual qualified through training or experience and delegating Research Chemical Hygiene Officer responsibilities to that person if the medical facility does not have someone specifically appointed to that role.

(14) Appointing a Biological Safety Officer if the VA research program involves the use of recombinant or synthetic nucleic acid molecules at BSL-3, or large scale (greater than 10-liter cultures) research on or production involving recombinant or synthetic nucleic acid molecules, as NIH Guidelines require.

(15) Reviewing and approving requests for a CDC or APHIS laboratory registration number and Certificate of Registration, as required, before VA research laboratories at the facility may receive, transfer control/ownership to another individual, or use select agents or toxins.

h. **VA Medical Facility Safety Officer.** The VA medical facility Safety Officer is responsible for:

(1) Ensuring that current inventories of all select agents and toxins, and chemical hazards in each VA local research laboratory are maintained and reviewing them at least semi-annually so that appropriate security measures can be implemented.

(2) Maintaining a complete list of the chemicals in the facility that have been designated or identified by OSHA or EPA as hazardous and ensuring that appropriate approvals for their handling and use are in place.

i. **VA Medical Facility Radiation Safety Officer.** The VA medical facility Radiation Safety Officer is responsible for overall oversight of radiation safety at the VA facility, including safety with regards to use of radioactive agents and sources in research.

j. **VA Medical Facility Police Service.** The VA medical facility police service has assumed responsibility for:

(1) Maintaining the security of VA research laboratories, providing emergency responses, conducting routine assessments of the vulnerability of the VA research laboratories to security breaches, and assisting the facility Research Office with the development and implementation of the RSSP.

(2) Ensuring that access to VA research laboratories is recorded and monitored appropriate to the level of security needed per the vulnerability assessment.

(3) Assisting VA research personnel prior to the purchase or installation of security devices and/or initiation of construction, in identifying devices and construction designs that effectively improve security.

k. **VA Medical Facility Research Chemical Hygiene Officer.** The VA medical facility Research Chemical Hygiene Officer as designated by the ACOS/R&D is responsible for:

(1) Ensuring that inventories of all chemicals in each local VA research laboratory are maintained by the Principal Investigator (PI) and reviewed at least semi-annually so that appropriate security measures can be implemented.

(2) Reviewing and approving the facility's complete list of chemicals used in research designated or identified by OSHA or EPA as hazardous. **NOTE:** *This does not need to be combined but can be reviewed for each VA research laboratory.*

(3) Fulfilling additional duties delegated to this role by the SRS.

l. **VA Medical Facility Research Biological Safety Officer.** If the VA research program involves the use of recombinant or synthetic nucleic acid molecules at BSL-3, or large scale (greater than 10-liter cultures) research on or production involving recombinant or synthetic nucleic acid molecules, NIH Guidelines require appointment of a Biological Safety Officer who must serve as a member of the Institutional Biosafety Committee (IBC) and who is responsible for the duties defined in the NIH guidelines (See https://osp.od.nih.gov/wp-content/uploads/2013/06/NIH_Guidelines.pdf. **NOTE:** *This linked document is outside of VA control and may not be conformant with Section 508 of the Rehabilitation Act of 1973.*).

m. **Research & Development Committee.** The R&D Committee is responsible for:

(1) Ensuring that the SRS includes experts on research safety, as established in the facility's RSSP and has the delegated authority for oversight of research safety. The experts may be individuals (holding VA appointments or serving the VA as external consultants) or may be relevant committees (including committees specifically appointed to serve the VA research service, existing committees that serve the VA facility, and existing committees at other institutions).

(2) Establishing an Institutional Biosafety Committee (IBC) of record if the facility research program includes work that falls under the scope of the most current edition of the NIH Guidelines For Research Involving Recombinant or Synthetic Nucleic Acid Molecules (https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.html). The IBC of the academic affiliate may serve as the VA IBC of record, under the following conditions:

(a) The affiliate agrees to provide the services required for VA research;

(b) An appropriate Memorandum of Understanding (MOU) is established with the affiliate; and

(c) The affiliate IBC is registered as the IBC of record for the VA facility.

(3) Ensuring that the SRS and, as appropriate, the IBC review all protocols that involve safety hazards to personnel and the environment and all research within the scope of the NIH Guidelines, respectively.

(4) Reviewing and, as appropriate, acting on communications from the SRS and IBC, including the minutes of all meetings.

n. **Subcommittee on Research Safety.** The SRS is responsible for managing implementation of the RSSP, which includes:

(1) Developing processes to activate and decommission laboratories as needed including transfers of assignment of laboratories from one PI to another.

(2) Developing a process to ensure that each VA research project conducted in a VA research laboratory (including off-site locations) is evaluated prior to initiation/activation for the involvement of hazards so that appropriate safety and security measures can be implemented. VA research involving hazards in a research laboratory may not be initiated in advance of approval by the SRS and, when appropriate, the IBC.

(3) Ensuring that each research project submitted to the SRS for approval is reviewed by a qualified individual designated by the SRS Chair or designee to:

(a) Identify the biological, chemical, and physical hazards involved in the work;

(b) Ensure that a complete list of chemicals involved in the research project, that are designated or identified by OSHA or EPA as hazardous, is reviewed and approved by the SRS and included in the facility-wide reviews to ensure that appropriate approvals for their handling and use are in place.

(c) Ensure that appropriate measures are in place to protect the safety of the personnel and environment.

(4) Reviewing and approving that any change in a research project that affects the safety of the personnel or the environment submitted by the PI for review and approval prior to the implementation of the change.

(5) Ensuring that current inventories of all hazardous agents in each VA local research laboratory are maintained and reviewed by the Chemical Hygiene Officer at least semi-annually so that appropriate security measures can be implemented.

(6) Reviewing inspection reports of each VA research laboratory annually, to ensure that appropriate safety equipment and procedures and security measures are in place for all of the projects/protocols being conducted in that laboratory. **NOTE:** *For VA research conducted in approved off-site facilities that are not owned, leased by VA, or occupied by VA under a legal agreement the SRS may rely on inspections conducted by non-VA entities with primary responsibility for the space (e.g., academic affiliate) provided that the inspections are conducted at least annually and the SRS reviews the results of those inspections.*

(7) Reviewing the results of all research laboratory and safety-related inspections (e.g., Environment of Care, Annual Workplace Evaluations, Security Vulnerability Assessments, inspections by regulatory bodies, etc.) and ensuring the implementation and completion of corrective actions, as appropriate.

(8) Ensuring that each of the following is evaluated, addressed, and reported according to regulatory requirements, including those of VHA Handbook 1058.01, Research Compliance Reporting Requirements, dated June 17, 2015:

(a) Any human death that may be the result of work (or other activity) in a research laboratory or dedicated research area (e.g., research specimen storage area);

(b) Any serious accident, injury, illness, or exposure (other than those that result in death) that may be the result of work (or other activity) in a research laboratory or dedicated research area (e.g., research specimen storage area);

(c) Any intrusion, physical security breach, break-in, or other security violation that occurs in dedicated research areas;

(d) Any unplanned suspension or termination of research by the ACOS/R&D or another facility official due to concerns about research laboratory security; and

(e) Any other deficiency that substantively compromises the effectiveness of the facility's research laboratory security program.

(9) Ensuring the development and implementation of research-specific plans for safety/biosafety, security, chemical hygiene and emergency management. Ensuring that appropriate drills are conducted annually by appropriate facility personnel, such as Facility Safety, Emergency Management, Engineering, and VA Police, to evaluate the effectiveness of the plans.

(10) Evaluating annually the effectiveness of the RSSP, and identifying and implementing any updates, revisions, or corrections needed. A summary of this evaluation must be documented in the SRS minutes and sent to the medical facility Director through the R&D Committee. This evaluation must include:

- (a) A review of the RSSP Plan;
- (b) The results of all relevant annual drills or exercises;
- (c) Summary of any research-related accidents or injuries;
- (d) Summary of results of safety inspections of VA research laboratories, including leased locations and reports from non-VA entities for approved non-VA off-site locations where VA research is conducted; and
- (e) Concerns raised during any Police vulnerability assessments.

(11) Coordinating the safety and security measures that apply to all of the facility's VA research laboratories. This includes:

- (a) Managing safety-related training;
- (b) Ensuring that a process is in place to identify individuals who require health surveillance and/or exposure monitoring, on the basis of their involvement in specific VA research projects, or their other risks of exposure to hazards involved in VA research; and
- (c) Working with Occupational Health and Facility Safety to ensure that appropriate surveillance and monitoring is provided.

(12) Ensuring that access to BSL-3 research laboratories is appropriately controlled by:

- (a) Reviewing and acting on requests for access to BSL-3 research laboratories, for employees (compensated, WOC, or IPAs) or contractors.
- (b) Reviewing at least annually the appropriateness of the security status of personnel with access to VA BSL-3 research laboratories. This review is to include consideration of each individual's need for access (based on the individual's duties in the research being conducted), the individual's appointment status, and the status of the individual's Security Risk Assessment by the Criminal Justice Information Services of the FBI.
- (c) Reviewing requests to construct a new BSL-3 facility, to make major renovations to an existing BSL-3 facility, or to re-activate an inactive BSL-3 facility before they are submitted to the medical facility Director, the VISN Director, ORD, and ORO.

NOTE: *The operations of the SRS are discussed in paragraph 7.*

o. **Institutional Biosafety Committee.** The IBC is responsible for oversight of local VA research according to the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (see https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.html). This includes, but is not limited to, the following:

(1) Reviewing and approving of applications for the initiation, continuation, and/or modification of VA research involving non-exempt recombinant or synthetic nucleic acid molecules.

(2) Approving protocol or research activities involving biohazards, which may be granted for a three-year period with re-certification annually.

(3) Determining the appropriate BSL for each protocol and ensuring that the corresponding safety measures are implemented prior to initiation of the research.

(4) Notifying investigators in writing or electronically regarding the outcome of the review of proposed research activities or proposed significant changes. The notification must include the date of approval, the specific BSL that applies to the protocol, and a description of any additional safety measures required by the IBC.

(5) Conducting and documenting an annual review of those portions of the RSSP that apply to the safety of VA research involving recombinant or synthetic nucleic acid molecules, identifying concerns and ensuring that corrective actions are completed, as appropriate. This report, or a summary thereof, will be provided to both the SRS and the R&D Committee.

NOTE: *The operations of the IBC are discussed in paragraph 8.*

p. **Principal Investigator or Laboratory Director.** Each PI or Laboratory Director is responsible for:

(1) Ensuring compliance with all regulatory and facility requirements that apply to safety or security in the research that the PI or Laboratory Director supervises.

(2) Submitting the documentation of each project for review and approval by the SRS and IBC, if applicable, prior to initiating the research. This documentation must include:

(a) A description of the work proposed;

(b) A list of all hazards involved in the work, description of procedures to meet current standards for safe handling, and where the hazards will be located;

(c) The measures that will be taken to ensure appropriate security of the hazardous materials and equipment; and

(d) The requirements to be met by personnel before participating in the research project.

(3) Ensuring that approval of the all appropriate subcommittees and the R&D Committee is secured before work begins on any proposed new VA research.

(4) Ensuring that protocols are conducted as approved by the SRS and/or IBC.

(5) Ensuring that any significant change in a research project that affects the safety of the personnel or the environment is submitted in writing to the SRS for review and approval prior to the implementation of the change.

(6) Submitting all materials required to the SRS for annual review of the VA laboratory and all open protocols.

(7) Ensuring that all those they supervise have:

(a) Been advised of the potential safety risks to themselves, the facility, and the environment, and are familiar with the security precautions to be followed in accessing, handling, transferring, containing, or destroying any hazardous materials or accessing any select agents or toxins.

(b) Ready access to the safety data sheets for chemicals and the inventory of hazardous agents stored or used in the laboratory.

(8) Establishing and enforcing standards of practice (including use of personal protective equipment) that minimize employee exposures to biological, chemical, physical, and radiation hazards.

(9) Ensuring that biological safety cabinets and chemical fume hoods within the laboratory are certified within the last 12 months, after being moved, or more frequently if indicated by safety risk assessment; and notifying the Research Office or Biosafety Officer if cabinets are not properly certified.

(10) Reporting problems and concerns about operation and containment practices and procedures to the appropriate subcommittees and authorities.

(11) Ensuring that all accidents are entered into the Automated Safety Incident and Surveillance Tracking System (ASISTS/WC-OSH/MIS) according to VHA Directive 7701, Comprehensive Occupational Safety and Health Program, dated May 5, 2017.

(12) Ensuring that the most current plans for research safety/biosafety, security, chemical hygiene, and emergency management are readily available to all employees in their work area, and that employees have been trained and are knowledgeable of the locations and contents of the plans.

(13) Maintaining the lowest reasonably achievable levels of employee exposure to hazardous agents. Employee exposures to chemicals must not exceed the Permissible Exposure Limits (PELs) established by OSHA at any time. In the absence of an OSHA PEL, employee exposures must not exceed the National Institute for Occupational

Safety and Health (NIOSH) Recommended Exposure Limits. Further information may be found at <https://www.osha.gov/dsg/annotated-pels/index.html>.

(14) Ensuring that an appropriate laboratory inventory of the agents outlined below is maintained. Agents that require implementation of special security measures must be clearly identified as such, and their inventory must be reviewed at intervals consistent with federal regulations. The reviews must be documented and made available upon request. The hazardous materials to be included are those in any of the following categories:

- (a) Chemicals that are defined as hazardous by OSHA or EPA.
- (b) Select agents.
- (c) Toxins.
- (d) Highly hazardous agents, including select agents and toxins.
- (e) Time-sensitive hazardous chemicals.

(f) Hazardous drugs, as identified by NIOSH in the most current version of the NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings, which may be found at <https://www.cdc.gov/niosh/topics/hazdrug/pubs.html>. Hazardous drugs include those that exhibit one or more of the following six characteristics in humans or animals: carcinogenicity; teratogenicity or other developmental toxicity; reproductive toxicity; organ toxicity at low doses; genotoxicity; and structure and toxicity profiles of new drugs that mimic existing drugs determined hazardous by the above criteria.

- (g) Gas anesthetic agents.
- (h) Controlled substances and other pharmaceuticals.

(15) Managing all biohazardous, radiological, chemical, and medical waste in accordance with Federal regulations, and all VA, VHA, and facility policies.

(16) Maintaining a copy of hazardous waste disposal inventory.

(17) Submitting a written corrective action plan to the SRS for each deficiency cited from the annual inspection by the SRS and ensuring that all corrective actions are completed in a time period specified by the SRS.

(18) Ensuring that any DURC is conducted in compliance with all VA and Federal requirements.

(19) Identifying those who are to work with select agents and/or toxins, and ensure that a proper Security Risk Assessment is completed by the Federal Bureau of Investigations (FBI), as required by 42 CFR 73.10, 7 CFR 331.10, or 9 CFR 121.10, prior to access being authorized. The Security Risk Assessment is in addition to the

routine background investigation required by VHA Directive 0710, Personnel Security and Suitability Program, dated October 11, 2018. **NOTE:** *Exempt amounts of the select agents or toxins do not require the additional Security Risk Assessment.*

q. **Individuals Working in VA Research Laboratory Facilities.** Each individual working in VA research laboratory facilities is responsible for:

(1) Complying with all educational and training requirements related to the individual's assigned duties and hazards and/or sensitive materials present in the laboratory or research facility.

(2) Assisting the PI/Lab Director in a risk assessment that documents all potential exposures to hazards to be encountered in the course of the individual's assigned duties.

(3) Report potentially work-related injuries, illnesses, and exposures to hazardous, toxic, or infectious materials according to facility policy and VHA Directive 7701.

(4) Report any loss, release, theft, misuse, or unauthorized disclosure of any hazardous materials according to the laboratory's SOPs, research service requirements, and facility policy.

(5) Be particularly attentive to any persons or activities that seem suspicious and promptly report them to a supervisor, other individual designated by the research service, and/or police service, if indicated, following all facility policies governing such reporting.

6. SUBCOMMITTEE ON RESEARCH SAFETY

a. **Subcommittee on Research Safety Establishment.**

(1) The VA medical facility R&D Committee must establish and maintain an SRS to oversee research safety. The SRS may be internal (administered within the VA medical facility) or external (administered by another VA or an affiliated university).

(2) An external SRS must be formally established with a memorandum of understanding (MOU) that addresses at least the following:

(a) The roles and responsibilities of the affiliate or other VA committee.

(b) Adherence to VA requirements.

(c) Appointment of at least one VA employee and an alternate to represent VA interests and requirements.

(d) Management of ongoing exchange of information between the VA facility and the institution hosting the external SRS regarding the actions of the external SRS. These included, but are not limited to:

1. Minutes of the meetings;
2. Documentation of review and approval of projects;
3. Reports of laboratory safety inspections;
4. Documentation of mandatory drills conducted;
5. Documentation of semiannual review of chemical inventories;
6. Reports of the findings of accident investigations; and
7. Reports of noncompliance.

b. **Membership.**

(1) **Number and Qualifications of Members.**

(a) Each SRS must have at least five voting members, in addition to the ex-officio members.

(b) When the research to be reviewed involves recombinant and synthetic nucleic acid molecules not exempt from the current NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, the SRS must be constituted per the NIH Guidelines as an IBC or arrange for a separate IBC with registration as such with NIH Office of Science Policy (NIH-OSP); alternatively, the SRS must ensure review and approval by a separate VA or affiliate IBC.

(c) It is necessary for the SRS membership to include members with expertise in all safety matters the SRS oversees. This typically includes:

1. Etiologic agents, including bloodborne and airborne pathogens.
2. Chemical carcinogens and other chemical hazards.
3. Physical, environmental, and radiation hazards.
4. Conducting scientific research.

(d) Among the voting members of the SRS, specific expertise regarding the following must be available:

1. Occupational safety and health;
2. Environmental protection;
3. Department of Transportation (DOT) International Air Transport Association (IATA) expertise; and

4. Knowledge of the space and facilities assigned to each PI to ensure that research operations can be conducted safely.

(e) The SRS must include member(s) from the facility safety committee, such as the facility Safety Officer or a member of the Facility Infection Control Committee; and the Radiation Safety Officer or an appropriate individual with Radiation Safety expertise.

(f) At least one individual who regularly attends Institutional Animal Care and Use Committee (IACUC) meetings to serve as liaison between the SRS and the IACUC, may be voting or non-voting.

(2) **Ex-Officio Members.** Ex-officio members must include:

(a) A liaison member from the facility R&D Committee (non-voting).

(b) An employee union safety representative, or other union designee, if required by the applicable union contract and whose voting status is determined by the applicable union contract. The role of the union ex-officio member is to assist in identifying safety issues related to research employees.

c. **Exemption From the Requirement for SRS Review.**

(1) Research that only involves the collection and analysis of biospecimens by VA personnel within clinical areas or clinical research areas, or the performance of standard clinical procedures in clinical areas or offices is exempt from the requirement for SRS review and approval. Completion of the Research Protocol Safety Survey (RPSS) is not required (See <http://vaww.va.gov/vaforms/medical/pdf/10-0398.pdf>. **NOTE:** *This is an internal VA Web site that is not accessible to the public.*)

(2) For research that clearly does not involve collection of specimens or use of VA laboratories, such as health services research, chart reviews, and database research, the R&D Committee may accept an affirmation from the PI that no hazards are involved. The RPSS form is not required and review by the SRS is not required. **NOTE:** *If the VA facility only conducts research that meets the exemptions in (1) and (2), the facility can request a waiver of the requirements for a SRS subcommittee from the CRADO.*

(3) Research conducted in VA research laboratories that does not involve any hazards must be documented by completion of the RPSS or alternative form, indicating that the answers to all questions are "No". (See <http://vaww.va.gov/vaforms/medical/pdf/10-0398.pdf>. **NOTE:** *This is an internal VA Web site that is not accessible to the public.*)

(4) The SRS Chair or another designated, qualified individual may conduct an administrative review to determine whether a protocol is exempt from SRS review. The process for conducting an administrative review should be described in the SRS guidelines and procedures. The outcome of this review must be documented as part of the SRS records, reported to the SRS at its next meeting, and documented in the meeting minutes. The individual conducting the review could be a voting member of the

SRS or a member of the research service staff as long as the SRS Chair determines the individual has sufficient expertise to accurately make the assessment. If anyone other than the Chair will conduct the review, the SRS must document this assignment in writing.

d. Review of Research.

(1) Every research protocol that involves biological, chemical, physical, or radiation hazards conducted in a VA research laboratory must be reviewed by the SRS before the work begins and as needed thereafter. **NOTE:** *Protocols may be project-specific or may be umbrella protocols that cover multiple projects.* If a proposed activity requires a containment level not currently available, the SRS must withhold its approval until such containment or resources are available.

(2) The SRS must receive sufficient information from the PI prior to reviewing the research including, but not limited to, the protocol and the RPSS or an alternative form that contains, at minimum, the same information as VA Form 10-0398. (See <http://vaww.va.gov/vaforms/medical/pdf/10-0398.pdf>. **NOTE:** *This is an internal VA Web site that is not accessible to the public.*)

(3) All research protocols that are subject to SRS review must be initially reviewed at a convened SRS meeting.

(a) SRS members must be present at a convened meeting in person or via teleconference, video conference, or other live interface that allows for full, real-time participation.

(b) A quorum (a majority of the total voting membership) must be present for the SRS to conduct any official business, including the review and approval of the protocol. If the quorum is lost at any time during a meeting, no further official business can be conducted until the quorum is restored. Members can only vote in person or via teleconference, video conference, or other live interface that allows for full, real-time participation.

(c) Any member with a conflict of interest, e.g., investigator on the study or other conflicts as stated in the SRS SOP, must be recused during deliberation and voting on that study. The recused member may answer questions about the study at the request of the SRS, but may not be present during deliberations, be counted toward the quorum, or vote on the committee's determination. The recusal of the individual and verification that quorum is maintained must be documented in the SRS meeting minutes.

(4) All research involving recombinant or synthetic nucleic acid molecules must be reviewed and approved by a properly constituted and registered IBC.

e. Initial Review.

(1) The SRS must assess at least the following in the initial review:

- (a) The risks associated with the research including, but not limited to, risks to personnel, research subjects, the facility, and the environment;
- (b) The level of containment, laboratory procedures and practices, personal protective equipment, and training required for the research to be conducted safely;
- (c) The experience, expertise, and training of personnel involved;
- (d) The adequacy of the available laboratory space and resources; and
- (e) The status of the research, with respect to the NIH Guidelines, when the research involves recombinant or synthetic nucleic acid molecule research and whether IBC approval has been obtained, if required.

(2) When a protocol is subject to review and approval by an IBC, the SRS must review the findings of the IBC, including but not limited to the assigned BSL and the required safety measures, prior to its final approval.

(3) The outcome of SRS review is determined by a majority vote of the voting members present, and may be to approve the research, to require modifications to secure approval, or to withhold approval of the research. The R&D Committee and the investigator must be notified in writing of the outcome of the SRS review.

(4) When the SRS grants approval, it must specify the duration (up to one year from the date of approval) that the approval is valid.

(5) When the SRS requires modifications, the required modifications may be for the protocol itself, the level of containment, laboratory procedures and practices, the use of personal protective equipment, laboratory safety or security requirements, or any other safety or security concerns the SRS may determine.

(6) The SRS may vote to allow designated member review (DMR) to verify that the requested modifications have been incorporated.

(7) When the SRS withholds approval, it must provide the investigator with the reasons for this action.

f. Annual Review.

(1) Each PI's VA laboratory program must be reviewed by the SRS at a convened meeting on an annual basis. The review must include:

- (a) A list of projects that utilize SRS approved protocols;
- (b) An assessment of all SRS approved protocols (individual or umbrella) to ensure that the hazards, BSL, risk assessments, training of personnel and status of the project are up to date;

(c) Laboratory inspection report including findings and plans to address any deficiencies;

(d) Summary of all changes or amendments to the safety components of the protocol approved since the last review;

(e) Changes in space allocation; and

(f) Reports of any issues related to employee safety and security.

(2) The outcome of the annual review by the SRS may be for the SRS to approve, require modifications to secure approval, or to withhold approval/terminate the protocol. Termination of the protocol may be because of, but not limited to, such issues as hazards that cannot be appropriately managed, continuing noncompliance by the PI/Laboratory Director, or for other appropriate reasons as determined by the SRS.

(3) The R&D Committee and PI must be notified in writing of the outcome of the SRS annual review. If a protocol is terminated, the SRS must notify the PI in writing of the date of termination of the study and the reasons for the action.

g. Amendments to Protocols.

(1) Any amendment must be reviewed and approved prior to implementation of any changes that affect the safety components or BSL of the protocol. **NOTE:** *Amendments are not required to be submitted to the SRS for protocols determined to be exempt from the requirement for SRS review as long as the amendment does not add hazards to the protocol.*

(2) The SRS must review amendments at a convened meeting unless the SRS has established an SOP that defines the criteria for amendments to be considered minor and therefore eligible for DMR review. In general, amendments that do not add new hazards or exposures to the personnel in the laboratory may be designated as minor, while changes in PI or addition of new hazards may not.

(3) When the SRS determines that modifications are required to secure approval of an amendment, the SRS may vote to allow DMR review.

(4) The SRS must notify the PI in writing of the outcome of the review, and if approval is withheld, the reasons for the action. The R&D Committee is notified via the minutes of the SRS.

h. Designated Member Review.

(1) Research activities that may be approved by DMR include the following:

(a) Protocol modifications required by the SRS to secure approval after full committee review of an initial submission at a convened meeting. When modifications are required to secure approval of an initial submission, a majority of the SRS members

present at the meeting may vote to allow DMR rather than return the modifications to the full committee. However, any member of the SRS may, at any time, request to see the revised protocol and/or request full committee review (FCR) of the protocol.

(b) Minor amendments as defined in the local SRS SOPs.

(c) SRS modifications required to secure approval of amendments. When changes are required to secure approval of an amendment, a majority of the SRS members present at the meeting may vote to allow DMR rather than return the amendment to the full committee, however, any member of the SRS may, at any time, request to see the revised protocol and request FCR of the protocol.

(2) Any voting committee member, including those not involved in the designated review process, may request that a protocol be returned to the SRS for full committee review at any point during the DMR process.

(3) DMRs must be conducted by at least one voting member of the SRS, determined by the Chair to have the appropriate expertise. The outcome of the DMR, including the date approval was granted, must be reported at the next convened SRS meeting and documented in the minutes of that meeting.

(4) Designated member reviewers may approve, require modifications to secure approval, or refer back to the SRS for full committee review. **NOTE:** *Designated member reviewers may not withhold approval (or terminate ongoing research) but must instead refer the item back to the full committee for consideration.*

7. INSTITUTIONAL BIOSAFETY COMMITTEE

a. If a VA facility intends to permit the conduct of any research that falls under the scope of the NIH Guidelines For Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines), it must establish its own IBC (internal) or obtain the services of another VA facility or an academic affiliate IBC (external). **NOTE:** *NIH Guidelines state that when possible and consistent with protection of privacy and proprietary interests, the institution is encouraged to open its IBC meetings to the public. NIH Guidelines also state that upon request, the institution shall make available to the public all IBC meeting minutes and any documents submitted to or received from funding agencies which the latter are required to make available to the public.*

b. An internal IBC may share membership with the SRS or be constituted as a separate subcommittee of the R&D Committee. The IBC is responsible for reviewing all research that involves non-exempt recombinant and synthetic nucleic acid molecules if the research is covered under Section I-C "General Applicability" of the NIH Guidelines. The IBC must meet all requirements for membership, review of research, and other activities as outlined by the NIH Guidelines.

c. Procedures for a VA IBC review and approval of VA research must be described in local guidelines.

d. The facility may assign other reviews to the IBC such as for research involving:

- (1) Select Agents and Toxins.
- (2) Stem cell research.
- (3) Nanotechnology.
- (4) Dual Use Research of Concern (DURC).

e. A VA research program may use an external IBC hosted by a second VA facility subject to the following conditions:

- (1) The IBC must be internal to the second VA.
- (2) The second VA facility must be located in the same community, in order to meet the NIH Guidelines requirement for community representation.
- (3) The IBC of the second VA must be knowledgeable regarding the containment facilities at the requesting VA facility.
- (4) The requesting VA facility must appoint a VA-compensated employee as a voting member to the IBC of the second VA facility.
- (5) The requesting VA facility must establish and maintain registration with NIH-OSP indicating that the IBC at the second VA facility serves as the IBC-of-record for the requesting VA facility.

f. A VA research program may use an external IBC hosted by an academic affiliate, subject to the following conditions:

- (1) The IBC services must be obtained through the use of an MOU that outlines the responsibilities of both the VA facility and the academic affiliate.
- (2) The VA facility must establish and maintain registration with NIH-OSP indicating that the affiliate IBC serves as the IBC-of-record for the VA facility.
- (3) The external IBC must review research in accordance with all VA policies and other Federal requirements.
- (4) Minutes of the external IBC meetings and other documents related to the review and approval of VA research and the external IBC-related oversight of approved VA research must be provided to the SRS, R&D Committee, or the facility Research Office within a reasonable amount of time, as described in the MOU.
- (5) At least one voting member of the external IBC must be a VA-compensated employee.

8. VA RESEARCH LABORATORY ACCESS AND PHYSICAL SECURITY

Access to VA research laboratories must be controlled at all times. Physical security of all VA research areas must meet appropriate standards determined by the facility police service (see VA Directive 0730, and VA Handbook 0730/4), applicable regulatory agencies (e.g., CDC, APHIS, NRC), and cognizant VA oversight offices (e.g., radiation or nuclear medicine offices). The facility's VA police service must be consulted prior to purchasing or installing security devices and/or before initiating construction designed to improve security.

9. INSPECTIONS OF VA RESEARCH AREAS

Officials authorized by VA, the Secretary of HHS, the Secretary of the USDA, Government Accountability Office, or other authorized Federal agencies, including such entities as the CDC, may conduct inspections of all research laboratories covered by this directive. Individuals conducting the inspections must be allowed to inspect the site and inspect and copy any records relating to activities covered by this directive, subject to compliance to applicable Federal laws, regulations and VA policies on access to Federal facilities, data and data systems to include facility security procedures (e.g., review of credentials, badging, signing security statements, etc.). The inspections may be either announced or unannounced.

10. TRAINING REQUIREMENTS

a. All individuals (VA employees appointed as full-time, part-time, intermittent, fee-basis, or WOC, as well as contractors), and individuals appointed through IPA actions, either working in or directly administering VA research laboratories, must be appropriately trained to ensure safety and security within research laboratories. These training requirements must include:

(1) Specific training, as necessary, related to the laboratory areas where they are assigned to work and to the hazards or agents that may be encountered while conducting research. This requirement includes site-specific initial and annual refresher training on the research safety (exposure control plan), chemical hygiene, hazardous waste, security, and emergency management, as well as OSHA-regulated chemicals, radiation hazards, and individual laboratory-specific safety plans.

(2) Training requirements set forth by VA, OSHA, EPA, CDC, DOT, NRC and other applicable agencies (e.g., bloodborne pathogen training, hazardous chemical and waste disposal training, personal protective equipment training, emergency response, fire extinguisher, and training on the shipping of hazardous materials).

b. All new research staff, staff with collateral occupational safety and health duties, and administrators (e.g., ACOS/R&D, AO/R&D) responsible for VA research laboratories must complete the required training prior to assuming their duties.

c. All individuals must receive additional training prior to assignments that may involve new risks or potential exposures, and when security systems and procedures are changed.

d. Training records must be maintained by the facility Research Office for both initial and refresher training. At a minimum, these records must include the identity of the individual, the date of completion of the training, and a description of the training.

11. RECORDS MANAGEMENT

All records regardless of format (paper, electronic, electronic systems) created in this directive shall be managed per the National Archives and Records Administration (NARA) approved records schedules found in VA Records Control Schedule 10-1. If you have any questions regarding any aspect of records management you should contact your facility Records Manager or your Records Liaison.

12. REFERENCES

- a. 7 U.S.C. 8401, Regulation of certain biological agents and toxins.
- b. 38 U.S.C. 7303, Functions of Veterans Health Administration: Research Programs.
- c. 38 U.S.C. 8117, Emergency preparedness.
- d. 42 U.S.C. 262a, Enhanced control of dangerous biological agents and toxins.
- e. 7 CFR 331, Possession, use, and transfer of select agents and toxins.
- f. 9 CFR 121, Possession, use, and transfer of select agents and toxins.
- g. 29 CFR 1910, Occupational Safety and Health Standards.
- h. 42 CFR 73, Select Agents and Toxins.
- i. VA Directive 0710, Personnel Security and Suitability Program, dated June 4, 2010.
- j. VA Directive 0730, Security and Law Enforcement, dated December 12, 2012.
- k. VA Handbook 0730/4, Security and Law Enforcement, dated May 29, 2013.
- l. VHA Directive 0710, Personnel Security and Suitability Program, dated October 11, 2018.
- m. VHA Directive 1105, Management of Radioactive Material, dated February 5, 2015.

- n. VHA Directive 1129, Radiation Protection for Machine Sources of Ionizing Radiation, dated February 5, 2015.
- o. VHA Directive 7701, Comprehensive Occupational Safety and Health Program, dated May 5, 2017.
- p. VHA Directive 7702, Industrial Hygiene Exposure Assessment Program, dated April 29, 2016.
- q. VHA Handbook 1058.01, Research Compliance Reporting Requirements, dated June 17, 2015.
- r. VHA Handbook 1200.01, Research and Development Committee, dated June 16, 2009.
- s. Centers for Disease Control and Prevention-National Institutes of Health. Biosafety in Microbiological and Biomedical Laboratories 5th Edition.
<http://bmbi.od.nih.gov/>.
- t. National Institutes of Health Office of Science Policy, Dual Use Research of Concern Policy, <https://osp.od.nih.gov/biotechnology/dual-use-research-of-concern/>.
- u. National Institutes of Health Office of Science Policy, Guidelines For Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)
https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.html.
- v. VA Office of Research and Development Program Guide 1200.06a, Dual Use Research of Concern.