

**VA NORTHEAST OHIO HEALTHCARE SYSTEM
Louis Stokes Cleveland DVAMC
Medical Research Service
Subcommittee on Research Safety Policy**

Effective Date: APRIL 14, 2021

SOP Title: ACCESS TO MEDICAL RESEARCH SERVICE SPACE

SOP Number: SRS—020

SOP Version: .09

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1. **PURPOSE:** To establish a security program for Medical Research Service.
2. **POLICY:** Medical Research Service will strive to provide a secure facility for the housing of hazardous materials and sensitive equipment.
3. **DEFINITIONS:**
 - a. **Employees** – This includes all VA employees (full-time, part-time, or without compensation) regardless of work site and non-VA employees who work on VA premises.
 - b. **Hazardous Materials** – Biological, chemical, gaseous, and radioactive materials. This also includes select agents, i.e. substances used in biochemical warfare.
 - c. **Sensitive Equipment** – Computers, laptops, diagnostic devices, etc. that may contain research data and/or employee/patient identifying information.
 - d. **RSC/CHO** - Research Safety Coordinator/Chemical Hygiene Officer.
 - e. **RSO** - Radiation Safety Officer.
 - f. **Suspicious Package** – Any package with one or more of the following characteristics including, but not limited to:
 - (1) A powdery substance, oily stains, discolorations, or crystallization on the outside
 - (2) Excessive wrapping/tape/string.
 - (3) Rigid, uneven, irregular/lopsided.
 - (4) Soft spots, bulges, excessive weight, protruding wires, and/or protruding aluminum foil.

Reference VHA Handbook 1200.06 for additional information regarding suspicious packages.

4. RESPONSIBILITIES:

a. ASSOCIATE CHIEF OF STAFF/RESEARCH (ACOS/RESEARCH):

(1) Ensures that the Medical Center Director, or designee, remains informed of all activities involving hazardous agents, sensitive materials, and sensitive equipment used in Medical Research Service space.

(2) Ensures that the RSC/CHO participates in the annual vulnerability assessment of research areas with Police Services and assists with the annual drills or exercises for safety, security, and incident responses.

(3) Challenges strangers/personnel not wearing proper VA Identification Badges and reports such individuals to the RSC and/or Police Service.

(4) Recognizes suspicious packages upon entry/exit and calls the Emergency Operator at extension 2222. Representatives from Police Service and the Facility Safety Office will arrive and assess/remove the suspicious package.

b. PRINCIPAL INVESTIGATOR/LABORATORY DIRECTOR:

(1) Controls access to his/her laboratory and/or office space within Medical Research Service in accordance with medical center policies.

(2) Ensures that personnel receive required training prior to beginning work, annually thereafter, and in response to incidents, as well as meet other requirements set forth in VHA handbooks.

(3) Ensures that personnel working under their direction have received approval from Medical Research Service to access laboratory and/or office space. This is only provided when all required personnel paperwork and training have been completed; appointments must also be approved by VA Police Service/PIV Office.

(4) Challenges strangers/personnel not wearing proper VA Identification Badges and reports such individuals to the RSC and/or Police Service.

(5) Ensures that visitors/collaborators and other individuals (housekeepers, engineering staff, etc) who have infrequent access to research areas are made aware/kept away from any hazards that they may encounter.

(6) Recognizes suspicious packages upon entry/exit and calls the Emergency Operator at extension 2222. Representatives from Police Service and the Facility Safety Office will arrive and assess/remove the suspicious package.

b. ANIMAL RESEARCH FACILITY SUPERVISOR:

(1) Controls access to the Medical Research Service Animal Research Facility (ARF) in accordance with medical center policies.

(2) Ensures that personnel complete all Institutional Animal Care and Use Committee (IACUC) required training and have been added to an Animal Component of Research Protocol (ACORP), which is associated with an R & D Committee-approved Research study. These must be completed prior to receiving access to the Animal Research Facility, beginning work, annually thereafter, and in response to incidents, as

well as meet other requirements set forth in VHA handbooks. Confirmation of these requirements are communicated to the RSC, who then downloads access to the Animal Research Facility onto approved individuals PIV Cards.

(3) Ensures that personnel working under their direction have received approval from Medical Research Service to access the ARF. This is only provided when all required personnel paperwork and training have been completed; appointments must also be approved by VA Police Service/PIV Office.

(4) Challenges strangers/personnel not wearing proper VA Identification Badges and reports such individuals to the RSC and/or Police Service.

(5) Ensures that visitors/collaborators and other individuals (housekeepers, engineering staff, etc) who have infrequent access to the ARF are made aware/kept away from any hazards that they may encounter.

(6) Recognizes suspicious packages upon entry/exit and calls the Emergency Operator at extension 2222. Representatives from Police Service and the Facility Safety Office will arrive and assess/remove the suspicious package.

c. EMPLOYEE:

(1) Completes all required personnel paperwork and training prior to beginning work, annually thereafter, and in response to incidents, as well as meet other requirements set forth in VHA handbooks. Access to Medical Research Service space will be granted when all requirements have been satisfied and appointments have been approved by VA Police Service/PIV Office.

(2) Ensures that visitors/collaborators and other individuals (housekeepers, engineering staff, etc) who have infrequent access to research areas are made aware/kept away from any hazards that they may encounter.

(3) Challenges strangers/personnel not wearing proper VA Identification Badges and reports such individuals to the RSC and/or Police Service.

(4) Recognizes suspicious packages upon entry/exit and calls the Emergency Operator at extension 2222. Representatives from Police Service and the Facility Safety Office will arrive and assess/remove the suspicious package.

d. RESEARCH SAFETY COORDINATOR/CHEMICAL HYGEINE OFFICER:

(1) Ensures that a security program is in place and is being implemented, as required by the VHA Handbook.

(2) Establishes clearance procedures for visitors and other individuals with an infrequent need to access research laboratory areas (repair technicians, pest management services, etc).

(3) Participates in the annual vulnerability assessment of research areas with Police Services and assists with the annual drills or exercises for safety, security, and incident responses.

(4) Maintains a daily log of changes in access that have been downloaded in the Lenel Security System. Reviews Lenel access reports for entries into Research daily.

(5) Reports breaches in security to ORO immediately. Breaches in security are communicated with the Research Compliance Officer, the ACOS/Research, the AO/Research, the SRS, Police Service, and all parties involved.

(6) Maintains key distribution records.

(7) Reviews Visitor Logbook entries.

(8) Develops and revises training materials covering Security Management in Medical Research.

e. SUBCOMMITTEE ON RESEARCH SAFETY (SRS):

(1) Annually reviews/updates/approves the Medical Research Service Safety Training Manual, which includes the Chemical Hygiene Plan, Hazardous Communication Plan, and the Hazardous Agents Control Program. After being approved by the SRS, it is submitted to the Research and Development (R & D) Committee for final approval.

(2) Annually prepares an annual review regarding the security and safety program in Medical Research Service, which is forwarded to the R & D Committee.

(3) Annually reviews/updates/approves SRS Policies involving the security and safety of the Medical Research Service.

5. PROCEDURES:

a. SECURITY AND PHYSICAL SECURITY SYSTEMS

(1) Laboratories in Medical Research Service must be secured with a state-of-the-art security system. This must include:

- A. Access control 24/7.
- B. An intrusion alarm system.
- C. Monitoring by VA Police Service.
- D. Compliance with VHA requirements.

(2) The physical security of laboratories in Medical Research Service must include:

- A. Keycard access or a system that is equal to, or exceeding, the security of a keycard system.
- B. Records of all keycard assignments.
- C. Logging of changes in access that have been downloaded in the Lenel Security System.
- D. Automatic closure of entry doors from non-research laboratory space.
- E. Unobstructed views of the exterior.
- F. Operational intrusion alarms.

(3) Each laboratory and office space have a unique key which is issued by the RSC/CHO.

b. ANNUAL VULNERABILITY ASSESSMENT:

(1) An Annual Vulnerability Assessment of laboratories in Medical Research Service identifies high-risk areas, sensitive materials/equipment, and physical security issues. Results of the assessment are provided to the SRS, R & D Committee, and Responsible Official, if applicable.

(2) Annual vulnerability assessments of all labs are conducted by A VA Police Service representative. Results from this assessment are to be forwarded to: The Facility Safety Office, the RSC/CHO, Radiation Safety Officer, and the Facility Industrial Hygienist.

(3) The same multidisciplinary team, as appropriate per incident, e.g. radioactive material loss, computer theft, etc., conducts vulnerability assessments after any incident affecting high risk areas, sensitive materials, sensitive equipment, and/or the physical security of research space (laboratories, offices, etc). Vulnerability Assessments conducted after a break-in and loss/theft are forwarded on to the SRS, Research and Development Committee, and the Responsible Official, if applicable.

6. REFERENCES: VHA Handbook 1200.6, Control of Hazardous Agents in VA Research Laboratories, dated October 21, 2005.

7. RESCISSION: SRS Policy 020 Access to Medical Research Service Space dated April 14, 2021. The rescission date of this Subcommittee on Research Safety Policy is April 13, 2022.

8. FOLLOW-UP: RSC/CHO