

RESEARCH SECURITY SUBCOMMITTEE

Standard Operating Procedures

POLICIES AND PROCEDURES

VA Long Beach Healthcare System

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INTRODUCTION

Purpose

This Standard Operating Procedure (SOP) prescribes the operating procedures of the Research Security Subcommittee (RSSC).

Scope

The availability of human pathogens, their products, chemicals, gases, radioactive materials, and/or radioactive sources for VA research, is essential for advancing medical knowledge to meet and improve 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. The protection of VA personnel, patients, visitors, and the surrounding community from terrorist events demands stringent controls for the use of hazardous agents capable of being used as weapons of mass destruction.

The VA Long Beach Healthcare System operates its research laboratories in compliance with policies, statutes, and regulations of appropriate Federal agencies including VA, Occupational Safety and Health Administration (OSHA), Environmental Protection Agency (EPA), Nuclear Regulatory Commission (NRC), Department of Transportation (DOT), Department of Health and Human Services (HHS), United States Department of Agriculture (USDA), and any applicable state or local regulations. All applicable guidelines issued by HHS, the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), the USDA and the Animal and Plant Health Inspection Service (APHIS), must be followed. This SOP specifically addresses security policies that are distinct from those relating to laboratory safety, but requirements may overlap with other policies. Policies, procedures, and responsibilities for research laboratory security, personnel identification and training, inventory controls, and the interactions with other VA facility personnel such as security and law enforcement personnel are addressed in this SOP.

The RSSC is charged by the R&D Committee with the responsibility to maintain the security of the research program in a manner that is consistent with VA policies, Federal statutes and regulations from Occupational Safety and Health Administration (OSHA), the Environmental Protection Agency (EPA), the Nuclear Regulatory Commission (NRC), etc., and any applicable State and local requirements.

The scope of this SOP includes the physical and organizational controls for the storage and use of select agents, toxins and other highly dangerous hazardous agents.

The provisions of this SOP apply to all research that is conducted completely or partially in VA facilities, conducted in approved off-site locations and facilities, or conducted by VA researchers while on VA official duty time. The research may be VA funded, funded from extra-VA sources, or conducted without direct funding.

ABBREVIATIONS

ACOS	Associate Chief of Staff
AO	Administrative Officer
CFR	Code of Federal Regulations
ORD	Office of Research and Development, VA Central Office
ORO	Office of Research Oversight
OSHA	Occupational Safety and Health Administration
PI	Principal Investigator
R&D	Research & Development
RCO	Research Compliance Officer
SOP	Standard Operating Procedures
VA	Veterans Administration
VAMC	VA Medical Center
WOC	Without Compensation

DEFINITIONS

Conflict of Interest: A convergence of an investigator's private interests with his or her research interests, such that an independent observer might reasonably question whether the investigator's professional actions or decisions are improperly influenced by considerations of personal financial gain.

Documentation: All records, in any form (including, but not limited to, written, electronic, magnetic, and optical records; and scans, x-rays, and electrocardiograms) that describe or record the methods, conduct, and/or results of a trial, the factors affecting a trial, and the actions taken. (ICH 1.22)

Select Agents and Toxins: A hazardous agent is a biological material including the CDC list of select agents and toxins (42 CFR Part 73), APHIS biological agents (7 CFR Part 331, 9 CFR Part 121), and products of such biological material, i.e., toxins. For purposes of this SOP, 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.

Investigator: An individual who is under the direction of the principal investigator (PI) who is involved in some or all aspects of the research project, including the design of the study, conduct of the study, analysis and interpretation of the collected data, and writing of resulting manuscripts. An investigator may be either compensated by VA, be appointed to work without compensation (WOC), or may be an employee assigned to VA through the Intergovernmental Personnel Act of 1970. The FDA considers an investigator and a principal investigator to be synonymous.

Ionizing Radiation: Particles or rays with sufficient energy to cause the ejection of orbital electrons from absorber atoms. Includes diagnostic and therapeutic procedures done for research purposes. Sources of radiation include: nuclear medicine, radiation therapy and radiology.

Principal Investigator: An individual who conducts a research investigation, i.e., under whose immediate direction research is conducted, or in the event of an investigation conducted by a team of individuals, is the responsible leader of that team. The FDA considers an investigator and a principal investigator to be synonymous.

Protocol: A document that describes the objective(s), design, methodology, statistical considerations, and organization of a trial. The protocol usually also gives the background and rationale for the trial, but these could be provided in other protocol referenced documents (ICH 1.44)

Quorum: More than half of the voting members are present including at least one non-scientist. In order for research to be approved, it must receive the approval of a majority of those members present at the meeting

Recusal: When an RSSC or R&D Committee or other committee member declines to participate in a matter because of a potential conflict of interest under the Code of Ethics. As distinguished from abstention, the official recusing him/herself will not be present in or participate in deliberations or voting on the matter where there are potential conflicts of interest.

Regulatory Noncompliance: Failure to adhere to institutional policies and procedures, state laws, federal laws or other regulations governing the conduct of human subjects research including failure to follow the requirements of VHA Handbook 1200.08. This includes such acts as failure to obtain or maintain approval for research or to adhere to an approved protocol, failure to submit applications for study continuing review, or adhere to the Safety Plan.

Research: as defined by the Department of Health and Human Services regulations means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. [45 CFR 46.102(d)]

Researcher: Principal investigator or the investigator

Standard Operating Policy and Procedures (SOPs): Detailed, written instructions to achieve uniformity of the performance of a specific function (ICH 1.55).

Suspension: An action recommended by the RSSC to the R&D Committee that temporarily or permanently stops all or some of the research activities must stop until issues have been satisfactorily resolved.

SECTION 01

RESPONSIBILITIES OF THE RESEARCH SECURITY SUBCOMMITTEE (RSSC)

The RSSC is an advisory subcommittee of the R&D Committee. It consists entirely of *ex officio* members who have knowledge of security issues by virtue of their appointments. The membership is determined by the requirements of VHA handbook 1200.08

The R&D Committee, the Research Office, and the RSSC are jointly responsible for the oversight and implementation of the Security Plan. The Security Plan is described in a separate document.

Generally, the RSSC has the responsibility to develop and review the Security Plan. The RSSC also conducts an ongoing review of the efficacy of policies and procedures and reviews emergent security issues. The RSSC investigates problems, develops an abatement plan, and recommends actions to the R&D Committee.

The R&D Committee is responsible to the medical center Director to ensure that the Security Plan is adequate and consistent with all VA and other Federal Policies and regulations as well as any applicable State or local laws and regulations. The R&D Committee reviews the findings of the RSSC and approves actions and policies.

The Research Office implements policies and procedures that are approved by the R&D Committee. The ACOS/R&D has the responsibility to ensure that the actions are implemented. This ACOS/R&D delegates this responsibility to the AO/R&D.

The RSSC will:

- Conduct a comprehensive multidisciplinary vulnerability assessment. The vulnerability assessment will identify threats and detect vulnerabilities.
- Formulate a plan for the abatement of vulnerabilities.
- Recommend a course of action to the R&D committee that will accomplish the plan.
- Establish benchmarks to evaluate the success of the implementation of the plan.
- Track and evaluate the efficacy of the abatement.
- Perform follow-up evaluations to ensure that identified deficiencies are permanently and effectively abated.
- Report the status of the abatement to the R&D committee on an ongoing basis.

SECTION 02 INFRASTRUCTURE OF RESEARCH SECURITY SUBCOMMITTEE

1. NUMBER AND QUALIFICATION OF MEMBERS

The RSSC membership must include the following *ex officio* **voting** members:

- The AO/R&D
- The Research Security Officer
- A representative from VA Police Service
- The facility Safety Officer,
- The Radiation Safety Officer
- A representative from Facilities Management
- A representative from Human Resources (HR)
- The Associate Chief of Staff, R&D

• The Research Compliance Officer, the Industrial Hygienist
the Information Security Officer (ISO) serve as *ex officio* **non-voting** members.

The Research Security Officer will serve as the chair of the RSSC.

3. APPOINTMENT OF MEMBERS

- a. Appointment Letters must specify:
 - The term of the appointment
 - The *ex officio* basis for the appointment.
 - The voting status for the appointment.
- b. Appointment Letters are signed by the Chair of the Research and Development Committee (R&DC).

SECTION 03 QUORUM AND VOTING

More than half of the voting members must present. In order for an action to be approved, it must receive the approval of a majority of those members present at the meeting

If actions are not unanimous then all dissenting opinions and alternative recommendations will be included in reports that are forwarded to the R&D committee.

SECTION 04 MEETINGS

- 1. Frequency.** The RSSC will meet at least on a semiannual basis, or more often as needed, at a date and frequency determined by the Chair.
- 2. Agenda.** An agenda is to be developed before each RSSC meeting and distributed to RSSC members at least one week before the meeting.
- 3. Recusals.** RSSC members are informed of potential conflicts through a review of meeting agendas. Agendas are distributed no later than one week prior to each RSSC meeting and contain information about the investigators, sponsors and primary reviewers of each project that will be under review. RSSC members review the agenda and will declare any potential conflicts of interest prior to the beginning of project reviews.

In general, the RSSC member, will recuse him or herself from participation in the discussion. If there is any question as to whether or not a conflict exists then the full RSSC will discuss the conflict of interest without the member present to determine if a conflict of interest is present. If a conflict of interest is present then recusal will be required.

SECTION 05 PROCEDURES

1. Semiannual Vulnerability Assessment. The assessment will include:

A. Physical Security. The adequacy and working condition of:

- Doors.
- Windows
- Wall openings
- Ceilings
- Partitions

Physical security of research laboratories and other research areas of the facility housing hazardous agents, meet appropriate standards determined by the OSLE (see VA Directive and Handbook 0730), regulatory agencies, and/or cognizant VA oversight offices.

(1) Security for all Research Laboratories. All research laboratories include the following:

(a) Control of access on a 24-hour, 7 days a week schedule, including weekends and holidays.

(b) Access to the research building is by keycard and to the lab by key.

(c) The control system maintains record of access. The record of access is reviewed weekly by the Security Officer and the findings documented. Irregularities identified during a review or in the course of daily activities, must be immediately reported to VA Police Service.

(d) The presence of an intrusion alarm system that is connected to, and otherwise monitored by, the facility VA Police Service. A video surveillance system is also used.

(e) Facility security standards are reviewed on an annual basis by the Research Security Subcommittee.

(f) The ACOS/R&D is responsible for informing the Police Service of any changes in research affecting a laboratory's security rating.

(2) Security for BSL-3 Laboratory. For the BSL-3 research laboratory additional security requirements must be implemented; these include:

(a) Access to the area is through the use of cardkey access.

- (b) Video surveillance of the entrance is in place.
- (c) The time of entrance and egress of staff and visitors from these areas must be recorded.
- (d) Access into the area from overhead is prevented. The means to prevent such access is equivalent or better than that found in VA Handbook 0730, Appendix B, Requirement D.
- (e) An audible alarm is present and monitored. The alarm is for both safety (to indicate emergencies such as fire, hazardous materials incident, or need to evacuate) and to indicate an intrusion. Strobe lights were installed as an added precaution.
- (f) A telephone is located in the area.

B. Access Security. (keys, badges, keycards, codes, etc.):

Personnel. All individuals must obtain formal approval prior to beginning work in the research laboratories and must be appointed as full-time, part-time or intermittent, as compensated, uncompensated (WOC) employee, or fee basis. In addition, if the individual will be working in a BSL-3 research laboratory the individual must obtain specific approval to work in the BSL-3 research laboratory. VA research laboratories that use agents that have been excluded from the select agents or toxin list or which uses exempt quantities of toxins are considered laboratories that fall under following subparagraph.

(1) VA Research Laboratories and BSL-3 Research Laboratories Not Using or Storing Select Agents or Toxins.

Prior to beginning work in a VA research laboratory that does not use or store select agents or toxins there are two general levels of approval that must be obtained. The first involves approval from Human Resources and the second approval from the Research Security Subcommittee.

(2) Prior to beginning work Human Resources will verify the person's credentials. HR will submit both a Standard Form (SF)-85, Questionnaire for Non-Sensitive Positions, for low-risk level positions and fingerprints to the Office of Personnel Management (OPM) for completion of a background check. The AO for R&D will verify that this has been done. Once it has been verified that this process has been initiated, the individual is considered approved to enter non-BSL-3 VA research laboratories unescorted and begin work. The AO will update the results of the background investigation once it has been completed and a suitability determination made according to VA and other Federal regulations.

Employees that will be working in a BSL-3 research laboratory not containing select agents or toxins must obtain approval to do so from the R&D Committee.

(3) HR will review applications from non-United States citizens for their current residency status in the United States prior to employment or granting access to research laboratory areas.

(a) HR is responsible for reviewing, verifying, and tracking citizenship and visa status. Follow-up with appropriate external agencies such as the Immigration and Naturalization Service may be necessary to clarify or validate a non-citizen's credentials. The research office must verify that this has been done.

(b) The individual's status as a legal alien will be verified annually.

(4) Students, fellows, residents, visiting scientists, and others who may be at the VA for short periods of time may be granted limited approval to access VA research laboratories or storage areas if:

(a) Their credentials have been verified.

(b) A background check has been completed as required by VA Directive and Handbook 0710, "Personnel Suitability and Security."

(c) Their citizenship status verified and they are either citizens or legal aliens.

(d) A determination has been made that they are in a low-risk category.

(e) Access is limited to daytime hours when approved or authorized VA employees are present.

(f) If access is requested to a BSL-3 research laboratory, the R&D Committee must approve the request.

(5) Individuals leaving VA employment or no longer working in the VA research laboratory are expected to comply with the procedures clearance procedures, including following all clearance procedures such as turning in identification badges, keycards, other access items, etc.

(6) In the event an individual with access to a research laboratory inexplicably disappears, is suspected to have violated procedures, or committed a security breach, VA Police Service and other security officials, including the VA OIG, will be notified immediately. **NOTE: Law**

enforcement officials will take necessary steps to treat the areas affected as potential crime scenes.

(7) The Research Security Officer will annually review WOC appointments for those individuals who have been granted authorization to enter research laboratories and will determine the appropriateness of their WOC appointment. The results of this review must be submitted to the RSSC for its concurrence. The RSSC must forward its findings and recommendations to the R&D Committee for approval.

(a) The RSSC and R&D Committee will record its concurrence in the minutes of the meeting where the issue was reviewed.

(b) The findings will be conveyed to the ACOS/R&D, the VA research laboratory director, and the individual. If the RSSC or R&D Committee does not concur, HR must also be notified and the individual's WOC appointment and authorization terminated.
NOTE: *The individual may continue in the WOC status if the individual qualifies for another position.*

(8) Personnel are to enter research laboratory areas only when required to perform their duties and responsibilities.

VA Research Laboratory Access. Access to research laboratories is controlled at all times. Research laboratories are not open to the public.

(1) All research laboratory areas, including animal housing areas and storage areas, include a state-of-the-art security system that generates permanent, dated records with identification of persons entering the area and times of entry. For BSL-3 laboratory the time persons exit is also recorded. Access control is on a 24-hour, 7 days per week schedule (i.e., includes holidays and weekends).

(a) An intrusion alarm system is present, connected to, and otherwise monitored by, the VA Police Service.

(b) The ACOS/R&D, or designee, must conduct and document a review of access records on a weekly basis. The ACOS/R&D has delegated this responsibility to the AO/R&D. The Research Service must retain the written record of each review. Irregularities identified during a review or in the course of daily activities must be immediately reported to VA Police Service, the RO, and the Research Service.

(c) Keycards are coded such that they only allow access to areas the person is authorized to enter. A record of keycard assignments, including a record of the expiration date, is current at all times.

i. Keycards are valid for the length of time the individual is assigned to the area requiring the keycard and the expiration date of the keycard is consistent with the expiration date of the individual's appointment or contract. If the individual is a noncitizen whose status must be ascertained yearly, then the keycard may only be valid for that period of time. Access for all authorized staff is re-evaluated every 90 days.

ii. Personnel leaving VA employment, or no longer working in the research laboratory, including WOC appointees and contractors, as well as non-citizens, must adhere to full clearance and checkout procedures. This includes turning in all identifications, keys, keycards, and other access items.

iii. Returned keycards and all passwords (to include Information Technology passwords and other passwords) are deactivated within 24 hours.

iv. For keycards that are not returned, an immediate assessment must be made regarding the potential for a breach in security. Once it is determined that a keycard was not returned, it is immediately deactivated.

(2) The following additional security procedures are implemented. Procedures to ensure that only individuals approved to do so may enter and work in BSL-3 research laboratory. Issues considered in implementing this policy include:

(a) All medical center personnel (full-time, part-time, WOC, fee basis), contractors, and others engaged in VA-approved research on a short-term basis, such as students, fellows, residents, and visiting scientists, must wear photo identification badges at all times.

(b) Individuals engaged in VA approved research on a short-term basis cannot enter the BSL-3 if the time is insufficient to obtain a specific approval to enter the BSL-3 laboratory.

(c) A record of access must be kept for all visitors to secure laboratory areas, including service providers, Environmental Services, Engineering Service, and safety personnel that have not obtained approval to access laboratories, the specific approval to

access the BSL-3 research laboratory. The record must specify their name, affiliation, purpose for visiting, times of arrival and departure, and the person who is escorting the visitor. Visitor access must be limited to hours when approved or authorized (as applicable) VA employees are present.

(d) Visitors must be accompanied and monitored at all times by a VA employee approved to enter the research laboratory area. The employee must be specifically approved to enter the BSL-3 laboratory if the visitor is allowed to enter the area. This employee is responsible for the visitor's activities and conduct, and for ensuring that the escorted visitor exits the area at the appropriate time.

Process To Obtain Authorized Entry: The Security Officer, as a designee of the Research Security Subcommittee (RSSC), will grant authorized access. The RSSC is responsible for the review of processes and decisions made by the Security Officer in relation to secured access.

(1) The process of obtaining authorization to enter the secured area begins with the Principal Investigator (PI). The PI must make a formal request to the Security Officer to identify each staff member that requires access to the secured area. The request is accomplished by completing the Request for Staff Access to Research Secured Laboratory (Attachment A).

(2) Each individual requiring access to the secured area must complete the Application for Access to Research Secured Area (Attachment B).

(3) The RSSC is responsible for approving security access according to policy. Criteria and elements to be considered when granting approval: acceptable and work related need to be in secured area; certification that individual is not prohibited person; Application and PI Request completed; copy of photo ID (drivers license preferred); statement of U.S. citizenship OR copy of current and legal permission to be in U.S.; initiation and eventually results from background record check; and verification that required training has been completed.

(4) The ACOS/R&D, the AO/R&D, or the Research Security Officer must review the continued status of staff access semi-annually. The review will include an inquiry from the AO/R&D or Security Officer to the PI, to determine whether specific staff requires continued access to the secured area.

(5) The RSSC must approve renewal of staff access semi-annually with annual approval required by the R&D Committee. Factors that will be considered when addressing requested renewal include

- (a) The number and nature of security exceptions by the individual;
- (b) Whether required training is current; and,
- (c) Security-related information deemed pertinent to the RSSC.

Utility System Security. (electricity, ventilation, water, wastewater); Security characteristics, maintenance, and oversight is provided by the Engineering Service. The RSSC member from Engineering will make a report to the RSSC of any changes to the security aspects of these systems or to the Security Officer between meetings as needed.

Security of Hazardous Agents. The RSSC oversees Security for exempt quantities of toxins and hazardous agents (listed on the ORD website: <http://www1.va.gov/resdev/>)

Primary responsibility for the review of Hazardous Agents, including Select Agents and Toxins, lies with the Subcommittee for Research Safety (SRS). The policies and procedures of the SRS are defined in a separate SOP.

The RSSC and the SRS have overlapping memberships in order to facilitate the exchange of information.

The Industrial Hygienist has the primary responsibility for reporting to the RSSC when the use of Hazardous Agents has been approved and when such agents have been ordered or delivered.

The Industrial Hygienist has the primary responsibility for reporting to the RSSC and the Safety Officer the status of the inventory of Hazardous Agents and the manner in which these agents have been disposed.

The RSSC will review policies and procedures in order to ensure that adequate measures are in place to prevent unapproved use or theft. Toxins and hazardous agents must be controlled by locking them when they are not in use or in the direct view of an approved individual.

Information Security. (information technology (cyber) or hard copies). The ISO has primary responsibility for information / cyber security. The facility maintains policies and procedures for the ISO. The ISO will apprise the RSSC of any security breaches or vulnerabilities. Review by the RSSC will ensure that the R&D Committee, the VA police and the Information Resources Management (IRM) are all aware of issues that involve Research Information Security.

Training. Training of facility personnel includes information on how to respond to intrusions and/or terrorist events, including security awareness training, and emergency procedures to detect and safely respond to unauthorized individual(s) in research laboratory areas.

2. Review of Emergent Security Problems. Vulnerability assessments must also be conducted after any incident. The Chair of the RSSC will assess if the problem involves high-risk areas, sensitive materials, or physical security issues. If one or more of these are involved, then the Chair will call a meeting of the RSSC to perform a vulnerability assessment.

3. Review the findings of Reviews by External Agencies or Officials. The RSSC will review all findings that involve Research Security that have been made by external agencies or officials. If vulnerabilities are identified, then the Chair of the RSSC will determine if the seriousness and or urgency of the findings require an immediate RSSC vulnerability assessment. If this is the case then the Chair will call a meeting of the RSSC. Otherwise the matter will be evaluated at the following semi-annual review.

4. Review of Policies and Procedures. The RSSC will review the Security Plan on an annual basis. The RSSC will also re-review the Security Plan after each emergent incident.

5. Implementation and Reporting. The AO/R&D has the primary responsibility for the implementation of the Security Plan. The AO/R&D will:

- Maintain agendas and minutes of the RSSC.
- Maintain records of RSSC investigations and recommendations.
- Maintain records of the findings of reviews of VALBHS Research Security by external agencies or officials.
- Place work orders to implement abatement plans.
- Coordinate corrective actions with other VA healthcare groups and with external contractors as required.
- Report progress made on abatement plans to the RSSC.
- Report RSSC findings of non-compliance to the R&D Committee.

6. Non-Compliance.

The RSSC will investigate all allegations of non-compliance with the policies and procedures of the Security Plan.

Failure to conform to the requirements and standards of the Security Plan may result in immediate withdrawal of VA research funding and/or suspension of the research program. Individuals who knowingly fail to follow the provisions of this SOP are subject to disciplinary action proportionate to the severity of the violation,

up to and including termination of VA employment or termination of a contract. Failure to comply with Title 42 Code of Federal Regulations (CFR) Part 73, 7 CFR Part 331, 9 CFR Part 121, and other Federal regulations may also result in criminal or civil penalties.

The RSSC has the authority to examine all records that involve research at VALBHS and may sequester such records for purposes of investigation. The RSSC may examine any laboratory or clinical space that is utilized for research purposes. The RSSC has the authority to interview all personnel or subjects that may be required to investigate alleged non-compliance with the Security Plan.

The RSSC will:

- Determine if there has been a non-compliance. A non-compliance will be determined if the evidence indicates that the non-compliance is more likely than not.
- Determine if the non-compliance is Serious or Continuing.
 - Serious non-compliance is defined as non-compliance that represents a breach of security that results in real or potential significant harm to VA personnel or guests.
 - Continuing non-compliance is defined as non-compliance for the same issue that occurs three times by the same research personnel within a 12 month span.
- Recommend a course of action to the R&D Committee.

In addition to these actions, several individual members of the RSSC have the authority to suspend research, or restrict access to facilities, that may represent an immediate security risk.

SECTION 06 ACTIONS

The RSSC will defer the consideration of actions if quorum is not achieved.

The RSSC may take the following actions if quorum is achieved::

- Table
- Approve
- Withhold Approval

SECTION 07 RECORD KEEPING

The AO R&D will be responsible for maintaining the following records:

1. Security Incident Reports. Security Incident Reports including:

- All security violation notices from any source; the VISN; and the facility security staff.
- All incidents reported to the VISN and VA Central Office.

2. External Inspections. A record must be kept of all inspections of the VA research laboratories covered by this SOP, including:

- Inspections by authorized entities such as CDC, VA OIG, USDA, GAO, ORD, ORO, the VA facility, and VISN Safety and Health officials.
- All inspections of the VA research laboratories covered and required by this SOP.

3. Internal Inspections. A record of all findings, deficiencies and corrective action based on the inspections listed in SOP.

4. Security Plans and SOP's. Records must also include a record of when last reviewed, the mechanism used to disseminate the plan, and new changes to affected research staff.

SECTION 08 AGENDAS & MINUTES

The RSSC will provide written notification of the results of RSSC review to the R&D Committee, the Research Office, and the PI. Written notification will be through the use of meeting minutes.

Agendas and meeting minutes will be prepared and maintained by the Safety Committee Coordinator.

Agendas and minutes of the Subcommittee on Research Safety (RSSC) must be prepared according to the following format.

A. AGENDA. An agenda is to be developed before each RSSC meeting and distributed to RSSC members at least 3 working days before the meeting. At a minimum, the agenda is to include:

- (1) **Approval of Minutes.** Approval of minutes of previous meeting (date).
- (2) **Unfinished Business.** List pending items and individual responsible.
- (3) **New Business.** Identify individual responsible when necessary.
 - (a) **Standing Recurring Reports.** Identify individual responsible.
 - (b) **Issues.** Any issues not previously addressed by the body.
 - (c) **Other.** Any other item that warrants review or discussion by the committee and is not routinely reviewed by the committee.
- (4) **Announcements**
- (5) **Next Meeting.** Date, time, and place of the next meeting.

B. MINUTES. Minutes of all RSSC meetings must be prepared according to the following format.

- (1) Identification of the subcommittee to be centered at the top of the page, including the Department of Veterans Affairs (VA) medical center name and number.
- (2) The first paragraph is to include:
 - (a) Place, date, and time of the meeting.

(b) Name of presiding officer (chairperson).

(c) The attendance record, which must list all individuals identified as members. Members are to be marked "Absent," if the Chairperson or recorder has not been notified in advance. Members are to be marked "Excused," if the Chairman or recorder was notified in advance. For each member, note their role on the committee and whether they are voting or nonvoting.

(d) Indication that a quorum is present. **NOTE:** *A quorum is defined as more than 50 percent of the voting members are present.*

(3) Succeeding paragraphs are to identify the recommendations, date of the meeting when the recommendation was initially made, action taken to date or a realistic date to expect resolution, and the status as "Closed" or "Pending."

NOTE: *A recommendation is not to be carried for more than two meetings awaiting a resolution unless there is clear documentation that a plan of action is being followed and an anticipated date for resolution is noted.*

(4) Minutes are not to be recorded verbatim except for recommendations; however, the substance of the discussion is to be reported clearly and concisely. After summation of the discussion, the minutes must reflect:

(a) **Conclusion.** This indicates what was concluded from the discussion; for example, "The follow-up action plan was ineffective, and the issue is not considered resolved at this time." If analysis of the data occurred in the meeting, then the conclusion of the analysis needs to be in the minutes.

(b) **Recommendation.** This includes who or what is expected to change.

(c) **Action.** This includes what action is appropriate in view of the cause, scope, and severity of the problem, and who is responsible for implementing the action.

(d) **Follow-Up or Evaluation.** This identifies the date a status report is due on the action plan, the date the action plan will be implemented, or the date the action plan will be evaluated for accomplishment of expected outcome or impact of the changes made.

- (5) The minutes must note which members excused themselves from voting on which issues(s) to prevent conflicts of interest.
- (6) Copies of any internal or external reports or correspondence with outside agencies referenced in the minutes need to be attached to the minutes if they are important to understanding the conduct of business.
- (7) RSSC members having a scientific or monetary conflict of interest for the issue under consideration may provide information helpful to the RSSC prior to deliberations, but must excuse themselves from the meeting once deliberations begin.
- (8) Minutes must be written and published within 3 weeks of the meeting date.
- (9) Minutes must be signed by the Chairperson of the RSSC.
- (10) Approved minutes must be forwarded to the Research and Development (R&D) Committee for review and approval. The R&D Committee may review the minutes for content regarding committee functions, education of members, and preparation of minutes. Recommendations for changes or improvements in RSSC procedures may be made, but the R&D Committee may not alter the RSSC minutes.
- (11) Minutes must be maintained by the R&D Office and made available to VA Central Office upon request.

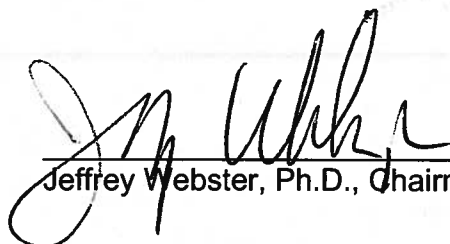
References

- (1) Public Law 107-188, "Public Health Security and Bioterrorism Preparedness and Response Act of 2002."
- (2) Title 5 CFR Parts 731 and 736.
- (3) Title 18 U.S.C. § 175b.
- (4) Title 7 CFR Part 331.
- (5) Title 9 CFR Part 121.
- (6) Title 10 CFR Parts 19 and 30, the Civil Service Reform Act of 1978, and the Whistleblower Protection Act of 1989.
- (7) Title 29 CFR 1910.38, 1910.120, 1910.1450 and 1960.
- (8) Title 42 CFR Parts 72 and 73.
- (9) VA Directive and Handbook 0710.
- (10) VA Directive and Handbook 0730.
- (11) VA Handbook 5005.
- (12) VHA Handbook 1100.19.
- (13) VHA Handbook 1200.07.
- (14) VHA Handbook 1200.08.
- (15) VHA Handbook 1200.06

Rescission: None.

Recertification: This SOP must be reviewed and approved at least annually by the R&D Committee.

Reviewed and Approved by the R&D Committee:



Jeffrey Webster, Ph.D., Chairman

10/8/09

Date

ATTACHMENT A

VA Long Beach Healthcare System

REQUEST FOR STAFF ACCESS RESEARCH SECURED AREA

1. **PURPOSE:** To formally request access for Investigator's employees and staff to the Research Secured Area.
2. **POLICY:** The information requested in this document must be supplied via submission of this form or Email before access to the secured area will be considered.
3. **RESPONSIBILITY:** It is the responsibility of each Investigator to formally identify the staff that must have access to the secured area in order to complete their research-related duties.
4. **PROCEDURE:** The Investigator submits the information requested to Research HCG. **NOTE:** Attachment B is also required.
5. **REQUESTED INFORMATION:**
 - a. Person making request: _____
 - b. Name of person for whom access is requested: _____
 - c. Immediate supervisor of person for whom access is requested: _____
 - d. Brief description of duties of person for whom access is requested (lab support, research assistant, etc):
 - e. Areas to which access is needed. Check all that apply:
 - (1) General Laboratory Area
 - (2) BSL3 (do not mark this box unless otherwise instructed)
 - (3) VMU (only mark this box if you expect to work with animal subjects)

Signature of Principal Investigator

(This PI must be the investigator assigned the laboratory space where the new staff member will work.)

ATTACHMENT B

VA Long Beach Healthcare System

APPLICATION FOR ACCESS TO RESEARCH SECURED AREA

1. **PURPOSE:** To formally apply for access to Research Secured Area.
2. **POLICY:** In order to be considered for access to the secured laboratory area, the applicant must submit this document to Research HCG. Note: the Principal Investigator must also complete ATTACHMENT A.

3. **REQUESTED INFORMATION:**

a. Full Legal Name:

b. Home Address (not Post Office Box):

c. Date of Birth:

d. Place of Birth:

e. Citizenship Status:

(1) U.S. Citizen

(2) Other

(Attach copy of document indicating legal authority to be in U.S.)

f. Select "Yes" or "No" for each item below. Any "yes" answers should be detailed in 3f(8) below.

(1) **Yes/ No** I am under indictment for a crime punishable by imprisonment exceeding 1 year.

(2) **Yes/ No** I have been convicted of a crime punishable by imprisonment exceeding 1 year.

(3) **Yes/ No** I am in fugitive status from any local, state, national, or international law enforcement agency.

(4) **Yes/ No** I am an unlawful user of any controlled substance.

(5) **Yes/ No** I am an alien illegally or unlawfully in the United States.

(6) **Yes/ No** I have been adjudicated as mental defective or have been committed to a mental institution.

(7) **Yes/ No** I have been discharged from the United States Armed Services under dishonorable conditions.

(8) Comments/Details/Notes: _____

Signature of Applicant

Date