VA NEBRASKA-WESTERN IOWA HEALTH CARE SYSTEM
Omaha, NE (636)

SUB-COMMITTEE FOR RESEARCH SAFETY (SRS) STANDARD OPERATING PROCEDURES

A MANUAL

For

SRS Members, Principal Investigators, & Staff

Revised March 2016

Frederick G. Hamel, Ph.D. , Acting ACOS/Research

3/17/2016
Date

I. PURPOSE:

The purpose of the Subcommittee on Research Safety (SRS) is to review all research activities involving biological, chemical, physical, and radiation hazards for compliance with all applicable regulations, policies, and guidelines.

II. POLICY:

It is NWIHCS and Omaha VA Medical Center's policy to comply with all applicable federal, state, and local regulations in the conduct of research activities involving biological, chemical, physical, and radiation hazards.

III. RESPONSIBILITY:

The SRS is responsible to the Medical Center Director through the ACOS/R&D and the Research and Development Committee for ensuring compliance with all applicable regulations, policies, guidelines, and standards of safety.

IV. MEMBERSHIP OF THE SRS:

A. Composition:

1. The SRS will have at least five members, exclusive of ex-officio members.

2. The SRS will include member(s) from the facility safety committee, the Institutional Animal Care and Use Committee (IACUC) and a representative from the Clinical Research Unit (CRU).

3. SRS members should possess expertise in:

   a. Etiologic agents, including bloodborne and airborne pathogens

   b. Recombinant DNA technologies

   c. Chemical carcinogens and other chemical hazards

   d. Physical and radiation hazards

B. Ex-Officio Members:

1. A liaison member from the local Research and Development (R&D) Committee (voting).

2. The Chemical Hygiene Officer, appointed by the Chief of Research Service (voting).

3. An AFGE union representative (voting).

V. FUNCTIONS OF THE COMMITTEE:

A. Research Activities:

Review all research activities (unless exempted by Federal Regulation and as outlined in Section VI.E.5.) involving biological, chemical, physical, and radiation hazards for compliance with all applicable regulations, policies, and guidelines, prior to submission for R&D review. This includes a review of all research applications that will be conducted at the VA facility or in VA leased space located off-site.

1. The review of the Research Safety Application, Biosafety & Chemical Risk Assessment Summary and the Form 10-0398 where applicable, must include a risk assessment of the facilities, level of containment, laboratory procedures, practices, training and expertise of personnel involved in the specific research conducted including recombinant DNA research.

B. Notification of SRS results:

SRS will provide written notification of the results of reviews to the R&D Committee, Medical Executive Committee (through R&D), and the Principal Investigator.

C. Conflict of Interest:

In general, members are considered to have a conflict of interest if they are participating in a proposed study as a principal or collaborating investigator, are a family member of an investigator, or if a financial arrangement, situation, or action affects or is perceived to exert inappropriate influence during the review of the research. Members with a conflict of interest relating to a study under review may not participate in any review involving that protocol except to provide information as requested by the SRS. They are required to disclose such interests, recuse themselves from deliberations and voting, and should leave the meeting room during the protocol discussion and vote. They are not counted towards quorum.

D. Risk Assessment:

The PI will complete a Biosafety & Chemical Risk Assessment Summary form for all new projects. The committee members confirm the appropriateness when they review the SRS Form. The Chemical Hygiene Officer reviews the chemical listingsection of the form to assure that the PI has listed appropriate precautions to be taken with chemicals used in the project.

e. Copies of any internal or external reports or correspondence with outside agencies referenced.

2. Minutes will be written and distributed for review and approval by the SRS.

3. Once the minutes have been approved by the SRS, at a fully convened meeting, they will be forwarded to the R&D committee and the Environment of Care committee for review and approval. Recommendations for changes or improvements in SRS procedures may be made, but neither committee can alter the SRS minutes.

4. Minutes will be filed in the Research Office and made available to VA Central Office upon request.

5. In the event that an urgent situation arises that is not outlined in this SOP, the committee agrees that the Chair or designee will have the immediate responsibility to correct the situation. The Chair or designee will then report the situation to the committee at the next meeting and the committee will decide on a policy to handle the specific situation in the future. Emergency procedure manuals (Emergency Preparedness Plan and Chemical Hygiene Plan) are available in each laboratory to assist laboratory personnel for first response to emergency situations. If necessary, the Chair or designee will enlist additional personnel (ex. Infection Control) to gain advice in resolving the emergent situation.

E. Voting:

Research proposals and amendments which are determined to be reviewed and approved at a convened full committee meeting, the vote will include the number for, against, abstaining, recused, and excused. A quorum, consisting of a majority of all the voting SRS members, must be present to conduct official business of the committee. The SRS Chair can make a motion and vote. The SRS may vote for the following actions:

1. Approved – approval granted by the committee.

2. Contingently Approved – the committee will specify what is required for final approval of the protocol.

3. Tabled – an item may be tabled without review or discussion due to lack of quorum or for other reasons, as outlined in the minutes.

4. Disapproved – the proposal may be disapproved for major safety concerns. The PI will be notified of the reasons for disapproval, and will be given an opportunity to respond in writing to the SRS by a given deadline.

3. The SRS Chair selects a committee member to review the Continuing Review submission. All members receive a copy of the renewal form and a current abstract.

4. After the meeting, a Notification of Approval/Contingencies letter will be sent to the Principal Investigator detailing any concerns of the committee members.

H. Closure of studies:

The closure of a study involving biological, chemical, physical, and radiation hazards will be initiated by the submission of an email or other correspondence with a request to close the study. The request will be reviewed and acknowledged by the SRS at a fully convened meeting.

I. Chemical Hygiene Plan:

The SRS is responsible for annually evaluating the effectiveness of the Chemical Hygiene Plan and making necessary revisions.

J. Personal Protective Equipment (PPE):

A PPE assessment must be completed and documented for each person in the laboratory. This Assessment should be reviewed by the PI annually and updated as needed.

K. Laboratory Inspections:

1. All research laboratories at Omaha VA Medical Center as well as VA leased space at the affiliates will be inspected annually for biohazards, and chemical and physical hazards.

2. Members of inspection teams will include a minimum of two SRS members.

3. Deficiencies noted during the inspections will be listed in a letter to the Principal Investigator. The PI must respond with a written corrective action plan by the deadline identified in the letter.

4. The list of deficiencies and the PI responses to these deficiencies are included in the agenda of the next scheduled SRS meeting. The report in the SRS minutes is reviewed by the R&D Committee.

L. Accident Reporting:

1. Injuries/accidents that occur in the research laboratory setting are reported to the immediate supervisor after individuals seek medical attention from Occupational Health or the Emergency Room.

b. Suspension of the research performed in the investigator's laboratory.

c. Restriction of personnel activities.

N. Laboratory Closures:

1. In addition to properly closing out all active research studies, the Principal Investigator should create a list of hazardous chemicals, biohazards, radioactive substances, freezer, refrigerator, and liquid N2 contents.

2. The Principal Investigator should send a letter to the SRS Chair indicating that:

   a. All experimental samples and laboratory solutions were properly disposed of;

   b. Arrangements have been made with the Safety Office to have all hazardous waste removed;

   c. Arrangements were made with the Radiation Safety Officer for a final laboratory check, and

   d. Arrangements have been made to disperse usable chemicals, cell lines, laboratory ware, and equipment to other on-site investigator laboratories. Chemicals not claimed are disposed of through the chemical hygiene officer.

   e. Personnel leaving the VA

O. Emergency Preparedness Plan:

The SRS Emergency Preparedness Plan follows the facility's Emergency Plan which addresses all types of threats or emergencies. These may include fires; explosions; spills; release of chemicals, biological agents, toxins or radioactive materials; bomb threats; severe weather and other natural disasters or emergencies. In addition to the Emergency Preparedness and Response Plan, the Research Chemical Hygiene Plan addresses research lab specific emergency contingencies. Included in this plan are personnel roles, training, escape procedures and emergency alerting and response procedures, emergency medical treatment and procedures for all employees during an emergency. Any radiation emergencies will be dealt with as recommended by the Facility 's Emergency Plan, Appendix 4 to Annex U, Radiation Exposure/ Contamination.

VIII. ATTACHMENTS:

1. Research Safety Application
2. Biosafety & Chemical Risk Assessment Summary
3. Research Protocol Safety Survey, VA Form 10-0398
4. SRS Roster

VA Nebraska-Western Iowa Health Care System

Research Safety Application

RESEARCH SAFETY ☐ **APPLICATION** ☐ **RENEWAL**

NOTE: If this is an Initial Application PIs must complete and submit a Bio-Safety & Chemical Risk Assessment Summary form and a VA Form 10-0398 Research Protocol Safety Survey.

PRINCIPAL INVESTIGATOR (PI): _____

VA RESPONSIBLE INVESTIGATOR: _____

Service: _____ Lab Location: _____

Phone ext.: _____ Pager: _____ Mail Code: _____

Project Title: _____

Funding Source (VA, NIH, etc.): _____

Personnel: List the names of all personnel, co-investigators, and collaborators who will work with the PI on this research proposal in VA or VA leased space:

_____

Does your proposal involve the use of any of the following items in a research laboratory setting?

	YES	NO
Chemicals (refer to Research Service Chemical Hygiene Plan):		
Toxic Chemicals (including heavy metals)?	☐	☐
Flammable, explosive, or corrosive chemicals?	☐	☐
Carcinogenic, mutagenic, or teratogenic chemicals?	☐	☐
Toxic compressed gases?	☐	☐
Acetyl cholinesterase inhibitors or neurotoxins?	☐	☐
Cell or tissue culture (Human or Animal)?	☐	☐
Human/Animal Tissues or fluids?	☐	☐
Microbiological or viral agents, pathogens, or toxins?	☐	☐
Poisonous, toxic or venomous plants or animals?	☐	☐
Controlled Substances?	☐	☐
Recombinant DNA?	☐	☐
Radioactive Materials?	☐	☐

What bio-safety level does your protocol require? N/A ☐ BSL1 ☐ BSL2 ☐ BSL3 ☐ BSL4 ☐

If unsure: go to: www.cdc.gov/biosafety/publications

If this is a renewal and there are no changes other than the location or lab personnel please mark the box.

No Changes: ☐

If any of the above answers are yes, and are a change from your latest approved Research Safety Application (Safety Form), please submit a new Research Safety Application (Safety Form), Bio-Safety & Chemical Risk Assessment Summary form and a VA Form 10-0398 Research Protocol Safety Survey.

VA HEALTH CARE | Defining EXCELLENCE in the 21st Century

Bio-Safety and Chemical Risk Assessment Summary

Date:
Principle Investigator:
Title of Project:

Bio-Safety Risk Factors

	Risk Group 1	2	3	4	N/A
Pathogenicity/virulence	☐	☐	☐	☐	☐
Infectious Dose	☐	☐	☐	☐	☐
Route of Spread	☐	☐	☐	☐	☐
Communicability	☐	☐	☐	☐	☐
Environmental stability	☐	☐	☐	☐	☐
Host range	☐	☐	☐	☐	☐
Economic impact	☐	☐	☐	☐	☐
Availability of prophylactic/treatment	☐	☐	☐	☐	☐
Vectors	☐	☐	☐	☐	☐
Concentration/volume	☐	☐	☐	☐	☐
Recombinant properties	☐	☐	☐	☐	☐
Collection of human bodily fluids	☐	☐	☐	☐	☐
Overall Risk Group	☐	☐	☐	☐	☐
Recommended Containment Level	☐	☐	☐	☐	☐

To determine the risk level is "Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th Edition". (http://www.cdc.gov/biosafety/publications/bmbl5/BMBL.pdf)

Chemical Risk Assessment

What Chemical Types will be utilized?	Toxic ☐	Corrosive ☐	Flammable ☐	Reactive ☐	N/A ☐
Are MSDS available?	Yes ☐	No ☐	N/A ☐		
Is PPE available?	Yes ☐	No ☐	N/A ☐		
Proper storage conditions and compatibility met?	Yes ☐	No ☐	N/A ☐		
Will any highly hazardous chemicals be utilized?	*Yes ☐	No ☐	*If yes, attach listing of name and quantity stored.		

This list can be found in CFR 1910.119 Appendix A
Examples include Formaldehyde, EtO, and 60% Perchloric Acid

Department of Veterans Affairs

RESEARCH PROTOCOL SAFETY SURVEY

PRINCIPAL INVESTIGATOR (PI): _____

PROJECT TITLE: _____

DATE OF SUBMISSION: _____

LIST VA AND NON-VA LOCATIONS IN WHICH PI CONDUCTS RESEARCH:

1. DOES THE RESEARCH INVOLVE THE USE OF ANY OF THE FOLLOWING?

a. Biological Hazards (Microbiological or viral agents, pathogens, toxins, select agents as defined in Title 42 Code of Federal Regulations (CFR) 72.6, or animals) YES ( ) NO ( )

b. Human or non-human cell or tissue samples (including cultures, tissues, blood, other bodily fluids or cell lines) YES ( ) NO ( )

c. Recombinant deoxyribonucleic acid (DNA) YES ( ) NO ( )

d. Chemicals:
   (1) Toxic chemicals (including heavy metals) YES ( ) NO ( )
   (2) Flammable, explosive, or corrosive chemicals YES ( ) NO ( )
   (3) Carcinogenic, mutagenic, or teratogenic chemicals YES ( ) NO ( )
   (4) Toxic compressed gases YES ( ) NO ( )
   (5) Acetylcholinesterase inhibitors or neurotoxins YES ( ) NO ( )

e. Controlled Substances YES ( ) NO ( )

f. Ionizing Radiation:
   (1) Radioactive materials YES ( ) NO ( )
   (2) Radiation generating equipment YES ( ) NO ( )

g. Nonionizing Radiation:
   (1) Ultraviolet Light YES ( ) NO ( )
   (2) Lasers (class 3b or class 4) YES ( ) NO ( )
   (3) Radiofrequency or microwave sources YES ( ) NO ( )

If the answer to <u>any</u> of these questions is YES, complete all sections of this survey that apply.

If <u>all</u> answers are NO, a documented review by the local Subcommittee on Research Safety is still required prior to submission. If the research involves the use of human subjects or human tissues, Institutional Review Board (IRB) review is required. ***NOTE:*** *Use of animals also requires submission of an Institutional Animal Care and Use Committee (IACUC)-approved Animal Component.*

VA FORM
MAY 2002 **10-0398**

e. Describe the containment equipment (protective clothing or equipment, biological safety cabinets, fume hoods, containment centrifuges, etc.) to be used in this research:

f. Describe the proposed methods to be employed in monitoring the health and safety of personnel involved in this research:

4. CELLS and TISSUE SAMPLES

a. Will personnel work with animal blood, human or non-human primate blood, body fluids, organs, tissues, cell lines or cell clones? YES ( ) NO ( )
If yes, specify:

b. Will research studies represent a potential biohazard for lab personnel?
NA ( ) YES ( ) NO ( )

If yes, specify the potential hazard and precautions employed to protect personnel in the laboratory:

NOTE: *If these studies involve animals, the Animal Component of Research Protocol (ACORP) must be completed.*

c. Specify precautions employed to protect personnel working in the laboratory:

7. CONTROLLED SUBSTANCES

a. Does your research involve the use of any substance regulated by the Drug Enforcement Agency? YES ( ) NO ( )

If yes, list controlled substances to be used:

(1) _____

(2) _____

(3) _____

(4) _____

(5) _____

(6) _____

b. Are all Schedule II and III drugs stored in a double-locked vault
NA ( ) YES ( ) NO ( )

NOTE: *The schedule of controlled substances can be found at the Internet site* http://www.usdoj.gov/dea/pubs/schedule.pdf

8. RADIOACTIVE MATERIALS

Does your research involve the use of radioactive materials? YES ( ) NO ( )

If YES, provide the following:

a. Identity of radioactive source (s): _____

b. Radiation Safety Committee Approval (date): _____

9. PHYSICAL HAZARDS

a. Are physical hazards addressed in the facility Occupational Safety and Health Plan?
YES ( ) NO ( )

b. Do employees receive annual training addressing physical hazards?
YES ( ) NO ( )

Department of Veterans Affairs
VA Nebraska-Western Iowa Health Care
System Omaha, NE 68105

January 2016

SUBCOMMITTEE FOR RESEARCH
SAFETY OF THE
RESEARCH AND DEVELOPMENT COMMITTEE

The following listed persons are appointed to serve as members of the Subcommittee on Research Safety:

Voting Members

Clemens, Dahn, Ph.D.	VA Practicing Scientist, Chair	1/16-12/16
Dhawan, Punita	VA Practicing Scientist	1/15-12/17
Fried, Robin	Safety Office Representative	1/16-12/18
Friedman, Kathryn	Clinical Research Unit Rep.	1/16-12/18
Osna, Natalia, Ph.D.	VA Practicing Scientist, Vice-Chair	1/15-12/17
Wyatt, Todd, Ph.D.	VA Practicing Scientist	1/16-12/18
Wiegert, Robert, BS, LATG	Chemical Hygiene Officer, ARF Supervisor & IACUC Rep.	9/06-12/16

Ex-Officio, Voting

Davis, John, Ph.D.	VA Practicing Scientist, R&D Comm. Rep.	1/16-12/18
Moore, Amber	AFGE Representative	1/14-12/17

Ex-Officio, Non-Voting

Finch, Rhonda	Subcommittee for Research Safety Coordinator
Hamel, Frederick G., Ph.D.	Acting Associate Chief of Staff/Research Service
Hudson, John, II, Ph.D.	Administrative Officer/ Research Service

Alternates for Voting Members

Cheng, Pi-Wan, Ph.D.	IACUC Representative
Synak, Corri BS	Safety Office Rep.
Egan, Joy	Clinical Research Unit Rep.

B. DON BURMAN, MHA
Director

Distribution: All Committee Members
Environment of Care Committee

Attachment 4