

RESEARCH SERVICE SAFETY MANUAL

TABLE OF CONTENTS

1. PURPOSE.....	3
2. POLICY.....	3
3. RESPONSIBILITIES.....	3
A. Service Chief.....	3
B. Facility Safety Office.....	3
C. Service Chemical Hygiene Officer.....	3
D. Laboratory Supervisor.....	4
E. Laboratory Workers.....	4
F. VA Leased Space.....	4
4. SECURITY OF RESEARCH FACILITIES.....	4
A. Policy.....	4
B. Identification.....	4
C. Authorized Access.....	5
D. Escorted Entry.....	6
E. Physical Security.....	7
F. Other Security Concerns.....	7
G. Reporting Requirements.....	7
5. RESEARCH DISASTER PLAN.....	9
A. Alert Notification Procedures Within the Research Building.....	9
B. Medical Alert Notification Procedures Outside the Research Building.....	9
C. Alert Notification Procedures for Non-Medical Emergencies Outside the Research Building.....	10
D. Violent Behavior Requiring Additional Staff Assistance.....	10
E. Active Shooter or Armed Assailant on Campus.....	10
F. Severe Weather.....	10
G. Tornado Warning.....	11
H. Radiological Incident.....	11
I. Internal HAZMAT Incident.....	12
J. Suspicious Package/Bomb Threat.....	12
K. Fire Plan.....	12
L. Evacuation Procedures.....	13
M. Utility System Failure.....	13
N. Annual Drills.....	13
6. CHEMICAL INVENTORY SOP.....	14
A. Purpose.....	14
B. Action.....	14
7. CHEMICAL EXPOSURE MONITORING.....	14
A. Purpose.....	14
B. Action.....	15
8. CHEMICAL HYGIENE PLAN.....	15
A. Standard Operating Procedures.....	15
B. Chemical Inventory.....	17
C. Safety Data Sheets (SDS's).....	17

D. Chemical Storage.....	17
E. Control Measures .....	18
F. Fume Hoods and Other Protective Equipment.....	19
G. Contaminated Waste Removal/disposal.....	19
H. Medical Consultation and Exams .....	20
9. HAZARD IDENTIFICATION.....	20
10. EMPLOYEE INFORMATION AND TRAINING .....	20
A. Policy.....	20
B. Training Requirement .....	21
11. HOUSEKEEPING .....	21
12. RECORDKEEPING .....	21
13. RESPIRATOR USAGE .....	21
A. User Requirements .....	21
B. Inspections .....	21
C. Fit-testing.....	21
D. Recordkeeping.....	21
14. RECORDS.....	21
15. REFERENCES .....	21
16. RECISION .....	22
17. FOLLOW-UP RESPONSIBILITY .....	22
18. REVIEW DATE .....	22
19. REVISION DATE .....	22

APPENDICES

APPENDIX A	DEFINITIONS.....	23
APPENDIX B	MEMORANDUM OF UNDERSTANDING REGARDING RESEARCH LABORATORY SAFETY (UNMC AND VA NWIHCS) .....	25
APPENDIX C	SAMPLE SAFETY DATA SHEET (SDS) .....	29
APPENDIX D	GUIDELINES FOR NIH DNA RESEARCH.....	34

## RESEARCH SERVICE SAFETY MANUAL

1. PURPOSE - To establish comprehensive policies and procedures in regards to work practices and use of equipment that will aid in protecting laboratory employees from health hazards presented by hazardous chemicals used in the work place at the VA Nebraska-Western Iowa Health Care System (NWIHCS).
2. POLICY - Employees shall be informed of proper procedures and the proper use of equipment made available to protect them from health hazards presented by hazardous chemicals.
3. RESPONSIBILITIES
  - A. Service Chief - It is the responsibility of the Chief of Research to:
    - (1) Implement this policy as it pertains to the Research Service.
    - (2) Appoint a Chemical Hygiene Officer (CHO) for the Research Service.
    - (3) Inform all employees of the Chemical Hygiene Officer.
    - (4) Ensure employees are provided with the information and training required under OSHA 29 CFR 1910.1450 and this Medical Center policy.
    - (5) Provide documentation of training given.
  - B. Facility Safety Office - It is the responsibility of the Facility Safety Office for the following:
    - (1) Provide technical assistance in determining chemical toxicity classification, chemical incompatibilities, measures to protect employees and selection of personal protective equipment.
    - (2) Assist PI's in performing risk assessments in regards to chemical use in laboratories.
    - (3) Perform exposure monitoring when and where necessary.
    - (4) Review records of certification of chemical fume hoods annually.
    - (5) Review the program with the Chemical Hygiene Officer annually. Updates of the policy will be implemented, as needed, after consultation with the Chemical Hygiene Officer.
    - (6) Dispose of hazardous waste.
  - C. Service Chemical Hygiene Officer – The Chemical Hygiene Officer is designated by the Research Service. It is the responsibility of the Research Service Chemical Hygiene Officer for the following:
    - (1) Provide technical guidance in the development and implementation of the Chemical Hygiene Plan.
    - (2) Provide training and information required by this policy.
    - (3) Ensure that hazard warnings are in place as required.
    - (4) Establish designated areas for common chemical storage.
    - (5) Monitor procurement, use and disposal of chemicals used in the laboratory.
    - (6) Ensure periodic audits of compliance with this policy are performed and documented.

- (7) Help project directors develop precautions and adequate facilities.
- (8) Be familiar with current legal requirements concerning regulated substances.
- (9) Seek ways to improve chemical hygiene.
- (10) Review the Chemical Hygiene Plan annually and notify the Facility Safety Office of any needed changes.

- D. Laboratory Supervisor - Has overall responsibility for chemical hygiene in the laboratory he/she supervises. These responsibilities include the following:
- (1) Ensure that workers know and follow the chemical hygiene rules; that protective equipment is available and in working order; and that appropriate training has been provided.
  - (2) Provide regular, formal chemical hygiene and housekeeping inspections including routine inspections of emergency equipment.
  - (3) Be familiar with current legal requirements concerning regulated substances.
  - (4) Determine, after consultation with the Facility Safety Office personnel, the required levels of protective apparel and equipment.
  - (5) Ensure that facilities and training are adequate for use of any material being ordered.
  - (6) Inform the Facility Safety Office of any location where chemical exposure monitoring may be warranted.
- E. Laboratory Workers - It is the responsibility of laboratory workers for the following:
- (1) Planning and conducting each operation in accordance with the facility's chemical hygiene procedures.
  - (2) Develop good personal chemical use habits by following the Standard Operating Procedures found in the Chemical Hygiene Plan.
  - (3) Inform Supervisor of locations where they believe chemical exposure monitoring may be warranted.
- F. VA Leased Space – The oversight of the safety and security of VA leased space will be managed by the university affiliate as outlined in a Memorandum of Understanding (MOU) between the institutions. See Appendix B.

#### 4. SECURITY OF RESEARCH FACILITIES

- A. Policy - The following policy is established to assure the security of all areas within the Research Service and the well-being of all occupants. It is applicable to Research staff and others desiring admittance into areas of the Research Service at the Nebraska Western Iowa Health Care System.
- B. Identification - Each employee, vendor, and/or contractor (VA or Without Compensation (WOC)), working in an area under the control of the Research Service (Building 1 and Building 15) is issued and is required to

wear their VA identification badge. The badge must be worn at all times while on station, with the employee's and WOC's picture and name clearly visible. Vendors and some contractors are presently given badges without picture IDs. Vendors and contractors without authorized access are required to sign in at the Hospital Information Desk (Visitors must be accompanied, at all times, by an *authorized* VA staff member.

C. Authorized Access is defined as Research-authorized PIV (Personal Identity Verification) card, ProxCard, or standard lock-and-key access to Research areas.

(1) Access authorization procedure

- a. Authorized Research Access - Requires the approval by Research Service Administrator or designee.
- b. Research Personnel - Only properly trained personnel will be granted research access. Access approval will be granted to trained PIs and their staff upon completion of the required training. This training is as follows:
  - i. The Research Safety Training Checklist modules applicable to the work site.
  - ii. For those working with animals, a meeting with the ARF Supervisor is required for training on building specific issues, such as building security, safety, personal protective equipment, occupational health issues. Depending on the nature of the work, additional training of staff may be required at the discretion of the Veterinary Medical Officer.
- c. Non-Research VA Personnel - Access for non-Research NWHCS staff including Environmental Management, Facilities Engineering and IT personnel requires training as follows:
  - i. For those working in the Animal Research Facility, meeting with the ARF Supervisor is required for training on building specific issues, such as building security, safety, personal protective equipment, and occupational health issues. Depending on the nature of the work, additional training of staff may be required at the discretion of the ARF Manager.
  - ii. For those working in Building 15, the doors remain locked at all times. ProxCard access is required during working hours, after hours, on weekends and on Federal holidays.
  - iii. Sign-off on the Hazards in the Research Service document. Documentation/recordkeeping of training is the responsibility of the individual services. Completion of training will be verified by the Administrative Officer for Research or designee before approval of authorized access.
- d. Research keys, PIV cards and HID ProxCards - Provided by the VA Police Service.

- (2) Access to any Research area requires a PIV card, ProxCard or standard lock-and-key. Strangers must be escorted from the area if they do not belong there.
- (3) Upon termination, card access shall be removed and all keys shall be returned to Police Service.
- (4) Research access privileges carry an implicit acceptance of responsibility for personnel safety. Failure to adhere to rules and safety guidelines described in the Research Safety Manual can result in immediate termination of research access. Reinstatement of access privileges will be at the sole discretion of the ACOS (Associate Chief of Staff) for Research.
- (5) Personnel authorized for Research access shall be reviewed by the ACOS or designee no less than semi-annually. Access privileges will be continued or removed as part of this review process based on the criteria stated in VHA Handbook 1200.06: 4.j.(3)(b)3. The results of this review will be submitted to the R and D Committee.
- (6) Research access documentation (including electronic access records from the VA Police) shall be reviewed each week by designees appointed by the ACOS for Research. A written record of these weekly reviews shall be retained by the Research Service. Irregularities must be immediately reported to the VA Police and the ACOS for Research.
- (7) Penalties for allowing others to use your PIV card/code could result in lack of access.

D. Escorted Entry is defined as entry of “visitors” into Research areas by authorized VA staff members.

- (1) All visitors to Research areas shall be accompanied and escorted by authorized personnel, i.e., individuals with PIV card access.
- (2) The Research areas are subject to strict guidelines implemented for the health and safety of all personnel. All non-authorized persons (including vendors, contractors, visitors, and employees without authorized access) are required to sign in and out of the ARF’s Visitor Log Book before entering these areas and must follow the instructions of their trained host. Visitations will be limited in scope and in movement, i.e., some areas of Research are off limits. Failure to follow escort’s instructions will result in immediate removal from Research. All visitors are to sign out when leaving the area.
- (3) Unescorted visits are prohibited. Persons with authorized access are to prevent unauthorized individuals from following them into secure areas unless they are serving as their escort.
- (4) Visitors shall conduct themselves in a safe and courteous manner. Visitors must not interfere with operations and ongoing research activities nor participate in any activity that places their own safety at risk or the safety of research scientists and other personnel. The presence of visitors must not negatively impact the welfare of research animals.

- (5) Individuals from Facilities Engineering and contractors under their supervision must be escorted to their work site. They may work unattended. For the Animal Research Facility, they will meet with the ARF Supervisor for training on building specific issues, such as building security, safety, personal protective equipment, occupational health issues, and the need to schedule work with investigators to minimize disruption to research and to protect the welfare of our animals. Depending on the nature of the work, additional training of staff may be required at the discretion of the ARF Supervisor.

E. Physical Security - Doors are to be locked when leaving the lab or office. Radioactive material (including radioactive waste), controlled substances and sensitive data must be under constant surveillance or locked away at all times.

F. Other Security Concerns

- (1) Know what materials are being brought into the laboratory. Packages containing specimens, bacterial or virus isolates, or toxins are to be opened in a biological safety cabinet.
- (2) Know what materials are being removed from the laboratory.
  - a. Biological materials and toxins for shipment to other laboratories are to be packaged and labeled in conformance with all applicable local, Federal, and international shipping regulations.
    - i) The recipient or receiving facility is to be known to the sender, and the sender is to make an effort to ensure that materials are shipped to a facility equipped to handle those materials safely.
    - ii) If biological materials or toxins are to be hand carried to other facilities, all applicable regulations must be followed.
  - b. Contaminated materials or equipment are to be decontaminated before they leave the laboratory area. Chemicals and radioactive materials must be disposed of in accordance with local, State, and Federal regulations.

G. Reporting Requirements

- (1) Initial reporting. Apparent or suspected intrusion, suspicious packages or mail, or other suspicious activity shall be reported immediately to the VA Police (extension 3333 or and/or to the ISO (Information Security Officer) as appropriate, and to the Research Office (extension 3542). This includes discovery of broken or forced windows or doors, even if nothing appears to be missing. The following shall likewise be reported immediately to the appropriate authority:
  - a. Malfunctioning security door(s). Research staff may need to monitor unlocked security doors upon request by VA Police.
  - b. Loss or compromise of keys, PIV cards, HID ProxCards, lock combinations, passwords, etc.

- c. Loss of equipment.
  - d. Suspicious persons, packages or mail, vehicles, or other activity.
  - e. Any sign that inventory or records of use for controlled substances or for toxic agents have been altered or otherwise compromised.
- (2) Reporting to the ACOS for Research. Within 5 business days of becoming aware of any situation described in subparagraphs a) through d) below, members of the VA research community are required to ensure that the situation has been reported in writing to the ACOS for Research.
- a. Physical Security. Any break-in, physical security breach, or other physical security problem affecting VA research that involves any of following:
    - i. Injury or harm to a human individual or laboratory animal.
    - ii. Loss of any quantity of a select agent or toxin.
    - iii. Loss of any quantity of a highly hazardous agent. Highly hazardous agents include select agents or toxins; agents, toxins, or other biological materials requiring handling at BSL-3 or higher containment; highly toxic chemicals and gases that have the potential for readily causing widespread harm if misused; and high risk radioactive materials or radiation sources.
    - iv. Substantial damage to the facility.
    - v. Substantial loss of equipment, physical resources, or research animals. This includes loss of any equipment that holds electronic data or documents.
  - b. Findings of Noncompliance. Any findings of noncompliance related to research laboratory security by any VA office (other than ORO) or any Federal or state entity (e.g., Department of Homeland Security) must be reported. Reports to ORO based on findings made by entities external to the facility must include a copy of the official findings.
  - c. Other Deficiencies. Any other deficiency that substantively compromises the effectiveness of the facility's research laboratory security program.
  - d. Suspensions or Terminations. Any suspension or termination of research (e.g., by the ACOS for Research or other facility official) related to concerns about research laboratory security.
- (3) Reports to the Facility Director and ORO. Within 5 business days of discovering, receiving a credible report of, or otherwise becoming aware of any situation described at subparagraph 7.b., the ACOS for Research must report the incident directly (without intermediaries) to the facility Director.
- a. The report must be made in writing with simultaneous copies to the SRS, R&D Committee, Local Union and the VA Police Service.
  - b. Within 5 business days of being notified of them, the facility Director must report the research laboratory security incidents to ORO.



## 5. RESEARCH DISASTER PLAN

### A. Alert Notification Procedures Within the Research Building

- (1) If you are the first person to become aware of an emergency situation, you will be in charge of the incident until you are relieved by an On-Site Incident Commander, such as a Police Officer or Safety personnel, who have training on handling specific types of emergency situations.
  - a. Remove patients/employees from the area of hazard.
  - b. Call emergency number (ext. 3333).
  - c. Notify the switchboard operator of the location and type of emergency.
  - d. Protect yourself and others from the hazardous situation such as limiting access to the hazardous area/condition.
  - e. Continue to assess/remain in control of the situation until the On-Site Incident Commander arrives to take control of the situation. Do not attempt to remedy the situation unless instructed by the On-Site Incident Commander. (NWIHCS allows employees to empty one fire extinguisher to attempt to extinguish a small trash can size fire prior to evacuation.)
  - f. Brief person assuming control of the situation and follow instructions.
- (2) When an actual or potential emergency situation is recognized or detected, the employee who discovers, or is notified of, the situation will ensure appropriate action is taken to protect the lives and property of those around them. The incident will be reported to the proper authority using the Emergency Alert Notification procedures. The individual who initiates notification is considered the On-site Incident Commander and will provide general oversight of response activity until relieved by a fully trained On-site Incident Commander. Once at the scene, the Police Officer on duty will generally assume the position of On-Site Incident Commander. If the situation is significant, the Medical Center Director or designee will serve as the Incident Commander during administrative hours. The Administrative Officer of the Day (AOD) will serve as Incident Commander during non-administrative hours.

### B. Medical Alert Notification Procedures Outside the Research Building

If you are the first person to become aware of an emergency situation, you will be in charge of the incident until you are relieved by an On-Site Incident Commander, such as a Police Officer or safety personnel, who have training in handling emergency situations. Medical Emergency outside the Hospital Building, staff calls 9-911 to report the medical emergency. Staff calls ext. 3333 hospital operator to notify of emergency. Inform that 9-911 has already been called. Hospital operator notifies: VA Police, Director's Office (administrative hours) or AOD (non-administrative hours). The VA Police go immediately to the scene, assess the victim, provide CPR, if needed, and await arrival of Omaha Fire and Rescue. Upon arrival of Omaha Fire and Rescue, the VA Police provide a report of activity prior to the arrival, and care of the victim is transferred to Omaha

Fire Response personnel.

C. Alert Notification Procedures for Non-Medical Emergencies outside the Research Building

- (1) If you are the first person to become aware of a non-medical emergency situation, you will be in charge of the incident until you are relieved by an On-Site Incident Commander, such as a Police Officer or safety personnel, who have training on handling emergency situations.
  - a. Remove patients/employees from the area of hazard.
  - b. Call ext. 3333.
  - c. Notify the switchboard operator of the location and type of emergency.
  - d. Protect yourself and others from the hazardous situation, such as limiting access to the hazardous area/condition.
  - e. Continue to assess/remain in control of the situation until the On-Site Incident Commander arrives to take control of the situation. Do not attempt to remedy the situation unless instructed by the On-Site Incident Commander.
  - f. Brief person assuming control of the situation and follow instructions.

D. Violent Behavior Requiring Additional Staff Assistance

- (1) Clear the area to avoid others from becoming involved.
- (2) Call ext. 3333
- (3) Follow Police instructions.

E. Active shooter or armed assailant on campus

- (1) Lock-in all visitors and staff in your immediate area.
- (2) Call ext. 3333 and provide location and description of Active Shooter.
- (3) Stay locked in (shelter in place) until Police clear the area.
- (4) Follow Police instructions.

F. Severe Weather

- (1) The National Weather Service issues outlooks, watches, warnings and advisories for all winter weather hazards. Use the information available to make an informed decision on what actions to take.
  - a. Outlook - Winter storm conditions are possible in the next 2-5 days. Stay tuned to local media for updates.
  - b. Watch - Winter storm conditions are possible within the next 36-48 hours. Prepare now!
  - c. Warning - Life-threatening severe winter conditions have begun or will begin within 24 hours. Act now!
  - d. Advisory - Winter weather conditions are expected to cause significant inconveniences and may be hazardous. If you are cautious, these situations should not be life threatening.
- (2) A major winter storm can last for several days and be accompanied by high winds, freezing rain or sleet, heavy snowfall, and cold temperatures. Some winter storms can be large enough to affect

several states; others may only affect a single community. Power outages or freezing of pipes may occur.

G. Tornado Warning

Telephone operators will monitor weather radio and utilize the overhead/audio paging system to announce a tornado warning. Upon announcement of tornado warning Research personnel in building #1 and #15 should proceed to interior rooms without windows and close doors until the all clear is sounded. Personnel on the 12<sup>th</sup> floor should move to the 9<sup>th</sup> floor and seek shelter in interior rooms without windows and close doors until the all clear is sounded.

H. Radiological Incident

Notify the Radiation Safety Officer immediately at ext. 3440 during administrative hours and ext. 3333 during non-administrative hours. The following protective actions should be followed by response personnel. Time, distance and shielding are the three golden principles of radiation protection. These three principles are common sense, when you think about them. The less time you spend near a radioactive source, the less your radiation exposure will be. Increasing your distance from the radioactive source is a very effective tool in reducing your exposure. For gamma and X-ray sources (penetrating radiation), every time you double your distance away from the source, the exposure rate drops by four times; therefore, even a small amount of distance can make a big difference in your exposure. Many materials can be used as shielding; lead and concrete are two effective shielding materials. Make use of existing shielding, such as concrete walls or something as simple as stepping around the side of a building. Utilize time, distance and shielding together to minimize your radiation dose. Respiratory protection for situations involving airborne particulate radioactive material, standard surgical masks are usually sufficient. A higher level of protection would be a High Efficiency Particulate Air (HEPA) filter, such as the N95 mask that is commonly available in the hospital setting. Fit testing and training must be provided for the N95 mask.

(1) Skin Protection

Personal protective equipment (PPE) includes all clothing and protective gear worn to protect individuals from hazards. The wearer must demonstrate competency to don and doff properly and provide proper maintenance. Hospital surgical gowns or Tyvek® suits with nitrile gloves are examples of appropriate protective clothing.

(2) Dosimetry

Personnel handling contaminated items must wear radiation dosimetry badges in order to monitor the amount of their radiation exposure. One type of dosimeter is a clip-on badge containing film or other radiation-sensitive material, such as a thermo luminescent dosimeter (TLD). Other types are pocket ionization chambers, electronic dosimeters or electronic alarming rate meters that chirp when the radiation level exceeds a pre-set level. The later

has been referred to as “radiation pagers.” The Radiation Safety Officer will distribute dosimeters.

I. Internal HAZMAT Incident

Chemical spills or releases may occur at any VA Medical Center (VAMC). Chemicals are used daily and stored throughout the Research Department. Typical hazards associated with chemicals include, corrosives, flammables, toxins, and explosives. Typical areas where chemicals are found include laboratories, ARF, and surgery suites. Storage of low-hazard chemicals, when stored with incompatibles, may result in fires, explosions, or toxic fumes if mixed or spilled together. The result of chemical spills may cause hazardous vapors to enter HVAC systems, create fires or explosions, or chemically burn a person’s body. Response to chemical spills is a two-tier step, depending upon the hazard of the spill or release. They include:

(1) Incidental Spill

A small spill presenting NO hazard to employee, or the environment. Research personnel will clean using appropriate spill kit and wear personal protective equipment. If needed, use proper decontamination materials.

(2) Emergency Spill

Isolate the spill area (evacuate). Deny entry to others. Call ext. 3333 and indicate location and type of hazardous release. Police will secure area. Seek/coordinate treatment of contaminated victims. Contact Safety Office for notification of EPA for any outside spill of oil or chemical at (402) 995-4442, ext. 4731, or ext. 4461.

J. Suspicious Package/Bomb Threat

Upon discovery of a suspicious package or mail by an employee or notification of an explosive device on campus by an outside caller, immediately contact police at ext. 3202. Obtain as much information as possible. Where is the bomb; When will it go off; what does it look like; Why was it placed? If suspicious package/bomb threat is announced on overhead page, search your immediate work area for a bomb. If a suspicious package/item is found, do NOT touch. Call Police at ext. 3202.

K. Fire Plan

(1) In the event of a fire, employee discovering the fire will notify all employees in the immediate area and follow fire response procedures:

R.A.C.E.

R – Rescue those in immediate danger.

A – Alarm – Pull manual alarm or call ext. 3333.

C – Contain the fire (close doors).

E – Extinguish the fire (if safe to do so) / Evacuate.

To operate a fire extinguisher, remember the word PASS:

P – Pull the pin.

A – Aim the hose.

- S – Squeeze the handle.
- S – Sweep from side to side.

(2) Oxygen Control During a Fire

Rooms R107, R113, R119 and R120 are equipped with an oxygen zone valve near the entrance to the rooms. During a fire the ARF employees or the Electronics Technician may shut off the oxygen before the arrival of the Omaha Fire Department.

L. Evacuation Procedures

The primary route of evacuation is horizontal. Visitors, volunteers and employees shall be moved to opposite ends of the same floor. If the primary route cannot be used then evacuate vertically using the stairwell to the next floor down. \*Elevators ARE NOT to be used for evacuation of a floor EXCEPT upon direction by the Omaha Fire Department.

M. Utility System Failure

(1) Computers

If your workstation fails, enter an Information Resources Management Services (IRMS) HELP desk ticket at ext. 4357 and use a different work station if available. If the computer system is down, notify the Research Automated Data Processing Applications Coordinator (ADPAC) and contact the IRMS HELP desk at ext 4357.

(2) Telephones

If your phone is the only one having problems, enter an IRM HELP desk ticket at ext. 4357.

(3) Electrical Power Failure

Notify the electric shop at ext. 4466 to report a power failure. The Research Department has limited emergency power. The elevator, second floor cold rooms, ARF PAC systems and a few red outlets in R214 will be powered by Research's generator. If power is out for any length of time, refrigerated or frozen samples and reagents should be transferred to the second floor cold rooms.

(4) Water System Failure

Notify the plumbing shop at ext. 3320 to report a water problem.

(5) Sewer Stoppage

Do not flush toilets. Notify the plumbing shop at ext. 3320 to report a sewer problem.

(6) Equipment Failure

For Research non-patient related equipment failures, contact the Research Electronics Technician at ext. 3270.

(7) Reverse Osmosis (R. O.) Water System Failure

Contact the Research Electronics Technician at ext. 3270.

N. Annual Drills

Annual drills will be conducted in coordination with the Emergency Preparedness Coordinator to assess the effectiveness of the plans in this manual with regard to safety, security and emergency preparedness. The SRS will review the results of these drills and revise the plans as

necessary.

## 6. CHEMICAL INVENTORY SOP

### A. Purpose

The Occupational Safety and Health Administration's (OSHA) Hazardous Communications Standard requires that employers inform their employees of all chemical hazards they may be exposed to in the workplace. This is accomplished through the maintenance of chemical inventories and Safety Data Sheets (SDS) for each of the listed chemicals. (See Appendix C for an example.) The actions described below document how the Research Service addresses this OSHA Standard.

### B. Action

1. Responsibilities of the Principal Investigator (PI).
  - a. Chemical Inventories shall be updated in "real time"; i.e., a new chemical is entered into the inventory when received. Chemical Inventories are submitted 2x per year for Safety review.
  - b. When a chemical is depleted or discarded, it shall be "archived" in the inventory. However, a chemical should only be archived if it will not be used again. If it is depleted, but may be used again, simply indicate that none is on hand.
  - c. Access to the facility SDS web site is available at <http://vawww.ceosh.med.va.gov/ceosh/MSDS.shtml> and training in maintaining the chemical inventory are required for at least one member of each research group.
  - d. For laboratories without access to the facilities SDS web site, hard copies of SDS's must be maintained in their lab.
2. Coordinated responsibilities of the Subcommittee on Research Safety (SRS)
  - a. When a new PI is given a laboratory, the PI shall be informed of initiating and maintaining a chemical inventory.
  - b. The GEMS Officer and the Chemical Hygiene Officer will semi-annually verify that each chemical inventory is current.
  - c. If there is noncompliance in maintaining a current chemical inventory, the PI will be notified by the Chair of the SRS or a delegated alternate that their inventory is not current. Approval of research protocols will be withheld until their inventory is compliant.

## 7. CHEMICAL EXPOSURE MONITORING

### A. Purpose

Regular monitoring of airborne concentration is not usually justified or practical, in laboratories, since use of chemicals often involves very small amounts or infrequent use. Monitoring may be appropriate when there is an OSHA-specific standard for the material being used or highly toxic substances are being used and the possibility of exposure exists.

Monitoring may be performed at the discretion of the Facility Safety Office when an employee believes an exposure problem exists.

**B. Action**

- (1) Risk assessments are conducted by the PI to determine where exposure monitoring may be needed.
- (2) Exposure monitoring is performed by the Facility Safety Office. Results will be provided to Occupational Health and NWI Industrial Hygienist upon receipt.
- (3) The laboratory shall inform the Facility Safety Office of any areas where it is believed by employees that monitoring is warranted.
- (4) If initial monitoring results disclose employee exposures at or above the action level, Permissible Exposure Level (PEL), or Threshold Limit Value (TLV), as applicable, then the exposure monitoring requirements of the relevant standard(s) shall be followed and attempts to reduce exposures below these levels will be implemented and documented along with periodic updates will be provided until resolved.
- (5) Employees shall be notified within 15 working days after the receipt of any monitoring results. This notification shall be in writing and a copy given to the affected individual and the local union. The Chemical Hygiene Officer, Facility Safety Office, or the office administering tests will provide employees with monitoring results.

**8. CHEMICAL HYGIENE PLAN**

**A. Standard Operating Procedures**

The Chemical Hygiene Plan (CHP) shall be readily available to employees and employee representatives. The CHP shall be reviewed and its effectiveness evaluated annually. It shall be updated as necessary. Because few laboratory chemicals are without hazards, general precautions for handling all laboratory chemicals should be adopted to include minimizing exposure and assuming that any mixture of hazardous chemicals is more toxic than the most toxic component.

The following procedures are used when working with chemicals:

- (1) Accidents and spills
  - a. Eye contact: promptly flush eyes with water for a prolonged period (15 minutes) and seek medical attention.
  - b. Ingestion: Encourage the victim to drink large amounts of fluid, if appropriate.
  - c. Skin contact: promptly flush the affected area with water and remove any contaminated clothing; use a safety shower when contact is extensive. If symptoms persist after washing, seek medical attention.
  - d. Clean-up: promptly clean up spills, using appropriate protective apparel and equipment and proper disposal.
  - e. If Laboratory personnel cannot safely clean up a chemical spill, they should isolate the area (evacuate) and deny entry to others,

call extension 3333 indicate to the operator there is a chemical spill, the location of the spill, and the content of the spill.

- (2) Avoid unnecessary exposure to chemicals.
  - a. Do not smell or taste chemicals.
  - b. Any apparatus that can discharge toxic chemicals (vacuum pumps, distillation columns, etc.) should be vented into local exhaust devices.
  - c. Inspect gloves and test glove boxes before use.
  - d. Do not allow release of toxic substances in cold rooms, since these have contained, re-circulated atmospheres.
  - e. Use only those chemicals for which the quality of the available ventilation system is appropriate.
  - f. Avoid eating, drinking, smoking, gum chewing or applying cosmetics or lip balm in areas where laboratory chemicals are present. Researchers should wash hands before conducting these activities.
  - g. Avoid storing, handling, or consuming of food or beverages in chemical storage areas or in refrigerators, glassware, or utensils designated for laboratory operations.
  - h. Handle and store laboratory glassware with care to avoid damage; do not use damaged glassware. Use extra care with Dewar flasks and other evacuated glass apparatus; shield or wrap them to contain chemicals and fragments should implosion occur. Use equipment for only its designed purpose.
  - i. Wash areas of exposed skin thoroughly before leaving the laboratory.
  - j. Avoid practical jokes or other behavior that might confuse, startle or distract another worker.
  - k. Do not use mouth suction for pipetting or starting a siphon.
    - l. Confine long hair, loose clothing and jewelry.
  - m. Wear shoes at all times in the laboratory, but do not wear open toed shoes.
  - n. Keep work area clean and uncluttered, with chemicals and equipment properly labeled and stored; clean up the work area on completion of an operation and at the end of each day.
  - o. Ensure that appropriate eye protection, when necessary, is worn by all persons, including visitors, in areas where chemicals are being used.
  - p. Wear appropriate gloves when the potential for contacting toxic materials exists; inspect the gloves before each use, wash them before removal, and replace them periodically.
  - q. Use any other protective and emergency apparel and equipment as appropriate.
  - r. Remove laboratory coats immediately upon significant contamination.
  - s. Take necessary precautions to possible spills while using toxic chemicals.
  - t. Use a hood for operations that might result in release of toxic chemical vapors or dust. Confirm adequate hood performance before use: keep hood sash at recommended working levels at all



times except when adjustments within the hood are being made. Keep materials stored in hoods to a minimum, and do not allow materials to block vents or airflow. Leave the hood on when it is not in active use, if toxic substances are stored in it or if it is uncertain whether adequate general laboratory ventilation will be maintained when it is off.

- u. In the event of a ventilation outage, while working with hazardous materials, close the sash immediately. Evacuate the laboratory and close the door. Notify the A/C shop (ext. 3280) of the outage and inform them that hazardous materials were in use. Contact the Research Office so they can make others aware of the ventilation outage.

- (3) Specific procedures and manuals for various laboratories may be attached as appendices to this Research Service Safety Manual. Work involving recombinant DNA must conform to the NIH guidelines (See Appendix D).

B. Chemical Inventory - In accordance with the Hazardous Materials Handling Policy, a chemical inventory is maintained and updated bi-annually for each laboratory and for the Research Service. These shall be submitted to the NWHCS GEMS Coordinator. Additionally, any new lab space or new chemicals should be reported to the GEMS Coordinator.

C. Safety Data Sheets - The SDS's must be readily available to employees in the work area. The SDS's are in alphabetical order along with a chemical inventory. The laboratory relies on the chemical manufacturer's information to ascertain whether the chemical is hazardous.

D. Chemical Storage - chemical storage is kept as small as practical.

- (1) All chemicals must be stored in containers labeled as to the content and appropriate warnings in accordance with OSHA GHS labeling requirements.
- (2) Chemicals should not be stored alphabetically as a general group. Rather, an effort should be made to segregate chemicals into the different compatibility groups listed in the table below, with alphabetical storage within compatible groups.
- (3) Separation of compatibility groups can be achieved by using different shelves within the same cabinet.
- (4) Ventilated cabinets and explosion-proof refrigerators will be used for storage of flammable chemicals. Maximal volume of flammable liquids is 2 gallons per 100 sq. ft. of lab space, excluding chemicals stored in flammable cabinets. Amount allowed is doubled if half the chemicals are stored in a flammable cabinet.
- (5) Cylinders of compressed gases are strapped or chained to a wall or bench top and are capped when not in use.

Compatible Storage Groups	
Group	Examples
Flammable Liquids	All alcohols, Acetone, Benzene, Methyl butane, Xylene
Compressed Gases	Oxygen, Nitrogen, Hydrogen, Arsine
Volatile poisons	Carbon tetrachloride, Chloroform, Formaldehyde
Acids	MINERAL ACIDS Oxidizing-Sulfuric, Nitric, Chromic Non-oxidizing-Hydrochloric, phosphoric ORGANIC ACIDS Acetic, Butyric, Formic, Propionic
Liquid bases	Sodium hydroxide, Ammonium hydroxide, Calcium hydroxide, Flutaraldehyde
Liquid oxidizers	Ammonium persulfate, Hydrogen peroxide
Non-volatile liquid poisons	Acrylamide solutions, Diethylpyrocarbonate, Ethidium bromide
Metal hydrides and pyrophorics (air or water reactive)	Sodium borohydride, Calcium Hydride, Lithium aluminum hydride
Dry Solids	Cyanogen bromide, Oxalic Acid, Sodium Cyanide

E. Control Measures - These shall include engineering controls, the use of personal protective equipment, hygiene practices and administrative practices.

- (1) Specific control measures will depend on the degree of toxicity of the substance and exposure potential. Chemicals that are known to be extremely hazardous shall have particular attention given to the selection of control measures.
- (2) Protective apparel and equipment shall consist of the following:
  - a. Protective apparel compatible with the required degree of protection for the substance being handled.
  - b. Readily accessible drench-type safety shower.
  - c. An eyewash fountain.
  - d. A fire extinguisher.
  - e. A telephone for emergency use should be available nearby.
  - f. Other items designated by the Chemical Hygiene Officer or Laboratory Supervisor.
- (3) Particularly Hazardous Substances - These are defined as select carcinogens, reproductive toxins and substances that have a high degree of acute toxicity. Specific consideration shall be given to the following provisions in regard to these substances and shall be included where appropriate:
  - a. Establishment of a designated area. The area will be posted and all employees working within the area will be informed of the hazardous substance(s) used there.

- b. Use of a containment device such as a chemical fume hood. This should be considered when using volatile substances, when generation of aerosols is likely, or when reactions that may result in the uncontrollable release of the substance are likely.
      - c. Procedures for safe removal of contaminated waste, indicated by filling out the disposal form and labeling the container.
      - d. Decontamination procedures.
      - e. Documentation, in writing, of any approved waiver of the above provisions.
    - (4) Prior Approval:
      - a. The Service Chemical Hygiene Officer shall determine circumstances under which a particular laboratory operation, procedure or activity shall require prior approval before implementation.
      - b. Prior approval must be in writing and it will detail special precautions to be taken in order to protect employees' health.
      - c. Any prior approval must be forwarded to the Facility Safety Office.
- F. Fume Hoods and Other Protective Equipment - Eyewashes, emergency showers, fire extinguishers and other protective equipment must be in proper working order at all times. Specific measures to ensure proper and adequate performance include the following:
- (1) Biohazard and chemical fume hoods are certified at least annually as to proper operation. The Facility Safety Office will review this certification. Stickers attesting to certification are placed on the hood's, exterior and certification reports are available in Engineering.
  - (2) Eyewashes are inspected and tested weekly to verify proper operation. A written record of this is maintained (work orders on quarterly basis).
  - (3) Safety showers are inspected monthly and tested and flushed annually. A written record of this is maintained by the Engineering Department.
  - (4) Fire extinguishers are inspected monthly by the Facility Safety Office.
  - (5) Other protective equipment shall be utilized as it pertains to individual laboratories.
- G. Contaminated Waste Removal/Disposal - To prevent harm to people and the environment, the disposal of waste laboratory chemicals will be conducted in accordance with Hazardous Waste Policy SAF-005, Hazard Materials Program. All disposal is done in accordance with the Nebraska Department of Environmental Control and the United States Environmental Protection Agency (EPA) regulations. This facility is considered a "small quantity generator" according to the EPA and an EPA identification number has been obtained. Fill out Hazardous Waste disposal form and call the Green Environmental Management Systems (GEMS) Coordinator at ex. 4442. Label containers with contents and hazard levels.

H. Medical Consultation and Exams

(1) Employees shall be encouraged to receive medical attention under the following circumstances:

- a. Whenever employees develop signs or symptoms associated with a hazardous chemical to which they may have been exposed in the lab.
- b. Routine exposures above the action level or PEL, as required by substance specific OSHA standards.
- c. Emergency exposures such as a spill, leak or other occurrence resulting in the likelihood of a hazardous exposure.

(2) The physician shall be provided the following information:

- a. The identity of the hazardous chemical (s).
- b. The SDS for the respective chemical (s).
- c. A description of the conditions under which the exposure occurred, including quantitative exposure data if available.
- d. A description of the signs and symptoms of exposure that the employee is experiencing, if any.

9. HAZARD IDENTIFICATION - Hazard identification with regard to labels on containers and SDS's, shall be accomplished as outlined in Policy SAF-005, Hazardous Materials Program (Includes Hazcom).

10. EMPLOYEE INFORMATION AND TRAINING:

A. Policy - Employees shall be provided with information training to ensure they are apprised of the hazards of the chemicals present in their work area.

The following additional information and training must be given to employees:

- (1) Employees must be informed of the location and availability of this policy, including the OSHA standard 1910.1450 (attached to this policy), and any reference materials on the hazards, safe handling, storage and disposal of hazardous chemicals in the laboratory.
- (2) The permissible exposure limits for OSHA-regulated substances or recommended exposure limits where there is no applicable OSHA standard. These limits may be obtained from SDS's or the Facility Safety Office.
- (3) The location and proper use of available protective equipment.
- (4) Emergency procedures in case of fire, accident or spill.
- (5) Proper waste disposal procedures, including the existence and use of the central hazardous waste storage facility.
- (6) Prior approved procedures or safety manuals.

B. Training Requirement - This additional training must be conducted annually and upon initial assignment of an employee to the lab or a new work area of the lab. Documentation of training must be forwarded to the Facility Safety Office (03S).

11. HOUSEKEEPING - Floors should be cleaned regularly by housekeeping. All employees of the housekeeping department are formally trained (by OVAMC) in the risks associated with working in a laboratory.

12. RECORDKEEPING - The Facility Safety Office has established and will maintain an accurate record for environmental monitoring, medical consultations, and examinations, including tests or written opinion required in accordance with 29CFR 1919.20.
13. RESPIRATOR USAGE - Respirators will be used according to the NWI Respiratory Protection Program. The employee receiving a respirator must receive medical approval and respirator training prior to being issued. The Respiratory Protection for Employee Comfort requires the following consideration.
  - A. User Requirements
    - (1) The employee receiving a respirator must receive both respirator training and medical approval.
    - (2) Initial respirator training must be given by a formalized program by Occupational Health during on-boarding at the time issued or later by the Facility Safety Office upon request.
    - (3) Medical approval is issued by Occupational Health and indicates that the employee is physically capable of performing his/her job duties while wearing a respirator. Medical approval must be given prior to an employee wearing a respirator.
  - B. Inspections - Employees who are assigned their own respirators will inspect them before and after each time they are used.
  - C. Fit-testing - Conducted IAW the Respiratory Protection Program.
  - D. Recordkeeping
    - (1) The Facility Safety Office will maintain the respirator training records.
    - (2) The Occupational Health Representative will maintain the Medical approval questionnaire for respirator usage.
14. RECORDS - All monitoring records shall be maintained for a period of 30 years as required by 29 CRF 1910.1200.
15. REFERENCES -
  - A. CFR 29 1910.1450
  - B. CRF 20 1910.20
  - C. CRF29 1910.1200
  - D. U.S. Department of Labor, final rule part II. Federal Register 29 CRF Part 1910. Occupational Exposure to Hazardous Chemicals in Laboratories, Wednesday, January 31, 1990.
  - E. National Research Council. Prudent Practices for Handling Hazardous Chemicals in Laboratories, National Academy Press, 1981.

- F. National Research Council. Prudent Practices for Disposal of Chemicals from Laboratories, National Academy Press, 1983.
  - G. VA Handbook 1200.06 Control of Hazardous Agents in VA Research Laboratories.
  - H. VA Handbook 1200.08 Safety of Personnel Engaged in Research.
  - I. AFGE Master Agreement, 2011
16. RECISION: Research Safety Manual, March 2015.
  17. FOLLOW-UP RESPONSIBILITY: Facility Safety Officer (Seth Burmeister)
  18. REVIEW DATE: Annually on the anniversary date of this memorandum.
  19. REVISION DATE: 4 April 2016

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

## Appendix A

### DEFINITIONS

1. Chemical Hygiene Officer - An employee, designated in writing by the respective Service, who is qualified by training or experience to provide technical guidance in the development and implementation of the Chemical Hygiene Plan.
2. Chemical Hygiene Plan - A written program which sets forth procedures, equipment, personal protective equipment (PPE) and work practices that are capable of protecting employees from the health hazards presented by hazardous chemicals used in their particular work area(s).
3. Designated Area - An area that may be used for work with select carcinogens (see A10" below), reproductive toxins or substances that have a high degree of acute toxicity.
4. Emergency - Any occurrence such as, but not limited to, equipment failure, rupture of containers or failure of control equipment which results in an uncontrolled release of a hazardous chemical into the work place.
5. Hazardous Chemical - Any chemical or material that presents a physical and/or health hazard.
6. Chemical Fume Hood - A device constructed and maintained to draw air from the laboratory and to prevent or minimize the escape of air contaminants into the laboratory, and which also allows chemical manipulation to be conducted in the enclosure without insertion of any portion of the employee's body other than the hands or arms.
7. Medical Consultation - A consultation which takes place between an employee and a licensed physician for the purpose of determining what medical examinations or procedures, if any, are appropriate, in cases where significant exposure to a hazardous chemical may have taken place.
8. Protective Laboratory Practices and Equipment - Those practices, procedures and equipment accepted by health and safety experts as effective or that can be shown to be effective in minimizing the potential for employee exposure to hazardous chemicals.
9. Reproductive Toxins - Chemicals which affect the reproductive capabilities, including chromosomal damage (mutations) and effects on fetuses (teratogenesis).
10. Select Carcinogens - any substance which meets one of the following criteria;
  - a. It is regulated by Occupational Safety and Health Administration (OSHA) as a carcinogen.
  - b. It is listed under the category, A (known to be carcinogens), in the latest edition of the Annual Report on Carcinogens, published by the National Toxicology Program (NTP).
  - c. It is listed under Group I, A (carcinogenic to humans), by the International Agency for Research on Cancer (IARC) Monographs, latest edition.

d. It is listed in either Group 2A or 2B by IARC or under the category, A (reasonably anticipated to be carcinogens), by the NPT, and causes statistically significant tumor incidence in experimental animals in accordance with any of the following criteria.

- (1) After inhalation exposure of 6-7 hours per day, five (5) days per week, for a significant portion of a lifetime, to dosages of less than 10mg/m<sup>3</sup>;
- (2) After repeated skin application of less than 300 mg/kg of body weight per week; or
- (3) After oral doses of less than 50 mg/kg of body weight per day.



## **Appendix B**

### **MEMORANDUM OF UNDERSTANDING REGARDING RESEARCH LABORATORY SAFETY**

UNIVERSITY OF NEBRASKA MEDICAL CENTER  
AND  
VA Nebraska-Western Iowa Health Care System

The Regents of the University of Nebraska, on behalf of its Medical Center (UNMC), and the VA Nebraska-Western Iowa Health Care System (NWI), make this agreement pertaining to personnel who plan to perform research at any NWI facility using UNMC funds as part of UNMC-sponsored research; and to personnel who perform research at UNMC where such research is funded with VA or VA Nonprofit-sponsored funds. This agreement is effective XXXXXXXXXX, and will be re-evaluated by all parties every five (5) years. This agreement is inclusive of all biomedical research. VA is authorized to enter into this agreement as set forth in VHA Handbook 1200.08, "Safety of Personnel Engaged in Research".

For the purpose of this agreement, "**UNMC-sponsored research**" is defined as research conducted by UNMC personnel (either faculty, staff, post-doctoral fellows, or students) and supported either by a contract, grant or gift awarded to The Regents of the University of Nebraska and administered by UNMC, including money from extramural sponsors, money awarded by the University of Nebraska under a University-managed research program, and any other internal University award appropriated for research support.

For the purpose of this agreement, "**VA-sponsored research**" is defined as research conducted by VA personnel and supported either by a contract, grant or gift awarded by or to the Department of Veterans Affairs, and administered by NWI, including money from extramural sponsors, VA Merit Awards, VA Career Development Awards, and other internal awards appropriated for research support. Also included, as VA-sponsored research is research conducted by VA personnel and supported either by a contract, grant or gift awarded by or to the Nebraska Educational and Biomedical Research Association (NEBRA), and administered by NEBRA, including money from extramural sponsors and internal awards appropriated for research support.

For the purpose of this agreement, the "**VA form**" is defined as the VA Research Protocol Safety Survey, and when necessary the "UNMC form" is defined as the Institutional Biosafety Committee (IBC) Protocol for Research Involving Biohazardous Materials.

By virtue of this agreement, the investigators and each institution (UNMC and NWI) is obligated to ensure continued compliance with all applicable laws and regulations governing laboratory safety. In this agreement, "Committee(s)" is used as a generic term to include the equivalent UNMC Institutional Biosafety Committee and the NWI Subcommittee of Research Safety (NWI SRS).

**When personnel perform research at either the UNMC or NWI facilities, all interested parties agree to the following arrangements in order to ensure that both parties provide appropriate oversight:**

#### **I. Protocol Review**

UNMC will perform its duties consistent with Department of Veterans Affairs ("VA" or "VHA") policies and procedures in addition to Occupational Safety and Health Administration ("OSHA"), Environmental Protection Agency ("EPA"), Nuclear Regulatory Commission ("NRC"), etc., and

any applicable State and local requirements. UNMC agrees to follow all National Institutes of Health (“NIH”) and Centers for Disease Control (“CDC”) guidelines

The necessary forms that all investigators will complete, as well as the necessary Committee approval process, are stated in Table 1. If both Committees must review a protocol, personnel may not initiate the research until both Committees approve the protocol. If there are differences not easily resolved between the two Committees, the chairpersons of the two committees will meet with the investigator to attempt to resolve the issues. However, both Committees must approve the final outcome of the resolution. By this agreement, the UNMC Institutional Biosafety Committee agrees to accept as valid the VA form as the policy dictates, and the NWI Safety Committee agrees to accept as valid the UNMC form as the policy dictates.

TABLE 1: PROTOCOL REVIEW PROCESS

Situation	Description	UNMC-Sponsored Research	VA-Sponsored Research
# 1	<b>Animals Housed or Used Solely at UNMC</b>	UNMC forms only. Reviewed by UNMC IACUC only. No VA IACUC approval or oversight.	
# 2	<b>Animals Housed or Used Solely at UNMC</b>		VA forms only. Pre-Reviewed by VA; reviewed by UNMC IACUC with Administrative Concurrence by VA IACUC.
# 3	<b>Animals Housed or Used Solely at VA</b>	VA forms only. Reviewed by VA IACUC with Administrative Concurrence by UNMC IACUC.	
# 4	<b>Animals Housed or Used Solely at VA</b>		VA forms only. Reviewed by VA IACUC ONLY. No UNMC IACUC approval or oversight.
# 5	<b>Animals Housed or Used at <u>both</u> UNMC and VA</b>	VA AND UNMC forms (if requested by UNMC; case-by-case basis). Reviewed and Approved by <u>both</u> UNMC and VA IACUCs.	
# 6	<b>Animals Housed or Used at <u>both</u> UNMC and VA</b>		VA forms only. Reviewed and Approved by <u>both</u> UNMC and VA IACUCs.

Prior to initiating changes, investigators who plan to make changes to an approved protocol must obtain the written approval of the appropriate Committee(s). In cases where both Committees reviewed the protocol, written approvals must be obtained from each of the two Committees prior to initiating such changes. Any modification to an approved protocol must be reported in writing to the appropriate Committee(s) as a matter of record keeping.

In the event that UNMC reviews a VA sponsored research project involving recombinant DNA the minutes for the protocol review will be sent to the VA's Research and Development Committee.

One member of the UNMC IBC shall be a VA employee with appropriate qualifications.

## **II. Personnel Qualifications**

The UNMC Institutional Biosafety Committee and NWI SRS may request records concerning their respective training programs (including, but not limited to, occupational health and safety programs) and the qualifications of all personnel (including scientists, research personnel, and animal care technicians) who are specifically performing research at NWI and involved in UNMC-sponsored research, or performing research at UNMC and involved in VA- or VA Nonprofit-sponsored research. The Committees will provide each other information on the changes in personnel and the safety-training program, as requested.

## **III. Reports**

Upon request, each institution shall provide the other with copies of documents related to protocol review, including the Committee approval letter, records of continuing review, and amendments. Upon request, each institution shall provide the other with copies of mandated evaluations of the programs, as well as any correspondence from NIH or VA ORO concerning the UNMC or NWI facilities that pertain to protocols relevant to this agreement.

## **IV. Facility Inspections**

At minimum, the NWI SRS will conduct yearly inspections of their facilities, including VA-leased space at UNMC. Should the UNMC require inspection of VA space in which UNMC-sponsored research is being conducted they can accept the annual inspection of UNMC sponsored research conducted at NWI or perform independent inspections. Likewise, the NWI Safety Committee can accept the annual inspection of the VA or VA Nonprofit-sponsored research program performed by UNMC. Specifically, if VA-or VA Nonprofit research is performed in UNMC's P3 facility NWI will accept the UNMC inspections and certifications of the P3 facility. Each institution shall be responsible for notifying the other of any serious deficiencies encountered during inspections that are related to protocols relevant to this agreement. Deficiencies according to NIH regulations or the guidelines set forth in the National Select Agent Program, the "Biosafety in Microbiological and Biomedical Laboratories" 5<sup>th</sup> addition, the VA Handbook 1200.08 "Safety of Personnel Engaged in Research", or the VA Handbook 1200.06 "Control of Hazardous Agents in VA Research Laboratories" will be submitted by the inspection team to the Responsible Official i.e., Biosafety Officer in consultation with the appropriate committees and/or individuals. A plan of correction to correct said deficiencies will be agreed upon by both Committees. The VA Safety Committee will review VA or VA Nonprofit-sponsored research that is conducted in the UNMC BSL-3 facility, but the VA Safety Committee will not inspect the facility itself. UNMC assumes the sole responsibility for inspection and compliance with Federal and State regulations regarding this facility. Upon request, UNMC will provide NWI with documentation of inspections and certification of compliance with Federal and State regulations.

**V. Use of Hazardous Agents**

The use of infectious agents, toxic chemicals, or radioisotopes requires the prior written approval of the Biosafety Committee, the Radiation Safety Committee, and/or the Office of Environment, Health and Safety of the institution(s) that approved the protocol.

**VI. Reports of Non-Compliance**

Each institution shall be responsible for notifying the other of any instances of non-compliance with respect to research safety in UNMC- or VA-sponsored research relevant to this agreement. The UNMC Institutional Biosafety Committee and NWI SRS shall be responsible for resolving any reports of non-compliance involving safety on VA-leased space at UNMC. The NWI SRS shall be responsible for resolving any reports of non-compliance involving safety in the NWI facility. If a case of non-compliance has been verified, if necessary, both parties shall submit a collaborative written report describing the circumstances and subsequent resolution to the appropriate State and Federal agencies as evidence of ongoing institutional self-monitoring when required.

UNMC agrees to promptly report to VA R&D Committee relevant information including, but not limited to, Adverse Events, research misconduct, research impropriety, conflict of interest, privacy concerns and security concerns, including data security. UNMC further agrees to identify the need for health surveillance of personnel involved in individual research projects, and if appropriate, advise the R&D Committee on the need for such surveillance. UNMC further agrees to ensure the collection of appropriate personnel samples to make employee exposure determinations whenever the proposed use of laboratory chemicals may potentially exceed OSHA Permissible Exposure Limits or Action Levels.

**VII. Emergency Response**

Each institution shall be responsible for responding to emergencies at there institution regardless of the sponsorship of the research. Should the emergency involve VA-sponsored research at UNMC or UNMC-sponsored research at NWI, the sponsoring institution will be notified once the emergency has been addressed

**VIII. Modification**

This agreement is subject to modification by the parties to refine and adjust the incumbent's hours and other terms of this agreement. The parties agree to provide as much notice as possible should modification or termination become necessary. Unless and until a party provides notification of a desire to modify or terminate this agreement, the agreement will automatically renew on an annual basis, on the anniversary date of the last signature of this agreement.

Director, VA Nebraska-Western  
Iowa Health Care System  
OMVAMC Institutional Official

Date

Vice Chancellor for Research UNMC  
UNMC Institutional Official

Date

## Appendix C

### Sample Safety Data Sheet (SDS)

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#### SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

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PRODUCT NAME:  
SYNONYMS:  
PRODUCT CODES:

MANUFACTURER:  
DIVISION:  
ADDRESS:

EMERGENCY PHONE:  
CHEMTREC PHONE:  
OTHER CALLS:  
FAX PHONE:

CHEMICAL NAME:  
CHEMICAL FAMILY:  
CHEMICAL FORMULA:

PRODUCT USE:  
PREPARED BY:

SECTION 1 NOTES:

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#### SECTION 2: HAZARDS IDENTIFICATION

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EMERGENCY OVERVIEW:

ROUTES OF ENTRY:

POTENTIAL HEALTH EFFECTS

EYES:

SKIN:

INGESTION:

INHALATION:

ACUTE HEALTH HAZARDS:

CHRONIC HEALTH HAZARDS:

MEDICAL CONDITIONS GENERALLY AGGRAVATED BY EXPOSURE:

CARCINOGENICITY

OSHA:

OTHER:

ACGIH:

NTP:

IARC:

SECTION 2 NOTES:

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**SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS**

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**INGREDIENT:**

<u>CAS NO.</u>	<u>% WT</u>	<u>% VOL</u>	<u>SARA 313 REPORTABLE</u>
	<u>ppm</u>	<u>mg/m3</u>	
OSHA PEL-TWA: OSHA PEL STEL : OSHA PEL CEILING:			
ACGIH TLV-TWA: ACGIH TLV STEL: ACGIH TLV CEILING:			

**SECTION 3 NOTES:**

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**SECTION 4: FIRST AID MEASURES**

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**EYES:****SKIN:****INGESTION:****INHALATION:****NOTES TO PHYSICIANS OR FIRST AID PROVIDERS:****SECTION 4 NOTES:**

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**SECTION 5: FIRE-FIGHTING MEASURES**

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**FLAMMABLE LIMITS IN AIR, UPPER:  
(% BY VOLUME) LOWER:****FLASH POINT:****F:****C:****METHOD USED:****AUTOIGNITION TEMPERATURE:****F:****C:****NFPA HAZARD CLASSIFICATION****HEALTH:****FLAMMABILITY:****REACTIVITY:****OTHER:****HMIS HAZARD CLASSIFICATION****HEALTH:****FLAMMABILITY:****REACTIVITY:****PROTECTION:****EXTINGUISHING MEDIA:****SPECIAL FIRE FIGHTING PROCEDURES:****UNUSUAL FIRE AND EXPLOSION HAZARDS:**

**HAZARDOUS DECOMPOSITION PRODUCTS:**

**SECTION 5 NOTES:**

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**SECTION 6: ACCIDENTAL RELEASE MEASURES**

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**ACCIDENTAL RELEASE MEASURES:**

**SECTION 6 NOTES:**

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**SECTION 7: HANDLING AND STORAGE**

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**HANDLING AND STORAGE:**

**OTHER PRECAUTIONS:**

**SECTION 7 NOTES:**

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**SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**

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**ENGINEERING CONTROLS:**

**VENTILATION :**

**RESPIRATORY PROTECTION:**

**EYE PROTECTION:**

**SKIN PROTECTION:**

**OTHER PROTECTIVE CLOTHING OR EQUIPMENT:**

**WORK HYGIENIC PRACTICES:**

**EXPOSURE GUIDELINES:**

**SECTION 8 NOTES:**

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**SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**

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**APPEARANCE:**

**ODOR:**

**PHYSICAL STATE:**

**pH AS SUPPLIED:**

**pH (Other):**

**BOILING POINT:**

**F:**

**C:**

**MELTING POINT:**

**F:**

**C:**

**FREEZING POINT:**

**F:**





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**WASTE DISPOSAL METHOD:**

**RCRA HAZARD CLASS:**

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**SECTION 13: DISPOSAL CONSIDERATIONS (con't)**

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**SECTION 13 NOTES:**

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**SECTION 14: TRANSPORT INFORMATION**

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**U.S. DEPARTMENT OF TRANSPORTATION**

**PROPER SHIPPING NAME:**

**HAZARD CLASS:**

**ID NUMBER:**

**PACKING GROUP:**

**LABEL STATEMENT:**

**WATER TRANSPORTATION**

**PROPER SHIPPING NAME:**

**HAZARD CLASS:**

**ID NUMBER:**

**PACKING GROUP:**

**LABEL STATEMENTS:**

**AIR TRANSPORTATION**

**PROPER SHIPPING NAME:**

**HAZARD CLASS:**

**ID NUMBER:**

**PACKING GROUP:**

**LABEL STATEMENTS:**

**OTHER AGENCIES:**

**SECTION 14 NOTES:**

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**SECTION 15: REGULATORY INFORMATION**

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**U.S. FEDERAL REGULATIONS**

**TSCA (TOXIC SUBSTANCE CONTROL ACT):**

**CERCLA (COMPREHENSIVE RESPONSE COMPENSATION, AND LIABILITY ACT):**

**SARA TITLE III (SUPERFUND AMENDMENTS AND REAUTHORIZATION ACT):**

**311/312 HAZARD CATEGORIES:**

**313 REPORTABLE INGREDIENTS:**

**STATE REGULATIONS:**

**INTERNATIONAL REGULATIONS:**

**SECTION 15 NOTES:**

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**SECTION 16: OTHER INFORMATION**

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**OTHER INFORMATION:**

**PREPARATION INFORMATION:**

**DISCLAIMER:**

## **Appendix D**

# **Guidelines for NIH DNA Research**

Nebraska Western Iowa Health Care System

### **Table of Contents**

- I. Introduction**
- II. Classification of Bio-hazard Agents by Potential Risk**
  - A. Risk Group 1 (RG1)
  - B. Risk Group 2 (RG2)
  - C. Risk Group 3 (RG3)
  - D. Risk Group 4 (RG4)
- III. Containment Standards**
  - A. Biosafety Levels
  - B. Standard Practices
- IV. Projects Requiring Prior Approval at Levels Above the IBC and SRS.**
  - A. Category 1
  - B. Category 2
  - C. Category 3
  - D. Category 4
  - E. Category 5
  - F. Category 6
- V. NIH Exemptions**
- VI. Responsibilities of the Principal Investigator**
  - A. General Responsibilities
  - B. Responsibilities Prior to Initiating Research
  - C. Responsibilities While Conducting the Research
  - D. Submissions to the Subcommittee on Research Safety
  - E. Submissions to the National Institutes of Health/Office of Biotechnology  
DNA  
Activities
- VII. Responsibilities of the IBC**
- VIII. Responsibilities of the Laboratory Personnel**
  - A. Laboratory Practices
  - B. Decontamination Procedures for Accidental Spills or Contaminations

## **I. INTRODUCTION**

Recombinant DNA molecules (in the context of the *NIH Guideline*), are defined as either: (i) molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or (ii) molecules that result from the replication of those described in (i) above.

Synthetic DNA segments which are likely to yield a potentially harmful polynucleotide or polypeptide (e.g., a toxin or a pharmacologically active agent) are considered as equivalent to their natural DNA counterpart. If the synthetic DNA segment is not expressed *in vivo* as a biologically active polynucleotide or polypeptide product, it is exempt from the *NIH Guidelines*.

Genomic DNA of plants and bacteria that have acquired a transposable element, even if the latter was donated from a recombinant vector no longer present, are not subject to the *NIH Guidelines* unless the transposon itself contains recombinant DNA.

The **Nebraska Western Iowa Health Care System (NWIHCS) guidelines** are based on the National Institute of Health (NIH) Guidelines [May 2011 Revisions of the Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines)] and are intended to adapt the NIH standards to research conducted at the NWIHCS. NIH Guidelines specify the practices for constructing and handling recombinant DNA (rDNA) molecules and organisms or viruses containing these molecules, and delineate the roles and responsibilities of the Institutional Biosafety Committee (IBC), the Principal Investigator (PI), and the NIH. Current revisions of the NIH Guidelines can be accessed at <http://oba.od.nih.gov>. The local NWIHCS Subcommittee on Research Safety (SRS) will follow the NIH Guidelines for the evaluation of proposed research projects using rDNA at this facility. All research studies at the NWIHCS must submit a Research Safety Application. **No work above BSL2 or RG2 is authorized within the NWIHCS facilities.**

## **II. CLASSIFICATION OF BIO-HAZARD AGENTS BY POTENTIAL RISK**

Safety considerations of rDNA research are found in Section II and its risk assessment in Section II A of the NIH Guidelines. The investigator must make an initial risk assessment based on the Risk Group (RG) of an agent (see Appendix B to Section II A, *Classification of Human Etiologic Agents on the Basis of Hazard*).

**A. Risk Group 1 (RG1):** Agents that are not associated with disease in adult humans. A strain of *Escherichia coli* is an RG1 agent if it lacks the O antigen and does not carry any active virulence factor (e.g. toxins) or colonization factors and does not possess any genes encoding these factors.

**B. Risk Group 2 (RG2):** Agents associated with human diseases which are rarely serious. Preventive or therapeutic interventions are often available.

**C. Risk Group 3 (RG3):** Agents associated with serious or lethal human disease having a high-risk level for the individual but low risk for the community. Preventive or therapeutic interventions may be available.

**D. Risk Group 4 (RG4):** Agents likely to cause serious or lethal human disease having a high-risk level for both the individual and the community. Preventive or therapeutic interventions are not usually available.

### **III. CONTAINMENT STANDARDS (SECTION II B, NIH GUIDELINES)**

#### **A. Biosafety Levels**

Containment precautions start with the implementation and adherence to standard microbiological practices and physical procedures utilizing special procedures, equipment, and laboratory installations (see Appendix G, *NIH Guidelines*). Experiments involving rDNA lend themselves to a third containment mechanism, namely, the application of highly specific biological barriers. Natural barriers exist that limit either: (i) the infectivity of a vector or vehicle (plasmid or virus) for specific hosts, or (ii) its dissemination and survival in the environment. Vectors, which provide the means for rDNA and/or host cell replication, can be genetically designed to decrease, by many orders of magnitude, the probability of dissemination of rDNA outside the laboratory (see Appendix I, *NIH Guidelines*). All personnel directly or indirectly involved with rDNA experiments must receive adequate training and instruction. This includes, but is not limited to, use of aseptic techniques and an understanding of the biology of the organisms used. Ultimately it is the responsibility of the PI to provide this instruction.

NIH Guidelines specify **four levels of physical containment** designed to be used with specific RG categories.

- 1. Biosafety Level 1 (BSL1):** This basic level of containment may be used with RG1 and some RG2 classified systems.
  - a. Agents with no known or minimal potential hazard may be used.
  - b. Work is generally conducted on the open bench top in a laboratory that is not isolated from the general traffic pattern of the building.
  - c. Special containment equipment is not usually warranted.
- 2. Biosafety Level 2 (BSL2):** Most RG2 and some RG3 systems may be used with this level of containment. Agents of moderate potential hazard are used in an environment similar to BSL1 but require:
  - a. Specific training of laboratory personnel in handling pathogenic agents.
  - b. Implementation of more stringent requirements for gaining access to the laboratory while work is in progress.
  - c. Use of biological safety cabinets or other appropriate physical containment equipment for procedures with a high potential to create aerosols.
- 3. Biosafety Level 3 (BSL3):** All RG3 and a few RG4 systems may be used with this level of containment. This level requires more stringent containment procedures for all manipulations.
  - a. Biological safety cabinets or other physical containment devices and personal protective equipment (PPE) are used at all times.
  - b. Special engineering and design features are incorporated into the laboratory to facilitate containment requirements.
  - c. Access to the laboratory is restricted at all times.
- 4. Biosafety Level 4 (BSL4):** This level of containment is required for most RG4 systems. The most rigorous standards of containment and isolation are enforced at this level.

- a. A completely controlled environment must be maintained.
- b. The air supply and exhaust, water supply system, liquid effluent from sinks, etc. must be isolated and designed to eliminate contamination of the outside environment.
- c. PPE is absolutely required and may include one-piece positive pressure suits if Class III biological safety cabinets are not provided.
- d. It is preferable to have a separate building designated for BSL4 activities, but well isolated and demarcated facilities may be established within existing structures.
- e. Access to the work area is through self-locking, self-closing doors and a changing room equipped with showers, which are used whenever exiting the facility.
- f. No street clothing is permitted into the work area. All clothing for entering the laboratory will be provided (this may be disposable). Only essential personnel may enter the facility, and they will sign a logbook recording the date with entry and exit times.

## **B. Standard Practices**

The VA NWIHCS currently is equipped for only **BSL1** and **BSL2** containment. Therefore, only the practices for these two levels will be set forth here. Any proposed work requiring BSL3 or BSL4 containment will need to be addressed specifically through the SRS.

### **1. Standard Practices for BSL1:**

- a. Access to the laboratory is limited or restricted while experiments are in progress. The level of access is left to the discretion of the PI.
- b. Work surfaces are decontaminated after any spill of viable material. Household bleach(10%), isopropyl alcohol, ethyl alcohol, , or similar commercial products are effective decontamination agents. Appropriate PPE will be worn during decontamination.
- c. An autoclave is available for decontamination of laboratory equipment and waste materials.
- d. Contaminated liquid and solid wastes shall be disposed of according to the procedures described under Guidelines for Handling Biological Hazards.
- e. Pipetting by mouth is prohibited. Mechanical devices are used for all pipetting operations.
- f. Eating, drinking, smoking and applying cosmetics are not permitted in the laboratories work area. The storage and consumption of food and drink is limited to break rooms, offices and Canteen.
- g. Hands are washed after handling organisms or animals containing recombinant DNA molecules and before exiting the laboratory.
- h. Procedures are performed in a careful manner designed to minimize the creation of aerosols.
- i. Laboratory coats or gowns, gloves, particle masks, safety glasses,

goggles, or face shields and any other PPE appropriate for the risk level are provided. A hand-washing sink and eyewash station are provided in each laboratory.

- j. Laboratory facilities are designed and maintained in a manner conducive to easy cleaning. Spaces between the benches, cabinets, refrigerators, freezers and other equipment are accessible for cleaning. Bench tops are impervious to water and resistant to acids, alkalis, organic solvents and moderate heat. Sink faucets are equipped with vacuum breakers.
- k. Windows remain closed at all times, as required by the NWIHCS to maintain the integrity of the air handling system. This also limits the possibility of insects or other organisms gaining entry to the work area.
- l. Insect and rodent control programs are in effect. The NWIHCS has a program currently in effect and any additional precautions taken are in compliance with those guidelines.

## **2. Standard Practices for BSL2:**

All of the practices outlined for BSL1 apply for BSL2 with the following additional precautions:

- a. Experiments of lesser bio-hazard potential can be conducted concurrently within designated areas of the same laboratory.
- b. Access to the laboratory is limited by the PI, who determines which personnel may enter or work in the laboratory as circumstances dictate.
- c. Laboratory coats, gowns, smocks, or uniforms are worn by personnel in the laboratory. This protective clothing should be removed and left in the laboratory prior to exiting whenever possible.
- d. Animals not required for the work being performed are not permitted in the laboratory.
- e. Special precautions are taken to avoid skin contamination when working with organisms or animals containing recombinant DNA molecules. Gloves are worn when handling experimental animals and when the risk of skin contact is high.
- f. Only needle-locking syringes are used for parenteral injection and aspiration of fluids. Extreme care is taken to avoid self-inoculation and the generation of aerosols. Needles are not removed, reguarded, bent or sheared following use. The syringe and needle assembly is left intact and promptly placed in a puncture-resistant container in which it may be decontaminated or taken for proper disposal.
- g. Accidents or spills resulting in the overt exposure to organisms containing recombinant DNA molecules are reported immediately to Occupational Health, the PI or supervisor, and the SRS. Medical evaluation, treatment and surveillance are provided as appropriate and written records are maintained. When warranted by the risk potential, baseline serum samples are collected from laboratory personnel and stored. Additional serum specimens may be taken periodically as required, depending on the agents being handled.
- h. *Guidelines for Handling Biological Hazards* is prepared to advise

personnel of special hazards and to provide instructions for safe practices. Everyone working in the laboratory is required to read and follow the procedures outlined in this document.

- i. Biological safety cabinets (Class I or II), as well as appropriate PPE or physical containment devices are used whenever procedures with a high potential for creating aerosols are conducted (e.g. homogenization, centrifugation, sonication, harvesting infected tissues). Large volumes or high concentrations of recombinant DNA molecules may be centrifuged in an open laboratory if sealed rotors, safety cups, or sealed beads are used. These carriers are only opened in a biological safety cabinet.

#### **IV. PROJECTS REQUIRING PRIOR APPROVAL AT LEVELS ABOVE THE IBC AND SRS**

There are **six categories of recombinant DNA experiments**, each requiring different levels of approval. All research at the NWHCS requires approval of the SRS, R&D Committee and ACOS for Research. However, there are some categories of rDNA research that require approval at levels higher. All are presented here for general information. The appropriate levels are primarily determined by the Risk Group in which the proposed experiment is classified. Experiments in Categories 1-3 are not possible at the NWHCS because of limitations in its facilities. No studies of human gene transfer, plants, or that require BSL-3 or -4 facilities will be conducted at the NWHCS.

**Category 1:** Experiments defined by the NIH Director as "Major Actions," human gene transfer experiments, or experiments which deliberately transfer a drug resistant trait to microorganisms not known to acquire it naturally require prior approval by the SRS, review by the NIH Recombinant DNA Advisory Committee (RAC), and approval by the NIH Director. In the case of human gene transfer experiments, the proposal must be simultaneously submitted to the NIH and the Food and Drug Administration (FDA). The procedure to be followed for submissions is summarized in the NIH Guidelines, Section I-A-1-a.

**Category 2:** Experiments involving toxins with LD50 in vertebrates of less than 100 nanograms per kilogram body weight may not be initiated without prior approval of the SRS and the NIH Office of Recombinant DNA Activities [NIH/ Office Biosafety Activities (OBA)] (examples: botulinum, tetanus and diphtheria toxins and *Shigella dysenteriae* neurotoxin). Specific approval has been given for the cloning in *Escherichia coli* K-12 of genes coding for toxic molecules with LD50 in vertebrates of 100 nanograms to 100 micrograms per kilogram body weight.

**Category 3:** All human gene transfer experiments involving the deliberate introduction of rDNA, or DNA or RNA derived from rDNA, must be submitted for review by both NIH/OBA and RAC prior to initiation. This submission is for registration purposes to ensure compliance with NIH Guidelines. The format for submission is given in the NIH Guidelines, Appendix M-1. Simultaneous submission to the FDA of an Investigational New Drug (IND) application is required. The format for this application is available in 21 CFR, Chapter 1, Subchapter D, Part 312, Subpart B, Section 23. Approval must be obtained from all the IBCs of each institution involved in the administration of the rDNA material to human subjects. The SRS does not require approval from institutions doing only production or *ex vivo* transduction into target cells of the rDNA.

**Category 4:** The SRS must approve all RG2, RG3 and RG4 experiments prior to their initiation. This includes: 1) the use of restricted agents as host-vector systems; 2)

cloning of DNA from RG2, RG3 or RG4 agents into nonpathogenic prokaryotic or lower eukaryotic host-vector systems; 3) use of infectious DNA or ribonucleic acid (RNA) viruses; 4) use of defective DNA or RNA viruses with a helper virus in tissue culture systems; 5) whole animal experiments which alter the animals genome by stable introduction of rDNA into the germ line (transgenic animals); 6) experiments using transgenic animals requiring BSL-2 or greater containment regardless of the source of the animals; 7) experiments with viable rDNA-modified microorganisms tested on whole animals; 8) large scale (more than 10 liters) cultures; and 9) experiments involving influenza viruses.

**Category 5:** Experiments using rDNA molecules containing no more than two-thirds of the genome of a eukaryotic virus require approval of the SRS when first initiated, as specified for RG1 classified agents which may be used under BSL-1 containment guidelines. Similarly, the use of transgenic rodents that can be contained at BSL-1 requires approval of the SRS.

**Category 6:** Experiments using materials which do not present a significant risk to health or the environment may be exempt in accord with NIH Guidelines (Appendix C., Section III-F-6). Such experiments include: 1) using rDNA molecules that are not found in organisms or viruses; 2) DNA segments from a single nonchromosomal or viral source; 3) DNA entirely from a prokaryotic or eukaryotic host (including its indigenous plasmid or mitochondrial, but not viral, DNA) when propagated only in that host; and 4) exchange of DNA segments between species if that exchange is by known physiological processes.

## **V. NIH EXEMPTIONS.**

The NIH Guidelines contain lists of natural exchangers (NIH Guidelines, Appendix A) and certified host-vector systems (NIH Guidelines, Appendix E) which are considered exempt from regulation. Further exemptions for additional classes of experiments and specific conditions for exceptions are outlined in Appendix C of the NIH Guidelines.

- A.** Experiments using recombinant DNA molecules containing less than one-half of any eukaryotic viral genome (all viruses from a single family being considered identical) that are propagated and maintained in cells in tissue culture may be exempt.
- B.** *Escherichia coli* K-12 host-vector systems may be exempt provided that: 1) the host does not contain conjugation proficient plasmids or generalized transducing phages; and 2) lambda, lambdoid, Ff bacteriophages or non-conjugative plasmids are used as vectors.
- C.** *Saccharomyces cerevisiae* and *Saccharomyces uvarum* host-vector systems are exempt and may be performed under BSL1 physical containment conditions or higher if specified by the SRS.
- D.** An exemption exists for the use of any asporogenic *Bacillus subtilis* or asporogenic *Bacillus licheniformis* strain which reverts to a spore-former at a frequency less than  $10^{-7}$ .
- E.** A list of exempt gram-positive organisms which may be used to propagate and maintain recombinant DNA molecules derived entirely from extrachromosomal elements of these organisms is provided in Appendix C-V of the NIH Guidelines.



## **VI. RESPONSIBILITIES OF THE PRINCIPAL INVESTIGATOR (SECTION IV-B-7 NIH GUIDELINES)**

### **A. General Responsibilities**

1. No experiments with recombinant DNA molecules which require prior approval by the SRS will be initiated or modified until that research has been approved by the SRS, or the IBC if not of an exempt status, even though other NIH requirements have been met. Initiation of research also requires approval of the Research and Development Committee and the ACOS for Research.
2. The IBC of the SRS will be informed prior to initiation of recombinant DNA experiments as defined in Section IV-D.
3. Any research-related accidents or illnesses, violations of NIH Guidelines, or significant problems will be reported in writing to the Chair or Coordinator of the SRS within 5 business days and other appropriate authorities (as applicable).
4. New information obtained which has bearing on the NIH Guidelines will be reported to the SRS and NIH/OBA.
5. Adequate training in good microbiological techniques will be received.
6. The SRS-approved emergency plans for handling accidental spills and contamination of personnel will be followed.
7. All requirements for shipping recombinant DNA materials will be observed (see NIH Guidelines Appendix H for shipping regulations).

### **B. Responsibilities Prior to Initiating Research**

1. The protocols describing the potential bio-hazards and precautions to be employed will be available to all laboratory personnel.
2. Laboratory personnel will be trained in the practices and techniques required to ensure safety and in the procedures for dealing with laboratory accidents.
3. Laboratory staff will be informed of the reasons and provisions for any precautionary medical practices that may be advised or requested.

### **C. Responsibilities While Conducting the Research**

1. Supervision of the performance of laboratory personnel to ensure the employment of the required safety techniques and practices.
2. Any significant problems pertaining to the operation and implementation of containment procedures will be reported in writing to the Chair or Coordinator of the SRS within 5 business days and other appropriate authorities (as applicable).
3. Conditions or work errors that may result in the release of recombinant DNA materials will be corrected.
4. Integrity of the physical containment facilities (e.g. biological safety cabinets) and the biological containment (e.g. purity and genotypic and phenotypic characteristics) of recombinant DNA materials will be ensured.

#### **D. Submissions to the SRS**

1. An initial determination will be made of the required levels of physical and biological containment as outlined in the NIH Guidelines. The SRS, through consulting the IBC, will make a determination whether the study meets the definition of exempt under NIH Guidelines. All studies of rDNA, including those that meet the criteria of the NIH Guidelines as exempt, must be reviewed by the SRS/IBC.
2. Appropriate laboratory practices and techniques will be selected for use in the research.
3. Address any possible dual use aspects of your experimentation; i.e., that can be used for terroristic purposes (e.g., enhance virulence of a pathogen/nonpathogen, render a vaccine ineffective or a pathogen resistant to antibiotics or antiviral agents, enable weaponization of pathogens, etc.).
4. An initial research protocol and any subsequent changes will be submitted to the SRS for review and approval. This is accomplished through completion of the Recombinant DNA portion of the VA Research Protocol Survey and SRS-4.
5. Communication with the SRS will be maintained throughout the conduct of the research project and at the annual continuing review of the research project.

#### **E. Submissions to NIH/OBA**

1. Information for new host-vector systems will be submitted for certification.
2. Petitions for exemptions from the NIH Guidelines will be submitted with notification of the SRS.
3. Petitions to conduct experiments requiring NIH/OBA and SRS approval and "Major Actions": (as defined in the NIH Guidelines, Section III-A-1) will be submitted with the concurrence of the SRS.
4. Petitions for the determination of containment for experiments requiring a case-by-case review by NIH/OBA will be submitted.
5. Petitions for the determination of containment for experiments not covered by the NIH Guidelines will be submitted.
6. Initiation of a clinical investigation will meet the compliance standards outlined in Appendix M-I-C of the NIH Guidelines.
7. All data submitted in accordance with these requirements will meet the confidentiality criteria described in Appendix M-I-C-5 of the NIH Guidelines, as required by the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

### **VII. RESPONSIBILITIES OF THE INSTITUTIONAL BIOSAFETY COMMITTEE (IBC)**

- A.** The IBC will review all recombinant DNA research projects at the VAHCS, regardless of the funding source, for compliance with the NIH Guidelines. This review will include: 1) the independent assessment of the containment levels for the proposed research required by the NIH Guidelines; 2) evaluation of the available facilities; 3) assessment of the procedures, practices, training and

expertise of laboratory personnel involved in recombinant DNA research; and 4) notification of the PI of the results of the Recombinant DNA Task Force review and approval.

- B.** Ongoing recombinant DNA research projects will be reviewed at least annually to ensure continued compliance with the NIH Guidelines.
- C.** A copy of the NIH Guidelines will be provided for each laboratory proposing to or currently conducting recombinant DNA research.
- D.** Emergency plans covering accidental spills and personnel contamination resulting from recombinant DNA research will be adopted (see Section VIII-B).
- E.** Any significant problems with or violations of the NIH Guidelines and any significant research-related accidents or illnesses will be reported in writing to the NIH/OBA within 30 days.
- F.** Experiments not explicitly covered by the NIH Guidelines will not be approved until the NIH (with the advice of the RAC when required) has established containment requirements that are compatible with facilities of the VAHCS.

## **VIII. RESPONSIBILITIES OF LABORATORY PERSONNEL**

### **A. Laboratory Practices**

1. Appropriate standard practices for the designated BSL will be followed. Refer to Section III for specific information.
2. Specific precautions established by the PI for performing laboratory procedures will be observed.
3. All containment conditions will be maintained.
4. All VAHCS guidelines and policies will be followed regarding: a) emergency procedures; and b) use, handling, and disposal of radioactive isotopes, carcinogens, hazardous chemicals, bio-hazard materials, and animals.
5. Safety training requirements will be met by attending all mandatory training sessions.
6. Whenever needed, training and advice will be obtained from other personnel with specific expertise in the area of concern.
7. Personnel will use Safety Data Sheets (SDS) and additional hazardous chemical communications to obtain information about chemicals and reagents prior to their use in the laboratory.
8. Information regarding biological hazards (toxins, infectious agents, etc.) will be obtained from commercial sources, appropriate literature, personnel with recognized expertise, and sources outside the VAHCS (see Appendix II-B).
9. Personnel will apply their personal knowledge and experience to the evaluation of procedures for potential risk.

### **B. Decontamination Procedures for Accidental Spills or Contaminations:**

1. In case of an accident in the laboratory which could potentially contaminate personnel or compromise containment conditions, specific procedures will be followed: a) isolate the hazard by restricting access to the area; b) remove contaminated clothing, gloves, PPE, etc. and place into appropriate

containers for disposal or decontamination; c) decontaminate the personnel involved with an appropriate disinfectant, neutralizing agent, and soap and water; d) after donning the appropriate PPE, decontaminate or neutralize the affected area of the laboratory using effective agents (see Section III-B-1-b).

2. The accident will be reported to the PI or other immediate supervisor promptly.
3. If the contaminating agent possesses a potential health risk or if personal injury has occurred, the personnel involved will proceed to Occupational Health for evaluation (Mod A, Room 105, ext. 5823).