

The George Washington University

Interim Policy for Compliance Regarding
Select Agents

I. INTRODUCTION & BACKGROUND

The purpose of this policy is to establish guidelines and procedures at The George Washington University (GW), in accordance with federal laws and regulations with respect to possession, use and disposal of Select Agents administered by, conducted by, or under the direction of, any employee or agent of the GW in connection with his or her GW responsibilities. This GW policy also applies to the submission, approval and management of research involving federally regulated Select Agents.

Select Agents are those infectious agents, biologically-derived toxins, and those genetic elements from any Select Agent containing nucleic acid sequence(s) which, if inserted into an appropriate host system are reasonably believed capable of producing disease or toxicosis. A list of the Select Agents as of October 2002 is found in Appendix 1, and the reader should consult CDC and USDA websites for current listings.

- All materials that are known to or reasonably suspected of containing one of the Select Agents, including tissue samples, unless exempted as a human or veterinary clinical specimen, are subject to this regulation.
- This policy will cover all research involving the use, *ex vivo* and *in vivo*, possession, transfer and disposal of Select Agents at GW campuses and/or other GW facilities.
- All users of Select Agents at all GW campuses must comply with the defined procedures for use of Select Agents. Failure to comply will result in prohibition of further use and confiscation of said substances. Additionally, any violations of procedures for use of Select Agents will result in disciplinary action up to and including termination.

Federal law provides that in the case of violations of the law, individuals are subject to federal criminal penalties, to include prison and fines.

II. Designation of Responsible Offices & Persons

The Office of Health Research, Compliance, and Technology Transfer (HRCTT) has the primary responsibility for regulatory compliance and policies for research at all GW campuses. In addition, the Institutional Research Safety Committee (IRSC) and the Office of Laboratory Safety and Compliance (OLSC) manage day-to-day operations of compliance with the Select Agents Act in research contexts.

III. Policy

- No Select Agents shall be acquired, used or transferred by any GW employee or agent, except for valid research purposes, without the express written permission of the President of the University or his designee.
- Only those researchers who have received written approval from the HRCTT Office and OLSC can order, possess, manipulate or otherwise have contact, either direct or indirect, with any Select Agent, in any quantity.

1. Requesting Use of Select Agents

- Proposed research involving the possession, use and disposal of any materials on the federal list of Select Agents must be submitted to the IRSC and the GW Responsible Facility Official (RFO) for review and approval. Approval for the use of the Select Agents also requires the review and approval of the CDC and/or the USDA.

- Principal Investigators involved in the use of Select Agents must submit relevant information on the proposed Select Agents experiments through the department chair, to the IRSC. The information must be submitted on the Protocol Risk Assessment and Hazard Management for Basic Science and Animal Research Protocols form, and must include the department chair's signature.
- The IRSC will make a recommendation to approve, modify, or disapprove biomedical research involving Select Agents, and forward that information to the HRCTT Office for final action.
- The HRCTT Office will make the final approval, sign and submit the application packet to the CDC or USDA, as appropriate, on behalf of the PI.
- Only after explicit written approval, may Select Agents be ordered. They must be ordered through the Enterprise Accounting System. There are no exceptions.

Once such research is approved by the HRCTT Office and the CDC or the USDA, all laboratories and related Select Agents documents must be ready and available for federal inspection (by the CDC or designee) at all times. All laboratories that have received Select Agent approval will be inspected on both an announced and unannounced basis by OLSC.

2. Required Documentation

- Submission of protocols for IRSC review will be on the CDC Application for Laboratory Registration and the GW Protocol Risk Assessment and Hazard Management for Basic Science and Animal Research Protocols form. (See Appendix 3 for appropriate form)
- Submissions must identify anyone who might potentially have access to the laboratory or area where the Select Agent work is to be completed, and must include the CV of the Principal Investigator, the CV of any other individuals to be authorized access to Select Agents; the CV of anyone who might otherwise have routine access to the area where the Select Agents are stored. All CV's should be no more than two pages; evidence of the adequate training of all members of the research team; be in biographical sketch format; and include the personnel certification form located in Appendix 2.

3. Review and Approval Process

- The IRSC requires that four (4) complete copies of the protocol, the CDC form and the appropriate GW forms be submitted for review.
- Inspection of and acceptance of the physical facility, biosafety containment, plans and procedures, training of personnel and other safety features in conjunction with the federal regulations must be performed by OLSC and documented to the IRSC.
- Upon review by the IRSC and the HRCTT Office, preliminary approval letters will be issued. Application with the CDC will be through the HRCTT Office.
- Upon notification of approval by the CDC, full approval for research will be granted by HRCTT for a period not to exceed one (1) year.

- Currently only the GW downtown Foggy Bottom campus is registered as a permissible facility in which to conduct research using Select Agents. If GW faculty members wish to conduct such research at any other location (such as the Loudoun or Mount Vernon campuses, or at the Hospital or Medical Faculty Associates facilities, or any other affiliate of the University), those facilities must obtain separate CDC or USDA registration and approval. Inspection of and acceptance of the physical facility, biosafety containment, training of personnel and other features of such facility must be documented and presented to the HRCTT Office in connection with GW's proposed approval of the research proposal. Transfer of Select Agent materials to or from any such affiliated facilities or institutions is prohibited, unless carried out with all appropriate approvals and documentation in the same manner as a transfer to or from an unaffiliated third-party facility. Faculty members or other researchers employed by the MFA or other affiliates are subject to this policy with respect to any research using Select Agents (which is currently expected to be carried out in Ross Hall), but GW is not responsible for any clinical or other uses that such persons might make of Select Agents obtained and used for their own employers or at other facilities.

No shipment or transfer of Select Agents materials will be permitted, per federal regulations, unless documentation has been submitted *in advance* to the HRCTT Office, and explicit *prior* written approval is granted.

4. Conducting Select Agent Research

- Additional specific requirements for handling toxins subject to this law must be met and are found in the OSHA document, 29 CFR § 1910.1450, Occupational Exposure to Hazardous Chemicals in Laboratories
- The Principal Investigator must prepare a Chemical Hygiene Plan (CHP). This document is subject to inspection and review by the HRCTT Office (or designee) and/or the CDC. Requirements of a CHP can be found on the OLSC website. A reference list is located in Appendix 4.
- Laboratory and experiment-specific Standard Operating Procedures (SOPs) will be documented in writing for the laboratory, approved by OLSC, and made immediately available to all lab personnel, the HRCTT Office (or designee), and CDC.
- The PI must provide and document in writing job and task specific on-the-job training for all lab personnel handling these materials.
- The PI must provide appropriate Personal Protective Equipment (PPE), approved for use by OLSC, and provide and document in writing on-the-job training for the use of PPE.
- The PI must provide and document in writing all decontamination and disposal SOPs for work with the specific Select Agents in their laboratories. All SOPs must be approved by OLSC. Decontamination and disposal procedures will be in compliance with all federal, state and local regulations concerning the infectious and/or hazardous wastes generated.
- Laboratories where Select Agent research occurs are subject to both announced and unannounced inspections by the HRCTT Office (or designee).

- The PI must resubmit all required documentation on an annual basis for approval for continued research.
- If the research to be conducted involving the use of Select Agents is externally funded, once approval is received from the CDC or the USDA, the PI, ORS and other appropriate university offices will be notified.

5. Facilities and Security

- There are specific facility, containment and security issues for Select Agents materials. Storage locations must meet or exceed current CDC recommendations and all applicable sections of the CDC publication “Biosafety in Microbiological and Biomedical Laboratories.”
- Facilities are subject to inspection by federal agencies (the CDC or designees).
- Follow-up inspections of the laboratory facility by the HRCTT Office (or designees, e.g. OLSC or Biosafety Officer) will be made, to ensure the facility continues to meet approved standards and record-keeping requirements.
- The University is required by federal law to grant access to Select Agents only to those persons that the University determines have a legitimate need to handle or use such agents or toxins. Thus, the University expects that as part of the routine laboratory security procedures that will be in place for approval of any research using Select Agents, other persons such as housekeeping staff and employees in nearby offices, will not have access to the Selects Agents. Nevertheless, all faculty, staff, students, and others who will have access to the Select Agents while they are in use or not secured must be registered and comply with the applicable provisions of federal law and regulations.
- Withdrawal of Select Agents materials from stock materials for use in procedures will be documented on the Select Agent Use and Storage Log in accordance with this policy (refer to appendix 5 for forms).
- Authorization for possession, use and manipulation of Select Agents may be denied or withdrawn by the RFO, and referred to the appropriate federal authorities for action may be made if:
 - Evidence exists that the PI or research personnel is not or is no longer capable of handling covered agents at the applicable biosafety level;
 - Evidence that the PI or research personnel has handled covered agents in a manner in contravention of the applicable biosafety level requirements;
 - Evidence that the PI or research personnel has failed to comply with any provisions of the law or has acted in a manner in contravention of the law;
 - Evidence that the PI or research personnel has failed to comply with any aspect of this policy; or
 - Evidence that the PI or research personnel has or intends to use covered agents in a manner harmful to the health of humans.

6. Select Agent Disposal or Transfer

- Upon termination of the need to use the specific Select Agent, that fact will be reported immediately to the HRCTT Office, by the PI, through the relevant Dept. Chair.
- All cultures and stocks of that Select Agent will be:
 - Securely stored in accordance with prudent laboratory practices;
 - Transferred to another registered facility in accordance with CDC rules and this policy, or
 - Destroyed on-site by autoclaving, incineration, or another approved sterilization or neutralization process, witnessed by the HRCTT Office (or designee).
- When a Select Agent, previously transferred to a GW facility in accordance with the law, is consumed or destroyed, the HRCTT Office must formally notify the registering entity. Formal notification must be noted on CDC Form EA-101 and a copy kept on record by the HRCTT Office for a period of five (5) years.
- **Inter and Intra-facility transfers must be requested in writing to the HRCTT Office. Before any materials are transferred or received from another institution, explicit written approval must be obtained from the HRCTT Office. A Material Transfer Agreement must be executed between the collaborating Institution.**

7. Records Management

- All records for Select Agents research must be kept a minimum of 5 years from the date of federal approval, per federal regulations.
- Copies of correspondence from any regulatory agency associated with the use of Select Agents on a study, resulting from inspections, audits or other agency (CDC, NIN, etc.) including communications, records and reports, must be provided to the HRCTT Office upon receipt.
- Closing of Protocols
 - Investigators will provide a final report the HRCTT Office at the closure of the study. Transfer of ownership of the materials and/or final destruction must be documented, and take place in accordance with Section III, Item 6 of this policy.
- Research Documentation
 - All research involving Select Agents must be performed in conformance with all applicable local, state and federal laws, regulations and guidelines governing the performance of Select Agents research.
 - In addition to other record retention requirements, research using Select Agents may produce records that are maintained by the Principal Investigator for future reference and review.

At a minimum, the investigator's file must include the original signed authorization forms and a list of participating laboratory personnel, along with documentation of Standard Operating Procedures.

Research records will be set up in the IRSC records management system.

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Appendix 1

Select Agents Lists

[Current as of October 21, 2002; see CDC and USDA websites for current lists]

Toxins

1. Abrin
2. Aflatoxins
3. Botulinum toxins
4. Clostridium perfringens epsilon toxin
5. Conotoxins
6. Diacetoxyscirpenol
7. Ricin
8. Saxitoxin
9. Shigatoxin
10. Staphylococcal enterotoxins
11. Tetrodotoxin
12. T-2 toxin

Exemptions: Toxins for medical use, inactivated for use as vaccines, or toxin preparations for biomedical research use at an LD50 for vertebrates of more than 100 nanograms per kilogram body weight are exempt. National standard toxins required for biologic potency testing as described in 9 CFR Part 113 are exempt.

Recombinant organisms/molecules

1. Genetically modified microorganisms or genetic elements from organisms from this list shown to produce or encode for a factor associated with a disease.
2. Genetically modified microorganisms or genetic elements that contain nucleic acid sequences coding for any of the toxins listed in this list, or their toxic subunits.

Viruses

1. Crimean-Congo haemorrhagic fever virus
2. Eastern Equine Encephalitis virus
3. Ebola viruses
4. Equine Morbillivirus
5. Lassa fever virus
6. Marburg virus
7. Rift Valley fever virus
8. South American Haemorrhagic fever viruses (Junin, Machupo, Sabia, Flexal, Guanarito)
9. Tick-borne encephalitis complex viruses
10. Variola major virus (Smallpox virus)
11. Venezuelan Equine Encephalitis virus
12. Viruses causing hantavirus pulmonary syndrome
13. Yellow fever virus

Exemptions: Vaccine strains of viral agents (Junin Virus strain candid #1, Rift Valley fever virus strain MP-12, Venezuelan Equine encephalitis virus strain TC-83, Yellow fever virus strain 17-D) are exempt.

Bacteria

1. Bacillus anthracis
2. Brucella abortus, B. melitensis, B. suis
3. Burkholderia (Pseudomonas) mallei
4. Burkholderia (Pseudomonas) pseudomallei
5. Clostridium botulinum
6. Francisella tularensis
7. Yersinia pestis

Exemptions: vaccine strains as described in Title 9 CFR, Part 78.1 are exempt.

Rickettsiae

1. Coxiella burnetii
2. Rickettsia prowazekii
3. Rickettsia rickettsii

Fungi

1. Coccidioides immitis

USDA High Consequence Pathogens

1. African Horse Sickness Virus
2. African Swine Fever
3. Akabane Virus
4. Avian Influenza Virus (Highly Pathogenic)
5. Blue Tongue Virus (Exotic)
6. Bovine Spongiform Encephalopathy Agent
7. Camel Pox Virus
8. Classical Swine Fever
9. Cowdria ruminantium (Heartwater)
10. Foot and Mouth Disease Virus
11. Goat Pox Virus
12. Japanese Encephalitis Virus
13. Lumpy Skin Disease Virus
14. Malignant Catarrhal Fever
15. Menangle Virus
16. Mycoplasma capricolum/M.F 38/M. mycoides capri (Contagious Caprine)
17. Pleuropneumonia Agent)
18. Mycoplasma mycoides mycoides (Contagious Bovine Pleuropneumonia Agent)
19. Newcastle Disease Virus (Exotic)
20. Peste Des Petits Ruminants
21. Rinderpest Virus
22. Sheep Pox
23. Swine Vesicular Disease Virus
24. Vesicular Stomatitis Virus

Other restrictions

The deliberate transfer of a drug resistance trait to microorganisms listed in this Appendix that are not known to acquire the trait naturally is prohibited by NIH "Guidelines for Research Involving Recombinant DNA Molecules," if such acquisition could compromise the use of the drug to control these disease agents in humans or veterinary medicine.

Additional Exemptions

1. Products subject to regulation under the Federal Insecticide Fungicide and Rodenticide Act (7 U.S.C. § 136 et seq.) and the Toxic Substances Control Act (15 U.S.C. § 2601 et seq.) are exempt.

2. Additional exemptions for otherwise covered strains will be considered when CDC reviews and updates the list of Select Agents in this law. Individuals seeking an exemption should submit a request to CDC that specifies the agent or strain to be exempted and explains why such an exemption should be granted. Future exemptions will be published in the Federal Register for review and comment prior to inclusion in the law.

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Appendix 2**

**The George Washington University
Statement of Personnel Qualifications**

Federal law requires that personnel handling and/or conducting procedures involving the use of Select Agents and disposing of Select Agent waste, must be appropriately qualified and trained, and must register and meet applicable provisions of federal laws and regulations.

Please complete one form for **EACH INDIVIDUAL** who will potentially have any direct contact Select Agents in your laboratory.

NAME Last:	Social Security No.	Work Phone	SA USE LOCATION (Bldg, rooms)
First:	Date of Birth:	Home Phone	
Middle:			
PRINCIPAL INVESTIGATOR	Room	PHONE	DEPARTMENT

Select Agent(s) to be used in your work e.g. the specific toxin or toxin subunit, infectious agent or rDNA materials

FORMAL EDUCATION AND / TRAINING:

Degree(s) Earned/Date(s): _____

Institution(s): _____

Other Related Training: _____

I have received the attached Notice to Prospective Select Agent Researchers and believe I qualify for approval as set forth in that notice and applicable law. I certify that I am qualified to perform the procedures listed, understand the risks associated with working with Select Agents, and will abide by all applicable Federal laws and Institutional Policy. I understand that violations of these policies will result in disciplinary action up to and including termination, and referral to appropriate Federal Authorities for further action.

Employee Signature

Date

I have received the attached Notice to Prospective Select Agent Researchers and believe I qualify for approval as set forth in that notice and applicable law. I certify that the above individual is competent with the Institutional and Federal procedures, policies, laws, and regulations regarding research using Select Agents. I understand that violations of these policies by myself or a member of my staff will result in disciplinary action up to and including termination, and referral to appropriate Federal Authorities for further action.

Principal Investigator's Signature

Date

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Notice to Prospective Researchers Using Select Agents

In accordance with the GWU Interim Policy for Compliance Regarding Select Agents, (see <http://www.gwumc.edu/research/labsafety.htm>), you should be aware of the following information in connection with your request to have access to Select Agents at GW:

- Federal law defines a “Restricted Person” as an individual who—
 - is under indictment for, or has been convicted of, a crime punishable by imprisonment for a term exceeding 1 year (i.e., felonies);
 - Is an unlawful user of any controlled substance (i.e., an illegal drug or a legal drug used illegally);
 - Is an alien illegally or unlawfully in the United States;
 - has been adjudicated as a mental defective or has been committed to any mental institution;
 - is an alien (other than an alien lawfully admitted for permanent residence) who is a national of certain countries designated by the Secretary of State as providing support for acts of international terrorism [currently this includes Cuba, Iran, Iraq, Libya, North Korea, Sudan and Syria]; or
 - has been discharged from the Armed Services of the United States under dishonorable conditions.

- Under the USA Patriot Act, Restricted Persons are not permitted to ship, transport, receive, or possess listed Select Agents. **Individuals who violate these restrictions are personally subject to serious criminal penalties.** See 18 U.S.C. § 175b. GW recommends that such Restricted Persons NOT have access to, work with, handle, complete paperwork, or otherwise perform any functions relating to such Select Agents.
- Pursuant to GW’s Interim Policy, all persons desiring or proposed to have access to Select Agents must submit applications for approval of such access both to GW and to the federal government.
- GW will first determine and tentatively approve access only for those persons whom GW determines have a legitimate need to handle or use such agents or toxins.
- As required by law, GW will also submit the names of such applicants to the Secretary of HHS and the U.S. Attorney General.
- The U.S. Attorney General will use criminal, immigration, national security and other databases that are available to the federal government to determine if the applicant is a Restricted Person, or if the applicant is reasonably suspected by any federal law enforcement or intelligence agency of:
 - committing a Federal crime of terrorism;
 - knowing involvement with an organization that engages in domestic or international terrorism or with any other organization that engages in international crimes of violence; or
 - being an agent of a foreign power as defined in 50 U.S.C. §§ 1801.

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Appendix 2**

- The Attorney General shall determine whether the applicant falls in any of the above categories and whether access should be granted or denied, and shall notify the Secretary of HHS, who will notify GW if the application is approved or denied. There are some statutory procedures for review of such determinations.
- No Select Agents may be ordered or obtained, or research begun, until GW receives notice of approval of access from the federal government, transmits that approval to the applicant, and gives GW's own confirmed approval for the research and access.
- Regulations in all of these areas are not final yet, so additional procedures and clarifications may be forthcoming.

I certify that I have read and understood the above provisions; I believe I qualify as a person who may have access to Select Agents; and I request that GW process my application for such access and research.

_____ Date: _____

For additional information, see:

OLSC – www.gwumc.edu/research/labsafety.htm

CDC – www.cdc.gov

HRCTT – www.gwumc.edu/research/

CHP - <http://www.gwumc.edu/research/labsafety/HSMComplete.061.pdf>

Guidelines for Research Involving r DNA: www4.od.nih.gov/oba/rac/guidelines.html

Biological MSDS: <http://www.hc-sc.gc.ca/pphb-dgspsp/msds-ftss/index.html>

Chemical MSDS: <http://siri.uvm.edu/msds/>

Biosafety in Microbiological and Biomedical Laboratories, CDC/NIH, 4th edition,

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Appendix 3**

**Protocol Risk Assessment and Hazard Management
for Basic Science and Animal Research Protocols**

The basic premise of the GW biosafety policy is that the Principal Investigator (PI) is responsible for the risk assessment and hazard management of biological (to include rDNA variants), chemical and radioactive agents used in research. Risk assessment is the evaluation of potential adverse health events and environmental contamination from a hazardous agent. Hazard management is the specification of policies and procedures that control health and environmental hazards. This form does not address the use of radioactive materials.

The submitted research protocol must explicitly demonstrate that the PI has completed a health, safety, and environmental risk assessment of the research agent(s). Each compliance review committee---Institutional Research Safety Committee (IRSC), Institutional Animal Care and Use Committee (IACUC), and Institutional Recombinant DNA Advisory Committee (IRAC)---requires the PI to complete the following:

Risk Assessment

1.0 I have reviewed the Material Safety Data Sheet(s), other references, and the literature on research with this agent(s). YES / NO

2.0 Agent _____ Agent _____
 ___biological___chemical___rDNA ___biological___chemical___rDNA
Biosafety Level: ___1___2___3 Biosafety Level: ___1___2___3

Agent _____ Agent _____
 ___biological___chemical___rDNA ___biological___chemical___rDNA
Biosafety Level: ___1___2___3 Biosafety Level: ___1___2___3

3.0 **Biological** agents are characterized by the following risk assessment factors:

- 3.1 Pathogenic to ___Humans___Animals___Plants___Environment
- 3.2 Route of transmission ___Inhalation___Mucocutaneous___Ingestion.
- 3.3 Stability (resistance to inactivation) ___High___Low.
- 3.4 Concentration (number of organisms per unit volume) ___High___Low.
- 3.5 Available animal data ___Yes___No.
- 3.6 Available prophylaxis or therapeutic intervention ___Yes___No.
- 3.7 Medical surveillance recommended ___Yes___No.
- 3.8 Staff trained and experienced with agent ___Yes___No.

4.0 **Chemical** agents are characterized by the following risk assessment factors:

- 4.1 ___Flammable___Reactive___Carcinogenic___Toxic___Corrosive___Oxidizer
- 4.2 Health Hazard Potential (based on NFPA 704) ___4___3___2___1___0
- 4.3 Flammability Hazard Potential (based on NFPA 704) ___4___3___2___1___0
- 4.4 Reactivity Hazard Potential (based on NFPA 704) ___4___3___2___1___0
- 4.5 Special Hazards (based on NFPA 704) ___OX___COR___~~W~~___ACID___☣
- 4.6 Quantity to be used ___Milliliters___Liters___Milligrams___Micrograms
- 4.7 P.P.E. Required ___Yes___No
- 4.8 MSDS available ___Yes___No

Responses to the risk assessment factors must be detailed in the protocol.

- 5.0 **DNA** agents are characterized by the following risk assessment factors:
- 5.1 Does the inserted gene encode a ___known toxin ___Yes ___No
 - 5.2 Is the pathogenicity attenuated ___Yes ___No
 - 5.3 Modes of transmission_____.
 - 5.4 Will it generate replication competent viruses ___Yes ___No.
 - 5.5 Does the gene encode a ___oncogene, ___alter the cell cycle? ___Yes ___No
 - 5.6 Does the viral DNA integrate into the host genome ___Yes ___No?
- The protocol must describe the rDNA constructs and method of transfer or transfection.
The construct description must include:

Gene Sources (genus, strain, species)	Gene Name	Nature of Insert/ Protein (toxin, marker, viral sequence, oncogene, etc)	Use of Construct (cloning for sequencing, expression in microbe, tissue, organ or culture)

Vector Type (plasmid, viral, cosmid, phage)	Vector Source (genus, species; if plasmid or viral)	Technical Name of Vector	Risk Attenuation (replication defective, helper virus, disarmed, K-12 derivative)

- Agent _____ requires Biosafety Level ___2 or ___3.
- Agent _____ requires Biosafety Level ___2 or ___3.
- Agent _____ requires Biosafety Level ___2 or ___3.
- Agent _____ requires Biosafety Level ___2 or ___3.

Responses to the risk assessment factors must be detailed in the protocol.

The reference for the biological and rDNA risk assessment and agent summary statements is *Biosafety in Microbiological and Biomedical Laboratories*, CDC/NIH, 4th edition, available in pdf format through www.gwumc.edu/research/labsafety.htm

The NIH, *Guidelines for Research Involving Recombinant DNA Molecules*, available at www4.od.nih.gov/oba/rac/guidelines.html

Chemical Material Safety Data Sheets (MSDS) are available from OLSC or at <http://siri.uvm.edu/msds/>

Biological Material Safety Data Sheets are available at

Hazard Management

1. Research staff, to include any newly hired staff, are experienced and trained for the procedures in this protocol ___Yes ___No.
2. Research staff will be actively supervised in the conduct of this research ___Yes ___No.
3. Research staff have reviewed the risk assessment for the agent(s) used in this study and have been given the opportunity to ask questions and discuss procedures ___Yes ___No.
4. Research staff were informed that certain medical conditions may increase their risk for health problems. These conditions include, but are not limited to: pregnancy, immunosuppression, animal related allergies, and chronic skin conditions. ___Yes ___No.
5. Research staff are current in their compliance training:
Chemical Hygiene Plan ___Yes ___No OSHA 1910.1450
Bloodborne Pathogens ___Yes ___No OSHA 1910.1030
Hazard Communication ___Yes ___No OSHA 1910.1200
Fire Safety ___Yes ___No OSHA 1910.157
6. The protocol contains instructions for what to do in the event of a splash, spill or release of the agent(s) ___Yes ___No.
7. The protocol contains instructions for what to do in the event of a suspected or known exposure (dermal, aerosol, ingestion, and needlesticks) ___Yes ___No.
8. Medical surveillance---the active medical examination, testing, and monitoring of researchers----is recommended for this study ___Yes ___No.
9. Does the manipulation of the research agent(s) produce aerosols ___Yes ___No.
10. The active manipulation of the research agent(s) will be conducted in a:
Biosafety cabinet ___ Chemical Fume Hood ___ Benchtop___
Centrifuge ___ Other (describe)_____
11. The protocol requires the use of personal protective equipment ___Yes ___No.
If Yes this would include: Gloves___ Lab Coat___ Gown___
Safety glasses ___ Face Shield ___ Respirator___ Shoe Covers___.
12. The protocol specifies routine decontamination of work areas and equipment ___Yes ___No.
13. The protocol specifies procedures for the disposal of research agent(s) ___Yes ___No.
14. Does this research require the shipping of hazardous materials (to include DOT, IATA, CDC, APHIS regulations) ___Yes ___No
If Yes then staff are required to complete DOT / IATA training.

Signature _____ Date: _____
Principal Investigator

Signature _____ Date: _____
Chair of Department

**Interim Policy for Compliance Regarding Select Agents
Appendix 4**

Select Agent Policy References and Acronym List

Acronyms

GW – The George Washington University, including the Medical Center, Downtown, Mount Vernon, and Loudon County Campuses.

SA – Select Agent, as defined by CDC (refer to Appendix 1 for complete list)

HRCTT – The Office of Health Research Compliance and Technology Transfer

OLSC – The Office of Laboratory Safety and Compliance

IRSC – Institutional Research Safety Committee

RFO – Responsible Facility Official

CDC – Centers for Disease Control and Prevention

OSHA – Occupational Health and Safety Administration

CHP – Chemical Hygiene Plan

CV – Curriculum Vitae

References

OLSC – www.gwumc.edu/research/labsafety.htm

CDC – www.cdc.gov

HRCTT – www.gwumc.edu/research/

CHP - <http://www.gwumc.edu/research/labsafety/HSMComplete.061.pdf>

APHIS – <http://www.aphis.usda.gov>

Guidelines for Research Involving r DNA - www4.od.nih.gov/oba/rac/guidelines.html

Biological MSDS - <http://www.hc-sc.gc.ca/pphb-dgsp/psp/msds-ftss/index.html>

Chemical MSDS - <http://siri.uvm.edu/msds/>

Biosafety in Microbiological and Biomedical Laboratories, CDC/NIH, 4th edition.

