



**THE GEORGE
WASHINGTON
UNIVERSITY**
WASHINGTON, DC

Responsible University Official:
Associate Vice President for Research
Responsible Office: Office of the Vice
President for Research
Last Revised Date: April 8, 2009

COMPLIANCE REGARDING SELECT AGENTS AND PATHOGENS

Policy Statement

Any activity involving Select Agents or Pathogens requires prior review and approval by the Institutional Biosafety Committee (IBC). Activity involving Select Agents (other than exempt quantities of listed Toxins) also requires express written permission from the Associate Vice President for Research. All IBC-approved activities involving Select Agents or Pathogens must be conducted in accordance with this policy. Failure to comply with this policy may result in disciplinary action up to and including termination.

Reason for Policy

Pathogens pose a health threat to workers and the community and must be handled in accordance with sound biosafety practices. Some Pathogens and Toxins called Select Agents are deemed by the federal government to pose an extremely high risk to human, animal or plant health and could be utilized for terrorist activity. Accordingly, federal laws place restrictions on persons who possess, order, receive, have access to, or dispose of Select Agents, and impose severe criminal penalties for possession that cannot be justified for specified peaceful purposes. This policy sets forth the approval and usage guidelines for activities involving Pathogens and Select Agents.

Who is Governed by this Policy

Faculty, staff and students

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Policy

I. Prior Approval

Anyone proposing to engage in activity involving an Agent or Toxin must first check the [Select Agent/ Toxin List](#) and the Centers for Disease Control (CDC) / National Institutes of Health (NIH) publication [Biosafety in Microbiological and Biomedical Laboratories](#) to determine if the Agent or Toxin is a Select Agent or Pathogen.

Prior to obtaining Pathogens or Select Agents, storage and use must be reviewed and approved by the Institutional Biosafety Committee (IBC) and Office of the Vice President for Research (OVPR). To obtain a review, complete and submit to the Biosafety Officer within the Office of Laboratory Safety (OLS) the IBC registration form along with an abstract or summary of the proposed research and a written protocol detailing the specific steps for material handling in the lab or animal facility. The protocol must address all hazards posed by the Select Agents or Pathogens to be used.

If the proposed work will include Select Agents there are additional requirements that will need to be met before approval will be granted. Requirements for approval include: registration, background checks, and written protocols that address biosafety and containment, security and incident response. Because of the many governmental requirements involved, the review process must be instituted well in advance of the proposed activity. Contact the Biosafety Officer within OLS at (202) 994-2630 to initiate the review process. Proposed use of materials

deemed to be exempt under the regulations due to low quantities still must be reviewed and approved by the IBC prior to engaging in the activity to confirm safety measures are in place and that the use is truly exempt. Note also that any Select Agent discovered in any patient or other specimen must be reported to OLS immediately (call the alternate number on the recording if no one answers).

As Select Agents pose a risk under Occupational Health and Safety Administration (OSHA) regulations, [Risk Management](#) must be made aware of the use and storage of Select Agents on campus. Once the IBC and the Associate Vice President for Research have approved the protocol involving use of Select Agents, OLS will notify Health & Safety of the intended use.

II. Usage

Those working with Pathogens or Select Agents first must complete biosafety training, and must read and comply with the university's [Biosafety Manual](#). Workers also must comply with all written protocols required by the IBC, all government regulations, and must cooperate in periodic reviews by the IBC. The IBC can at any time make changes to the requirements for the material.

If the activity also will involve recombinant DNA, review and approval is required in accordance with the [Policy Regarding Use of Recombinant DNA \(rDNA\)](#).

III. Storage, Disposal and Transfer

Storage and disposal of Pathogens must comply with the [Biosafety Manual](#) and the conditions of the IBC approval. All storage, disposal or transfer of select agents must comply with federal law and the conditions of its registration. In the event of transfer of Pathogens or Select Agents off campus, contact the Biosafety Officer for requirements on transfer and shipping. If the transfer will be to another country or to a foreign national, review the university's [Export Control Policy](#) and contact OVRP before transfer.

Further information and guidelines regarding Select Agents and Pathogens, and regarding IBC guidance and forms, is available on the [OLS website](#).

Definitions

Agents Substance, whether biological or chemical, capable of producing an effect or reaction in living matter. An agent that is "infectious" is one that has the potential to produce disease.

Pathogens Those infectious Agents identified by the CDC or NIH as having a biosafety level (BSL) of 2 or higher due to their ability to cause disease in healthy human adults.

Select Agents Pathogens (including genetically altered forms) or Toxins deemed by the CDC or U.S. Department of Agriculture to pose a high risk to human, animal or plant health and could be utilized for terrorist activity. Also included are nucleic acids from these agents that could produce an infectious form or code for a toxin. The lists are incorporated in 42 CFR §73, 7 CFR §331 and 9 CFR §121 but a complete list can be found at [here](#).

Toxins Poisonous compounds produced by certain microorganisms, plants or animals that produce disease.

Related Information

[Biosafety Manual](#)

[Chemical Hygiene Policy](#)

[Export Control Policy](#)

[Hazardous Waste Management Policy](#)

Health and Safety Manual

[Personal Protective Equipment Policy](#)

[Policy Regarding Use of Recombinant DNA \(rDNA\)](#)

Office of Laboratory Safety

Office of Risk Management: Lab Safety & Research - Select Agents

CDC/NIH [Biosafety in Microbiological and Biomedical Laboratories](#)

OSHA: Occupational Exposure to Hazardous Chemicals in Laboratories, 29 CFR §1910.1450

Select Agent Regulations (Centers for Disease Control), 42 CFR Parts 72 and 73

Select Agent Regulations (Department of Agriculture), 7 CFR Part 331, 9 CFR Part 121

Select Agent/ Toxin List

USA PATRIOT Act of 2001, P.L. 107-56

www.selectagents.gov

Contacts

Contact	Telephone	Email
OLS	(202) 994-8258	marielj@gwu.edu

OVPR (Biosafety)	(202) 994-6255	askovpr@gwu.edu
OVPR (Export Controls)	(202) 994-8267	rdonnall@gwu.edu
Office of Laboratory Safety	(202) 994-8267	labsafety@gwu.edu

Document History

- **Last Reviewed Date:** April 27, 2017
- **Last Revised Date:** April 8, 2009
- **Policy Origination Date:** December 13, 2002

Who Approved This Policy

Leo M. Chalupa, Vice President for Research
Louis H. Katz, Executive Vice President and Treasurer
Beth Nolan, Senior Vice President and General Counsel

This policy, as well as all [university policies](#), are located on the [Office of Compliance and Privacy's](#) home page.