

## Mount Holyoke College

### VI(c). SELECT AGENTS

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The Public Health Security and Bioterrorism Preparedness Act of 2002 and the USA Patriot Act of 2001 require that academic and research institutions collect information regarding "select agents" and register and obtain approval for possession with the federal government. The Department of Health and Human Services (DHHS) and the U.S. Department of Agriculture (USDA) have issued separate but complementary regulations. In order for the College to comply with the DHHS Select Agent Regulations (42 CFR 73) and the USDA Agricultural Bioterrorism Protection Act of 2002 regulations (7CFR 331 and 9CFR 121), you must notify and obtain approval from the Office of Environmental Health and Safety (EH&S) prior to possession of any agent on the list of Select Biological Agents and Toxins, High Consequence Pathogens and Toxins, or Plant Pathogens.

If you are proposing to possess an agent on the list of Select Biological Agents and Toxins, High Consequence Pathogens and Toxins, or Plant Pathogens, the initial step is to file a Select Agent Registration Form with EH&S. Registration with the CDC is required, so you should anticipate a significant delay in obtaining approval due both to security requirements and procedures that will need to be established at the College and to extensive review of the application by the CDC. There may be requests that the College cannot accommodate because of facility restrictions and security requirements. All registration requests trigger a Center for Disease Control (CDC) security risk assessment. The CDC Select Agent Program web site has a set of FAQs where you can learn more.

#### LINKS

List of Select Biological Agents and Toxins, High Consequence Pathogens and Toxins, and Plant Pathogens at:

[http://www.selectagents.gov/resources/List%20of%20Select%20Agents%20and%20Toxins\\_111708.pdf](http://www.selectagents.gov/resources/List%20of%20Select%20Agents%20and%20Toxins_111708.pdf)

CDC Select Agent Program FAQs at: <http://www.cdc.gov/od/sap/faq.htm>

Public Health Security and Bioterrorism Preparedness Act of 2002 at:

[http://www.aphis.usda.gov/programs/ag\\_selectagent/PL107-188.pdf](http://www.aphis.usda.gov/programs/ag_selectagent/PL107-188.pdf)

USA Patriot Act at:

[http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=107\\_cong\\_public\\_laws&docid=f:publ056.107.pdf](http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=107_cong_public_laws&docid=f:publ056.107.pdf)

DHHS Select Agent Regulation (42 CFR 73) at:

<http://www.selectagents.gov/resources/42%20CFR%2073.pdf>

Agricultural Bioterrorism Protection Act of 2002 (7CFR 331 and 9CFR 121) at:

[http://www.aphis.usda.gov/programs/ag\\_selectagent/downloads/FinalRule3-18-05.pdf](http://www.aphis.usda.gov/programs/ag_selectagent/downloads/FinalRule3-18-05.pdf)

**Mount Holyoke College  
Office of Environmental Health & Safety**

**SELECT AGENT Registration Form**

In order to comply with federal law, Principal investigators must register the possession of Select Agents. Failure to comply may result in criminal penalties. [Select Agents](#) include 1) microorganisms listed as Select Agents by the CDC, 2) genetically modified microorganisms or genetic elements from organisms on the list, shown to produce or encode for a factor associated with a disease, and 3) genetically modified microorganisms or genetic elements that contain nucleic acid sequences coding for any of the toxins on the list or their toxic subunits. The USA Patriot Act of 2001 prohibits “Restricted Persons” from possessing, shipping, transporting or receiving Select Agents. Finally, the Patriot Act prohibits the possession of a “Biological Agent, Toxin or Delivery System” of a type or in a quantity that, under the circumstances, is not reasonably justified by a prophylactic, protective, bona fide research, or other peaceful purpose. (As used here, “Biological Agent, Toxin or Delivery System” is broader than Select Agents.)

Principal Investigators must fill out and sign this SELECT AGENT Registration Form. Send the **signed** form to: Nancy Apple, Director of Environmental Health & Safety, Office of Environmental Health & Safety. She will contact you for additional information. If you have any questions about the regulations, and Select Agents, please contact Nancy Apple (neapple, ext. 2529).

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Date: \_\_\_\_\_

**PRINCIPAL INVESTIGATOR:**

Last Name: \_\_\_\_\_ First Name: \_\_\_\_\_ Middle Initial: \_\_\_\_\_

Department: \_\_\_\_\_

Position Title \_\_\_\_\_ e-mail: \_\_\_\_\_

Phone: \_\_\_\_\_

Lab Locations (Give buildings and room #s): \_\_\_\_\_

**LAB MANAGER (if applicable):**

Last Name: \_\_\_\_\_ First Name: \_\_\_\_\_ Middle Initial: \_\_\_\_\_

Position Title \_\_\_\_\_ e-mail: \_\_\_\_\_

Phone: \_\_\_\_\_

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1. Specify below any Select Agent organisms or toxins to be used in your laboratory

**A. [Microorganisms/Infectious Agents](#)**

Agent (Genus & Species)	Strain	Recombinant	Antibiotic Resistance (Specify)
		<input type="checkbox"/> No <input type="checkbox"/> Yes	
		<input type="checkbox"/> No <input type="checkbox"/> Yes	
		<input type="checkbox"/> No <input type="checkbox"/> Yes	
		<input type="checkbox"/> No <input type="checkbox"/> Yes	
		<input type="checkbox"/> No <input type="checkbox"/> Yes	

**B. Biological Toxins**

Toxin Name	Type of Toxin	Amount	Supplier

2. A. Will you use, store or generate genetically modified microorganisms or genetic elements from organisms listed as Select Agents?

No  Yes, specify:

- B. Will you use, store or generate genetically modified microorganisms or genetic elements that contain nucleic acid sequences coding for any of the toxins listed as Select Agents or their toxic subunits?

No  Yes, specify:

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Principal Investigator (Signature)

Date