

SELECT AGENT RESEARCH
SF424 (R&R) – Version H

BACKGROUND

Select agents are hazardous biological agents and toxins that have been identified by HHS or the U.S. Department of Agriculture (USDA) as having the potential to pose a severe threat to public health and safety, to animal and plant health, or to animal and plant products. The Centers for Disease Control and Prevention (CDC) and the Animal and Plant Health Inspection Service (APHIS) Select Agent Programs jointly maintain a list of these agents.

CONTENT INSTRUCTIONS

Please follow the [Select Agent Research Application Guidelines](#) and any guidance provided in your specific funding opportunity announcement (FOA) when completing the Select Agent Research attachment.

Excluded select agents

If the activities proposed in the application involve only the use of a strain(s) of select agents which has been excluded from the list of select agents and toxins, the select agent requirements do not apply. Use this section to identify the strain(s) of the select agent that will be used and note that it has been excluded from this list. The CDC maintains a list of exclusions, which is available on the [Select Agents and Toxins Exclusions](#) website.

Applying for a select agent to be excluded

If the strain(s) is not currently excluded from the list of select agents and toxins but you have applied or intend to apply to HHS for an exclusion from the list, use this section to indicate the status of your request or your intent to apply for an exclusion and provide a brief justification for the exclusion.

All applicants proposing to use select agents

Address the following three points for *each site* at which select agent research will take place. *Although no specific page limitation applies to this section, be succinct.*

- 1. Identify the select agent(s) to be used in the proposed research.**
- 2. Provide the registration status of all entities where select agent(s) will be used.**
 - *An “entity” is defined as “any government agency (Federal, State, or local), academic institution, corporation, company, partnership, society, association, firm, sole proprietorship, or other legal entity.”
 - If the Performance Site(s) is a foreign institution, provide the name(s) of the country or countries where select agent research will be performed.
- 3. Provide a description of all facilities where the select agent(s) will be used.**
 - a. Describe the procedures that will be used to monitor possession, use, and transfer of select agent(s).
 - b. Describe plans for appropriate biosafety, biocontainment, and security of the select agent(s).
 - c. Describe the biocontainment resources available at all performance sites.

Use of URLs and hyperlinks in this attachment is not allowed unless specified in the FOA.

RESOURCES

[NIH Grants Policy Statement, Section 4.1.24.1.1: Select Agents](#)

Review NIH's policies on research involving select agents or toxins.

[Federal Select Agent Program](#)

In addition to housing Select Agent Research regulations and policies, the Federal Select Agent Program website provides a list of select agents and toxins and excluded strains, compliance guidance, training, and many more resources related to research involving Select Agents and Toxins.

[Select Agents and Toxins Exclusions](#)

The select agent regulations established a procedure by which an attenuated strain of a select biological agent or toxin that does not pose a severe threat to public health and safety, animal health, or animal products may be excluded from the requirements of the select agent regulations. A list of excluded strains of HHS and USDA select agents and toxins is available here.

[NIAID Select Agent Awards SOP](#)

This NIAID webpage describes the standard operating procedure (SOP) that should be followed so that all grants that possess, use or transfer select agents comply with the select agent policy.