



## Office of Research and Sponsored Programs

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## NIH Select Agent Research Guidance

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### **Who must complete the “Select Agent Research” attachment:**

Include a “Select Agent Research” attachment if your proposed activities involve the use of select agents at any time during the proposed project period, either at the applicant organization or at any performance site.

### **Format:**

Attach this information as a PDF file.

### **For more information:**

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 APHIS Select Agent Programs jointly maintain a list of these agents. See the [Federal Select Agent Program website](#). See also the NIH Grants Policy Statement, Section 4.1.24.1.1: Select Agents.

### **Content:**

**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 as per 42 CFR 73.3, the select agent requirements do not apply. Use this “Select Agent Research” attachment 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.
  - a. 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.
  - b. \*An “entity” is defined in 42 CFR 73.1 as “any government agency (Federal, State, or local), academic institution, corporation, company, partnership, society, association, firm, sole proprietorship, or other legal entity.”
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.