

# Review of Biohazards Including Select Agents

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***NOTE: This guidance covers the review of Biohazards and Select Agents BOTH for funding opportunities using the Simplified Review Framework and for funding opportunities not using the Simplified Review Framework.***

**Biohazards** are biological organisms or their products (such as toxins) that pose a threat to human health.

**Select Agents** are hazardous biological agents and toxins identified by DHHS 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 (List of Select Agents can be found at: [Select Agents and Toxins](#)).

## **For BOTH the Simplified Review Framework and *non*-Simplified Review Framework**

### **Biohazards** - under Additional Review Criteria

Reviewers are asked to identify potential biohazards (including select agents) and other hazards such as radioactivity, dangerous chemicals, or recombinant DNA that are known in their professional community to pose a particularly significant risk to research personnel and/or the environment and to determine whether proper handling procedures and adequate protections are addressed. Assessments should be documented in the Biohazards section of the critique template.

### **Questions to consider** in your assessment:

1. Will all personnel handling hazardous materials be properly trained?
2. Do the proposed protocols address safety concerns?
3. Does the investigator propose the use of adequate containment facilities/procedures?

**Documenting your assessment:** Although issues regarding Biohazards are not independently scored, they can adversely affect assessment under the review criteria:

- Inappropriate or inadequate plans for the safe handling of biohazards (criteria that address the proposed approaches)
- Lack of knowledge about appropriate methods and containment (criteria that address the investigators)
- Lack of appropriate containment procedures and facilities (criteria that address the research environment)

Egregious concern(s) that endangers the public should raise the option of classifying the application as: NRFC (Not Recommended for Further Consideration).

## **ONLY for *non*-Simplified Review Framework**

### **Select Agent Research** - under Additional Review Considerations

In addition to considering biohazard issues, applications that use select agents should be assessed for appropriate inclusion, in the Select Agent Research section, of the following required non-scorable issues for each site where select agents will be used:

1. Identify the select agent(s) to be used in the proposed research.
2. Provide the registration status of all entities (organizations) where select agents will be used; provide the name of the country for any foreign institutions involved.
3. Describe all facilities where the select agent(s) will be used including procedures to monitor possession, use and transfer of the select agents; plans for appropriate biosafety, biocontainment, and security of the select agents; and the biocontainment resources available at all performance sites.

Reviewers are asked to assess the information provided in this section under the Select Agent Research heading in the Additional Review Considerations section of the critique template.