

RISK-BENEFIT ASSESSMENT

1. Purpose

The purpose of risk-benefit assessment is to assess the potential benefits and the potential risks of the proposed research in a clear and thorough manner. Weighing the risks and benefits of Category 1 and Category 2 research can be challenging because risks and benefits are not always easily quantified in ways that are comparable.

2. Responsibility

If the research is assessed to be Category 1 or Category 2, the Principal Investigator and IRE, should conduct risk-benefit assessments. The federal funding agency (for Category 1) or federal department (for Category 2) will evaluate the research institution's risk-benefit assessment and determine whether the potential benefits justify the potential risks prior to the funding decision.

3. Funding Information

Name of Principal Investigator	
Funding Agency	
Title of the Grant	
Grant Number	
Start Date of Funding	
Duration of Grant	

4. Points to Consider in Assessing the Benefits of Category 1 and Category 2 Research

- a) What are the potential benefits to public health, agriculture, food security, economic security, or national security from the research?
- b) What potential solution(s) does the research offer to an identified problem or vulnerability?
- c) How would the research be useful to the scientific, public health, national security, or agriculture communities?
- d) How will the knowledge, information, technology, or products generated from the research be broadly applicable (e.g., to human health, multiple scientific fields, populations of organisms)?
- e) If a benefit has been identified, in what time frame (e.g., immediate, near future, years from now) might this research benefit public health, agriculture, food security, economic security, or national security?

5. Risk Benefit Assessment

1. Are there other ways in which the potential benefits of the research could be achieved that would reduce the anticipated risks?

Response:

2. Could the knowledge, information, products, or technologies of concern be more readily applied to improvements in surveillance, development of MCMs, or other beneficial purposes than to malevolent applications? What reasons or evidence support the answer to this question?

Response:

3. What is the time frame in which potential benefits might be realized? Does it rely on other research endeavors?

Response:

4. How might the potential benefits and the anticipated risks be distributed across different human, animal, and plant communities? Who or what will be the likely beneficiaries of the potential benefits? Who or what will bear the anticipated risks? Is it likely that one or more specific populations will bear the burden of the anticipated risks?

Response:

5. Considering the anticipated risks along with potential benefits, are the risks of such a feasibility and magnitude that they warrant proceeding after developing and implementing a risk mitigation plan? Are the potential benefits of significant magnitude to warrant proceeding despite the risks?

Response:

6. What is the most responsible way to proceed? Do measures in the risk mitigation plan effectively and measurably reduce the anticipated risk?

Response: