

## Draft Document

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FOA ID:

FOA Title:

Research Topic: The effects of influenza vaccine on immunocompromised persons

Title: Project Summary

### ## Project Summary

The research project aims to investigate the effects of influenza vaccine on immunocompromised individuals. Immunocompromised persons, including those with solid organ transplants, hematopoietic stem cell transplants, solid cancers, hematologic malignancy, and autoimmune conditions receiving biologic therapies, are at high risk of complications from influenza infection. Despite the challenges of low vaccine immunogenicity in this population, some evidence suggests that the influenza vaccine can be effective in reducing severe disease. Various strategies have been explored to enhance vaccine immunogenicity, such as high-dose vaccines, adjuvanted vaccines, and intradermal vaccines. The project will focus on evaluating the impact of different influenza vaccine strategies in immunocompromised individuals to improve vaccine effectiveness and protect this vulnerable population from influenza-related morbidity and mortality.

Title: Project Narrative

### ### Project Narrative

The research project aims to investigate the impact of influenza vaccine on immunocompromised individuals, including those with solid organ transplants, hematopoietic stem cell transplants, solid cancers, hematologic malignancy, and autoimmune conditions receiving biologic therapies. The study will focus on evaluating the effectiveness and immunogenicity of the seasonal influenza vaccine in this vulnerable population. By analyzing the existing evidence on vaccine efficacy, immunogenicity, and strategies to enhance vaccine response, the research seeks to provide valuable insights into optimizing influenza vaccination protocols for immunocompromised persons.

Title: Facilities & Resources

### ### Facilities & Resources

The research project on "The effects of influenza vaccine on immunocompromised persons" will require access to the following facilities and resources:

1. **Laboratory Facilities**: Equipped with necessary tools for sample analysis and vaccine effectiveness testing.
2. **Clinical Research Center**: To conduct trials and studies involving immunocompromised individuals receiving the influenza vaccine.
3. **Data Management System**: To securely store and analyze data collected during the research study.

4. **\*\*Specialized Equipment\*\***: Such as high-dose influenza vaccines, adjuvanted vaccines, and intradermal vaccines for comparative studies.
5. **\*\*Qualified Personnel\*\***: Including researchers, clinicians, and support staff experienced in working with immunocompromised populations and vaccine trials.
6. **\*\*Ethics Review Board Approval\*\***: Ensuring all research protocols adhere to ethical standards and guidelines.
7. **\*\*Funding\*\***: To support the procurement of necessary supplies, participant compensation, and overall research operations.

These facilities and resources are essential for conducting a comprehensive study on the effects of influenza vaccine on immunocompromised persons.

Title: Research Plan

### Research Plan

**\*\*Specific Aims:\*\***

- Identify the specific objectives and goals of the research focusing on the effects of influenza vaccine on immunocompromised persons.
- Clearly outline how these goals will be achieved through the study.

**\*\*Research Strategy:\*\***

- Establish an administrative infrastructure to oversee the implementation of activities related to the research project.
- Describe how the research team will provide support for addressing the research hypotheses concerning immunocompromised individuals.
- Detail the management plan for resources, subcontractors, and consultants.
- Explain the communication strategy among collaborators and stakeholders.

**\*\*Immunological Analyses:\*\***

- Describe the immunological analyses that will be conducted to assess the impact of influenza vaccination on immunocompromised individuals.
- Explain the rationale for including control groups in the study.
- Outline strategies for identifying and characterizing human subjects, including data collection and sample quality standards.

**\*\*Data Management Plan:\*\***

- Detail internal and external data acquisition strategies to ensure harmonization of data management procedures.
- Describe how data quality, analyses, and dissemination will be managed.
- Explain how data uniformity and high-quality content will be maintained across all study sites.
- Provide details on training for data and sample collection procedures.

This research plan aims to investigate the effects of influenza vaccine on immunocompromised individuals, emphasizing the importance of immunological analyses and robust data management practices.

Signature:

Additional Signature: