TITLE

**DMID Protocol Number:**

**Sponsored by:**

National Institute of Allergy and Infectious Diseases (NIAID)

**DMID Funding Mechanism:**

**Industrial Support Provided by:** *(if applicable)*

**Principal Investigator:**

**DMID Protocol Champion:**

**DMID Medical Monitor:** *(if applicable)*

**DMID Clinical Affairs Specialist:** *(if applicable)*

**DMID Regulatory Affairs Specialist:** *(if applicable)*

**Draft or Version Number:**

**Day Month Year**

Statement of Compliance

SIGNATURE PAGE

The signature below constitutes the approval of this protocol and the attachments, and provides the necessary assurances that this trial will be conducted according to all stipulations of the protocol, including all statements regarding confidentiality, and according to local legal and regulatory requirements and applicable US federal regulations and ICH guidelines.

|  |  |  |  |
| --- | --- | --- | --- |
| Site Investigator:\* | | | |
| Signed: |  | Date: |  |
|  | *Name*  *Title* |  |  |

*\* The protocol should be signed by the local investigator who is responsible for the study implementation at his/her specific site; ie, if Investigational New Drug study, the individual who signs the Form FDA 1572.*

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SUPPLEMENTS/APPENDICES

A: Study Schedule

List of Abbreviations

|  |  |
| --- | --- |
| AE | Adverse Event |
| CFR | Code of Federal Regulations |
| CIOMS | Council for International Organizations of Medical Sciences |
| CRF | Case Report Form |
| DMID | Division of Microbiology and Infectious Diseases, NIAID, NIH, DHHS |
| DSMB | Data and Safety Monitoring Board |
| FDA | Food and Drug Administration |
| FWA | Federal-Wide Assurance |
| GCP | Good Clinical Practice |
| ICF | Informed Consent Form |
| ICH | International Conference on Harmonisation |
| IEC | Independent or Institutional Ethics Committee |
| IRB | Institutional Review Board |
| ISM | Independent Safety Monitor |
| JAMA | Journal of the American Medical Association |
| MOP | Manual of Procedures |
| N | Number (typically refers to subjects) |
| NEJM | New England Journal of Medicine |
| NIAID | National Institute of Allergy and Infectious Diseases, NIH, DHHS |
| NIH | National Institutes of Health |
| OCRA | Office of Clinical Research Affairs, DMID, NIAID, NIH, DHHS |
| OHRP | Office for Human Research Protections |
| ORA | Office of Regulatory Affairs, DMID, NIAID, NIH, DHHS |
| PI | Principal Investigator |
| SAE | Serious Adverse Event |
| SMC | Safety Monitoring Committee |
| SOP | Standard Operating Procedure |
| WHO | World Health Organization |

Protocol Summary

**Title**:

**Population**:

**Number of Sites**:

**Study Duration**:

**Subject Duration**:

**Objectives**:

Primary:

Secondary:

**Schematic of Study Design**:

# Key Roles

**Individuals**: **DMID Representative**:

**Principal Investigator**: *Site investigator responsible for conducting the study*

**Medical Monitor:** (if applicable)

**Institutions**:

# Background Information and Scientific Rationale

## Background Information

## Rationale

## Potential Risks and Benefits

### Potential Risks

### Known Potential Benefits

# Objectives

# Study Design

# Study Population

## Selection of the Study Population

## Inclusion/Exclusion Criteria

# Study Procedures/Evaluations

## Study Procedures

## Laboratory Evaluations

### Laboratory Evaluations/Assays

### Special Assays or Procedures

### Specimen Collection, Preparation, Handling and Shipping

#### Instructions for Specimen Preparation, Handling, and Storage

#### Specimen Shipment

# Study Schedule

## Screening

## Enrollment/Baseline, if applicable

## Follow-up and Final Visits, if applicable

## Early Termination Visit, if applicable

## Criteria for Discontinuation or Withdrawal of a Subject (or a Cohort), if applicable

# Assessment of Outcome Measures

## Specification of the Appropriate Outcome Measures

### Primary Outcome Measures

### Secondary Outcome Measures

# Safety assessment and reporting

## Definition of Adverse Event (AE)

## Definition of Serious Adverse Event (SAE)

## Reporting Procedures

### Serious Adverse Event Detection and Reporting

### Reporting of Pregnancy

### Procedures to be Followed in the Event of Abnormal Laboratory Test Values or Abnormal Clinical Findings

### Type and Duration of the Follow-up of Subjects After Adverse Events

## Halting Rules

# Clinical Monitoring Structure

## Site Monitoring Plan

# Statistical Considerations

## Study Outcome Measures

## Sample Size Considerations

## Participant Enrollment and Follow-Up

## Analysis Plan

# Access to Source Data/Documents

# Quality Control and Quality Assurance

# Ethics/Protection of Human Subjects

## Declaration of Helsinki

## Institutional Review Board

## Informed Consent Process

### Informed Consent/Assent Process (in Case of a Minor or others unable to consent for themselves)

## Exclusion of Women, Minorities, and Children (Special Populations)

## Subject Confidentiality

## Future Use of Stored Specimens

# Data Handling and Record Keeping

## Data Management Responsibilities

## Data Capture Methods

## Types of Data

## Timing/Reports

## Study Records Retention

## Protocol Deviations

# Publication Policy

# Literature References

SUPPLEMENTS/APPENDICES

Appendix A: Study Schedule