



IITRI Preclinical Study Sponsor Information Form

Please complete all applicable sections.

Section 1: Sponsor Details

Full Name: _____

Title/Role: _____

Company Name: _____

Company Address: _____

Email Address: _____

Phone Number: _____

Section 2: Study Overview

Proposed Study Title: _____

Brief Description of Study Objectives: _____

Target Indication/Disease Area: _____

Section 3: Timeline

Desired Study Start Date: _____

Expected Completion Date: _____

Critical Milestones: _____

Section 4: Study Specifics

Type of Study: _____

Species/Model Requested: _____

Number of Animals: _____

Route of Administration: _____

Dose Levels: _____

Frequency & Duration of Dosing: _____

Histopathology Required?: _____

Section 5: Test Article Information

Name of Test Article: _____

Formulation Details: _____

Storage & Handling Requirements: _____

Stability Information: _____

Section 6: Bioanalytical & Immunology Requirements

Do you need a TK/PK study?: _____

Preferred drug measurement method (ELISA/ECL, LC-MS, PCR):

Do you have a method to transfer or should IITRI develop the method?:

Do you want the method to be qualified or validated?: _____

Does your study require immunogenicity or immunotoxicity readouts? (ADA, Flow Cytometry, Cytokine Analysis): _____

Do you need a biodistribution study?: _____

Section 7: Infectious Disease Study Details

Pathogen: _____

Strain: _____

Method of Infection: _____

Challenge Dose: _____

Endpoints: _____

Viral Load Measurement Options (qPCR, Plaque Assay, TCID50):

Histopathology Required?: _____

Additional Biomarkers or Readouts: _____

Section 8: Funding Information

Funding Mechanism (Grant, Subcontract, Direct Payment):

Name of Grant or Program: _____

Grant Submission Date: _____

Do you require a Letter of Support from IITRI?: _____

Is this part of an SBIR application?: _____

Other Funding Details or Notes: _____

Section 9: Regulatory & Compliance

GLP Compliance Required?: _____

Any Specific Regulatory Guidelines (FDA, EMA, etc.): _____

Section 10: Additional Notes

Special Requirements or Considerations: _____

Attachments (Protocol Draft, Supporting Data, etc.): _____

Date: _____