**PROTOCOL EVALUATION FORM**

**FOR INITIAL REVIEW (Form 2.7B)**

**TO THE PRINCIPAL INVESTIGATOR:** *OBTAIN AN ELECTRONIC COPY OF THIS FORM AND ENCODE ALL INFORMATION REQUIRED IN THE SPACE PROVIDED. PRINT NAME, DATE AND SIGN THIS FORM BEFORE SUBMISSION. INDICATE WITH A (✓) CHECK MARK THE APPROPRIATE TICK BOX.*

|  |  |  |  |
| --- | --- | --- | --- |
| **Date of Submission (MMM/DD/YYYY)** |  | **IRB Protocol Number** |  |
|  |
| **Sponsor** |  | **Sponsor’s Protocol Number** |  |
|  |
| **Principal Investigator** |  | **Co-investigator(s)** **(if any)** |  |
|  |
| **Principal Investigator’s Signature** |  | **Principal Investigator’s Contact Number** |  |
|  |
| **Protocol Title**  |  |
| **TO THE PRINCIPAL INVESTIGATOR:***INDICATE THE LOCATION OF THE ASSESSMENT POINT (E.G. PAGE NO.) IN THE SECOND COLUMN. INDICATE* ***N/A*** *IF NOT APPLICABLE.* **TO THE PRIMARY REVIEWER/ INDEPENDENT CONSULTANT:** *IF YOU HAVE NO FURTHER COMMENTS, PUT A (√) CHECK MARK ON THE SPACE PROVIDED.OTHERWISE, SPECIFY THE ISSUES ON THE SPACE PROVIDED. PLEASE DO NOT USE PENCIL IN ACCOMPLISHING THIS FORM.* |
| **ASSESSMENT POINT** | ***LOCATION*** | **REVIEWER’S COMMENTS** |
| APPROVED/SUFFICIENT/NO FURTHER COMMENT**(put a check ✓ mark)** | FOR REVISION (specify issues) |
| 1. Title
 |  |  |  |
| 1. Objectives
 |  |  |  |
| 1. Significance of the Study/Social Value
 |  |  |  |
| 1. Literature Review/ Investigator’s Brochure
 |  |  |  |
| 1. Research Design
 |  |  |  |
| 1. Sampling Design, Sample size or Number of subjects to be enrolled
 |  |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| 1. Statistical/ Data Analysis
 |  |  |  |
| 1. Methodology
 |  |  |  |
| 1. Control Arm (Placebo, if any)
 |  |  |  |
| 1. Standard Therapy
 |  |  |  |
| 1. Inclusion Criteria
 |  |  |  |
| 1. Exclusion Criteria
 |  |  |  |
| 1. Withdrawal or Discontinuation Criteria
 |  |  |  |
| 1. Specimen Handling
 |  |  |  |
| 1. Principal Investigator’s Qualifications
 |  |  |  |
| 1. Duration
 |  |  |  |
| 1. Conflict of Interest
2. Involvement of the Investigator in any other similar or competing trial

*(\*For COVID-19 vaccine protocols only)*  |  |  |  |
| 1. Privacy and Confidentiality
 |  |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| 1. Informed Consent Process
 |  |  |  |
| 1. Assent
 |  |  |  |
| 1. Vulnerability
 |  |  |  |
| 1. Recruitment
 |  |  |  |
| 1. Risks
2. Levels of Risk
3. Types of Risk
4. Source of Risk
 |  |  |  |
| 1. Benefits
2. Direct benefit to participants
3. Benefits to society
 |  |  |  |
| 1. Compensation
 |  |  |  |
| 1. Community Consideration

(i.e. recruiting, consenting the parent participants and their children |  |  |  |
| 1. Participant’s follow-up and management of the study
 |  |  |  |
| 1. Provision for monitoring and auditing the conduct of the research, including constitution of the Data Safety Monitoring Board (DSMC)/ Food and Drug Administration (FDA) Approval
 |  |  |  |
| 1. Data Collection Tool/ Case Report Form
 |  |  |  |

**TO THE PRINCIPAL INVESTIGATOR:** *PRINT NAME, DATE AND SIGN THIS FORM BEFORE SUBMISSION.*

Submitted by:

 **Signature above Printed Name Date (MMM/DD/YYYY)**

***--------------------------------------------------------------------------------------------------------------------------------------------------------------------***

***(To be filled out by IRB Primary Reviewer/Independent Consultant)***

**TO THE PRIMARY REVIEWER/ INDEPENDENT CONSULTANT:** *PUT A (√) ON THE APPROPRIATE TICK BOX. IF THE PAPER IS FOR REVISION, SPECIFY MODIFICATION REQUIRED ON THE SPACE PROVIDED. IF THE PAPER IS DISAPPROVED, STIPULATE THE REASON FOR SUCH DECISION ON THE SPACE PROVIDED. PRINT NAME, SIGN AND DATE THIS FORM. PLEASE DO NOT USE PENCIL.*

***NOTE:*** *FOR PROTOCOLS UNDER FULL BOARD REVIEW, THE PRIMARY REVIEWERS MUST BE PRESENT DURING THE DELIBERATION FOR FINAL DECISION. TO PREPARE FOR THE FULL BOARD MEETING, KINDLY RETURN THE ACCOMPLISHED EVALUATION FORMS (2.7B AND 2.8) TO THE IRB SECRETARIAT AT LEAST ONE (1) WEEK PRIOR TO THE SCHEDULED MEETING. THANK YOU.*

***TO BE FILLED OUT BY THE PRIMARY REVIEWER***

*Reviewer’s Recommendation*

[ ] Approval

 [ ]  Minor Modification:

 Summary of Revisions:

 [ ]  Major Modification:

Summary of Revisions:

[ ]  Disapproval

 Reason:

[ ]  Pending Decision

 Reason:

|  |  |  |
| --- | --- | --- |
| **Primary Reviewer’s Name** | **Signature** | **Date (MMM/DD/YYYY)** |
|  |  |  |

**TO THE IRB SECRETARIAT:***SPECIFY THE DELIBERATION DATE OF THE PROTOCOL.*

**Date of Meeting:**

 **(MMM/DD/YYYY)**