**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.*

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| --- | --- | --- | --- | --- | --- | --- | --- |
| **Date of Submission (MMM/DD/YYYY)** | | | Click here to enter text. | | | **IRB Protocol Number** | Click here to enter text. |
|  | | | | | | | |
| **Sponsor** | | | Click here to enter text. | | | **Sponsor’s Protocol Number** | Click here to enter text. |
|  | | | | | | | |
| **Principal Investigator** | | | Click here to enter text. | | | **Co-investigator(s)**  **(if any)** | Click here to enter text. |
|  | | | | | | | |
| **Principal Investigator’s Signature** | | | Click here to enter text. | | | **Principal Investigator’s Contact Number** | Click here to enter text. |
|  | | | | | | | |
| **Protocol Title** | | | Click here to enter text. | | | | |
| **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 | Click here to enter text. | |  |  | | |
| 1. Objectives | Click here to enter text. | |  |  | | |
| 1. Significance of the Study/Social Value | Click here to enter text. | |  |  | | |
| 1. Literature Review/ Investigator’s Brochure | Click here to enter text. | |  |  | | |
| 1. Research Design | Click here to enter text. | |  |  | | |
| 1. Sampling Design, Sample size or Number of subjects to be enrolled | Click here to enter text. | |  |  | | |

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| 1. Statistical/ Data Analysis | Click here to enter text. |  |  |
| 1. Methodology | Click here to enter text. |  |  |
| 1. Control Arm (Placebo, if any) | Click here to enter text. |  |  |
| 1. Standard Therapy | Click here to enter text. |  |  |
| 1. Inclusion Criteria | Click here to enter text. |  |  |
| 1. Exclusion Criteria | Click here to enter text. |  |  |
| 1. Withdrawal or Discontinuation Criteria | Click here to enter text. |  |  |
| 1. Specimen Handling | Click here to enter text. |  |  |
| 1. Principal Investigator’s Qualifications | Click here to enter text. |  |  |
| 1. Duration | Click here to enter text. |  |  |
| 1. Conflict of Interest 2. Involvement of the Investigator in any other similar or competing trial   *(\*For COVID-19 vaccine protocols only)* | Click here to enter text. |  |  |
| 1. Privacy and Confidentiality | Click here to enter text. |  |  |

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| --- | --- | --- | --- |
| 1. Informed Consent Process | Click here to enter text. |  |  |
| 1. Assent | Click here to enter text. |  |  |
| 1. Vulnerability | Click here to enter text. |  |  |
| 1. Recruitment | Click here to enter text. |  |  |
| 1. Risks 2. Levels of Risk 3. Types of Risk 4. Source of Risk | Click here to enter text. |  |  |
| 1. Benefits 2. Direct benefit to participants 3. Benefits to society | Click here to enter text. |  |  |
| 1. Compensation | Click here to enter text. |  |  |
| 1. Community Consideration   (i.e. recruiting, consenting the parent participants and their children | Click here to enter text. |  |  |
| 1. Participant’s follow-up and management of the study | Click here to enter text. |  |  |
| 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 | Click here to enter text. |  |  |
| 1. Data Collection Tool/ Case Report Form |  |  |  |

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

Submitted by:

Click here to enter text.Click here to enter text.

**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)**