**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.*

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| **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 AN (X) MARK ON THE SPACE PROVIDED. OTHERWISE, YOU MAY OPT TO INDICATE COMMENTS FROM THE STUDY BELOW.* | | | | |

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| **ASSESSMENT POINT** | | | | | | | | | | | | | | | | | | | | | **Page number**  **(in the protocol)** | **REVIEWER’S COMMENTS** |
| RECOMMENDATIONS/ FOR REVISION (specify issues) |
| 1. Title | | | | | | | | | | | | | | | | | | | | |  |  |
|  | Clear | | | | | |  | | | | Not Clear | | | | | | | | | |
| 1. Objectives | | | | | | | | | | | | | | | | | | | | |  |  |
|  | Clear | | | | | |  | | | | Not Clear | | | | | | | | | |
| 1. Significance of the Study/Social Value | | | | | | | | | | | | | | | | | | | | |  |  |
|  | Appropriate | | | | | |  | | | | Not Appropriate | | | | | | | | | |
| 1. Literature Review/ Investigator’s Brochure | | | | | | | | | | | | | | | | | | | | |  |  |
|  | Sufficient | | | | | |  | | | | Not sufficient | | | | | | | | | |
| 1. Research Design | | | | | | | | | | | | | | | | | | | | |  |  |
|  | Clear | | | | | |  | | | | Not Clear | | | | | | | | | |
| 1. Sampling Design, Sample size or   Number of subjects to be enrolled | | | | | | | | | | | | | | | | | | | | |  |  |
|  | Clear | | | | | |  | | | | Not Clear | | | | | | | | | |
| 1. Statistical/ Data Analysis | | | | | | | | | | | | | | | | | | | | |  |  |
|  | Appropriate | | | | | |  | | | | Not Appropriate | | | | | | | | | |
| 1. Methodology | | | | | | | | | | | | | | | | | | | | |  |  |
|  | Clear | | | | | |  | | | | Not Clear | | | | | | | | | |
| 1. Control Arm (Placebo, if any) | | | | | | | | | | | | | | | | | | | | |  |  |
|  | Appropriate | | | |  | | | | Not Appropriate | | | | | | |  | | | Not Applicable | |
| 1. Standard Therapy | | | | | | | | | | | | | | | | | | | | |  |  |
|  | Appropriate | | | |  | | | | Not Appropriate | | | | | | |  | | | Not Applicable | |
| 1. Inclusion Criteria | | | | | | | | | | | | | | | | | | | | |  |  |
|  | Appropriate | | | | | |  | | | | Not Appropriate | | | | | | | | | |
| 1. Exclusion Criteria | | | | | | | | | | | | | | | | | | | | |  |  |
|  | Appropriate | | | | | |  | | | | Not Appropriate | | | | | | | | | |
| 1. Withdrawal or Discontinuation Criteria | | | | | | | | | | | | | | | | | | | | |  |  |
|  | Appropriate | | | | | |  | | | | Not Appropriate | | | | | | | | | |
| 1. Specimen Handling | | | | | | | | | | | | | | | | | | | | |  |  |
|  | Appropriate | | | | | |  | | | | Not Appropriate | | | | |  | | | Not Applicable | |
| 1. Principal Investigator’s Qualifications | | | | | | | | | | | | | | | | | | | | |  |  |
|  | Clear | | | | | |  | | | | Not Clear | | | | | | | | | |  |  |
| 1. Duration | | | | | | | | | | | | | | | | | | | | |  |  |
|  | Clear | | | | | |  | | | | Not Clear | | | | | | | | | |
| 1. Conflict of Interest   (Involvement of the Investigator in any other similar or competing trial) | | | | | | | | | | | | | | | | | | | | |  |  |
|  | Yes | | | | | |  | | | | No | | | | | | | | | |
| 1. Privacy and Confidentiality | | | | | | | | | | | | | | | | | | | | |  |  |
|  | Sufficient | | | | | |  | | | | Not sufficient | | | | | | | | | |
| 1. Informed Consent Process | | | | | | | | | | | | | | | | | | | | |  |  |
|  | Clear | | |  | | | Not Clear | | | | | |  | | | | Not Applicable | | | |
| 1. Assent | | | | | | | | | | | | | | | | | | | | |  |  |
|  | Appropriate | | | | | |  | | | | Not Appropriate | | | | | | | | | |
| 1. Vulnerability | | | | | | | | | | | | | | | | | | | | |  |  |
|  | Clear | | | | | |  | | | | Not Clear | | | | | | | | | |
| 1. Risks 2. Levels of Risk 3. Types of Risk 4. Source of Risk | | | | | | | | | | | | | | | | | | | | |  |  |
|  | Appropriate | | | | | |  | | | | Not Appropriate | | | | | | | | | |
| 1. Benefits 2. Direct benefit to participants 3. Benefits to society | | | | | | | | | | | | | | | | | | | | |  |  |
|  | Appropriate | | | | | |  | | | | Not Appropriate | | | | | | | | | |
| 1. Compensation | | | | | | | | | | | | | | | | | | | | |  |  |
|  | Appropriate | | | | | |  | | | | Not Appropriate | | | | | | | | | |
| 1. Community Consideration (i.e. recruiting, consenting the parent participants and their children) | | | | | | | | | | | | | | | | | | | | |  |  |
|  | Clear | | | | | |  | | | | Not clear | | |  | | | | Not Applicable | | |
| 1. Participant’s follow-up and management of the study | | | | | | | | | | | | | | | | | | | | |  |  |
|  | | | Appropriate | | |  | | | | Not Appropriate | | | |  | | | | | | Not Applicable |
| 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 | | | | | | | | | | | | | | | | | | | | |
|  | | Appropriate | | | | | |  | | | | Not Appropriate | | |  | | | | | Not Applicable |
| 1. Data Collection Tool/ Case Report Form | | | | | | | | | | | | | | | | | | | | |  |  |
|  | Sufficient | | | | | |  | | | | Not Sufficient | | | | | | | | | |

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

*PUT AN (X) MARK ON THE SPACE PROVIDED UNDER DECISION, AND YOU MAY OPT SUMMARIZE THE COMMENTS FROM THE STUDY BELOW.*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Decision:** |  | Approval |  | Disapproval |
|  | Minor Modifications Revision |  | Pending Decision |
|  | Major Modifications |  |  |

|  |  |
| --- | --- |
| **Summary of comments:** |  |

***(To be filled out by IRB Primary Reviewer/Independent Consultant):*** *PLEASE ALSO INDICATE YOUR PRINTED NAME AND SIGNATURE ON THE SPACE PROVIDED BELOW****.***

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

***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.*