**INFORMED CONSENT EVALUATION FORM**

**(Form 2.8)**

**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 BE FILLED OUT BY THE REVIEWER**

**TO THE REVIEWER/ INDEPENDENT CONSULTANT:***PUT A (✓) CHECK MARK ON THE TICK BOXES, IF APPLICABLE. SPECIFY YOUR COMMENTS ON THE SPACE PROVIDED.*

1. **INFORMED CONSENT DOCUMENT REVIEW**

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| --- | --- | --- |
| 1. Does the Informed Consent document state that the procedures are primarily intended for research? | | Comment: |
| Yes | No |

|  |  |  |
| --- | --- | --- |
| 1. Is there identification of those responsible and the procedure for obtaining the informed consent? | | Comment: |
| Yes | No |

|  |  |  |
| --- | --- | --- |
| 1. Does the Informed Consent document contain comprehensive and relevant information? | | Comment: |
| Complete | Incomplete |

|  |  |  |
| --- | --- | --- |
| 1. Is the information provided in the protocol consistent with those in the consent form? | | Comment: |
| Consistent | Inconsistent |

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| --- | --- | --- |
| 1. Are study related risks mentioned in the consent form? | | Comment: |
| Complete | Incomplete |

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| --- | --- | --- |
| 1. Is the language in the Informed Consent document understandable? | | Comment: |
| Clear | Unclear |

|  |  |  |
| --- | --- | --- |
| 1. Is the Informed Consent translated into the local language/dialect? | | Comment: |
| Clear | Unclear |

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| --- | --- | --- |
| 1. Is there justification for inclusion of research individuals who cannot consent and the arrangement for obtaining consent from such consent? | | Comment: |
| Yes | No |

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| --- | --- | --- |
| 1. Are the different types of consent forms (assent, patient representative) appropriate for the types of study participants? | | Comment: |
| Complete | Incomplete |

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| --- | --- | --- |
| 1. Are names and contact numbers from the research team and the IRB in the informed consent? | | Comment: |
| Yes | No |

|  |  |  |
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| 1. Is there protection of privacy and confidentiality of the research participants during and after the completion of the research? | | Comment: |
| Yes | No |

|  |  |  |
| --- | --- | --- |
| 1. Is there any inducement in the participation? | | Comment: |
| Likely | Unlikely |

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| --- | --- | --- |
| 1. Is there provision for medical / psychosocial support? | | Comment: |
| Appropriate | Inappropriate |

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| --- | --- | --- |
| 1. Is there provision for treatment of study-related injuries? | | Comment: |
| Appropriate | Inappropriate |

|  |  |  |
| --- | --- | --- |
| 1. Is there a provision for compensation? | | Comment: |
| Appropriate | Inappropriate |

|  |  |  |
| --- | --- | --- |
| 1. Is there a consent process in emergency situations in the research protocol? | | Comment: |
| Appropriate | Inappropriate |

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| --- | --- | --- |
| 1. Does the investigator ensure that the participants will receive available information during the course of the research relevant to their participation? | | Comment: |
| Yes | No |

|  |  |  |
| --- | --- | --- |
| 1. Does the investigator ensure that the informed consent process is continuing? | | Comment: |
| Yes | No |

|  |  |  |
| --- | --- | --- |
| 1. Does the Informed Consent contain provisions for receiving and responding to queries and complaints from participants or representatives during the course of the research? | | Comment: |
| Yes | No |

|  |  |  |
| --- | --- | --- |
| 1. Is there a statement that participation is voluntary and that there are steps to be taken if research participants voluntarily withdraw during the course of the research? | | Comment: |
| Yes | No |

**TO THE PRIMARY REVIEWER/ INDEPENDENT CONSULTANT:** *PUT A (√) MARK ON THE TICK BOX NEXT TO YOUR RECOMMENDATION. IF THE PAPER IS FOR REVISION, SPECIFY THE 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 ON THE SPACE PROVIDED.*

***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.*

1. **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 DATE OF DELIBERATION OF THE PROTOCOL.*

**Date of Meeting:**

**(MMM/DD/YYYY)**

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

Submitted by:

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