**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.*

|  |  |  |  |
| --- | --- | --- | --- |
| **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:** *IF YOU HAVE NO FURTHER COMMENTS, TICK THE BOX ON THE SPACE PROVIDED. OTHERWISE, YOU MAY OPT TO INDICATE COMMENTS FROM THE STUDY BELOW.*

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 |

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

|  |  |  |
| --- | --- | --- |
| 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 |

|  |  |  |  |
| --- | --- | --- | --- |
| 1. Are the different types of consent forms (assent, patient representative) appropriate for the types of study participants? | | | Comment: |
| Complete | Not Applicable | 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 | Not Applicable | Inappropriate |

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| --- | --- | --- | --- |
| 1. Is there provision for treatment of study-related injuries? | | | Comment: |
| Appropriate | Not Applicable | Inappropriate |

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

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| --- | --- | --- | --- |
| 1. Is there a consent process in emergency situations in the research protocol? | | | Comment: |
| Appropriate | Not Applicable | 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 |

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| --- | --- | --- |
| 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 |

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| --- | --- | --- |
| 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 |

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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:** |  |

|  |  |  |
| --- | --- | --- |
| **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.*