Form 12.2 Informed Consent Evaluation

**Eastern Visayas Health Research and Development Consortium - Ethics Review Committee**

**INFORMED CONSENT EVALUATION**

|  |  |  |  |
| --- | --- | --- | --- |
| ERC Protocol No. |  | Date (D/M/Y): |  |

|  |  |
| --- | --- |
| Protocol Title: |  |

|  |  |
| --- | --- |
| Principal Investigators: |  |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 1. INFORMED CONSENT DOCUMENT REVIEW | | | | | **COMMENTS/**  **WHAT SHOULD BE IMPROVED?** |
|  | Does the Informed Consent document state that the procedures are primarily intended for research? | | | |  |
|  |  | Yes |  | No |  |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Are procedures for obtaining Informed Consent appropriate? | | | |  |
|  |  | Yes |  | No |  |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Are the responsibilities of the participants indicated? | | | |  |
|  |  | Yes |  | No |  |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Does the Informed Consent document contain comprehensive and relevant information? | | | |  |
|  |  | Complete |  | Incomplete |  |

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

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|  | Are study related risks mentioned in the consent form? | | | |  |
|  |  | Complete |  | Incomplete |  |

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| --- | --- | --- | --- | --- | --- |
|  | Is the language in the Informed Consent document understandable? | | | |  |
|  |  | Clear |  | Unclear |  |

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|  | Is the Informed Consent translated into the local language/dialect? | | | |  |
|  |  | Yes |  | No |  |

|  |  |  |  |  |  |
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|  |  | | | | **COMMENTS/**  **WHAT SHOULD BE IMPROVED?** |
|  | Are there vulnerable participants? | | | |  |
|  |  | Yes |  | No |  |

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

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| --- | --- | --- | --- | --- | --- |
|  | Are names and contact numbers from the research team and the ERC in the informed consent? | | | |  |
|  |  | Yes |  | No |  |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Does the ICF provide privacy & confidentiality protection? | | | |  |
|  |  | Yes |  | No |  |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Is there any undue inducement for participation? | | | |  |
|  |  | Yes |  | No |  |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Is there provision for medical / psychosocial support? | | | |  |
|  |  | Appropriate |  | Inappropriate |  |

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| --- | --- | --- | --- | --- | --- |
|  | Is there provision for treatment of study-related injuries | | | |  |
|  |  | Appropriate |  | Inappropriate |  |

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| --- | --- | --- | --- | --- | --- |
|  | Is the amount paid to participants stated? | | | |  |
|  |  | Appropriate |  | Inappropriate |  |

Recommendation

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| DECISION: |  | Approval |  | Minor Revision |
|  |  |  |  |
|  | Major Revision/ Resubmission |  | Disapproval |

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| Comments (Identify items for revision) |  |

|  |  |  |  |
| --- | --- | --- | --- |
| Reviewer’s Name |  | Date: |  |

|  |  |
| --- | --- |
| Signature: |  |