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 |  |

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

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

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

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

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

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

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

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

 Recommendation

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

|  |  |
| --- | --- |
| Comments (Identify items for revision) |  |

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

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