**Annexure: (UOR/10-001)**

ICF assessment form

**Ethics Review Committee**

**Faculty of Medicine, University of Ruhuna**

**ICF ASSESSMENT FORM**

|  |  |
| --- | --- |
| Application Number: | Date reviewed (D/M/Y): |
| Reviewer’s Name: | Signature: |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Informed Consent Forms** | | **Yes** | **No** | **NA** | **Comments** |
| 1 | Are the written and oral information to be given to the research participants appropriate, adequate and complete? |  |  |  |  |
| 2 | Is the language used in information sheets clear  and understandable?  **N.B. Check the use of scientific words.** |  |  |  |  |
| 3 | Is there a statement to the effect that the participation in the research is voluntary? |  |  |  |  |
| 4 | Are translations of all forms consistent and accurate? |  |  |  |  |
| 5 | Is there an opportunity for the participant to ask questions regarding the research? |  |  |  |  |
| 6 | Are there provisions for the participant to withdraw unconditionally from the research without penalty or loss of care? |  |  |  |  |
| 7 | If biological samples are being collected, are the participants informed about  - What is being collected  - What tests will be done with them  - Whether they will be stored for future studies  - If stored for how long and what is expected to be done with samples |  |  |  |  |
|  |  |  |  |  |  |
|  | **Informed Consent Forms** | **Yes** | **No** | **NA** | **Comments** |
| 8 | **Consent Form** – has the participant consented for all procedures planned?  e.g. Immediate activities of study, storing of samples, recording of interviews etc. |  |  |  |  |
| 9 | Is Assent Form provided adequate? |  |  |  |  |
| 10 | Are contact details of PI and other appropriate investigators for site given in the information sheet? |  |  |  |  |
| 11 | Are there provisions for study participants to make complaints if needed? e.g. ERC contact details |  |  |  |  |

**General/ any other comments**

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Signature:………………………………….

Name of the reviewer: ……………………………………..

Date:………………………………………..