|  |  |  |  |
| --- | --- | --- | --- |
| NEC LOGO  (no name) | **NATIONAL ETHICS COMMITTEE**  **STANDARD OPERATING PROCEDURES** | | |
| **CHECKLIST TO INFORMED CONSENT FORM AND PROCESS** | NEC Form No. | 5 |
| SOP No. | 05 & 06 |
| Version No. | 2 |
| Version Date | 15 July 2014 |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Title of Study |  | | | | | | |
| NEC Code | |  | Type of Review | |  | | |
| Principal Investigator | |  | Institution | |  | | |
| Reviewer | |  | | Primary reviewer | | | Yes  No |
| **Guide questions for reviewing the informed consent process and form** | | | | | | | |
| Is it necessary to seek the informed consent of the participants?  Unable to Assess  Yes  No  If NO, please explain. | | | | | | | |
| If YES, are the participants provided with sufficient information regarding: | | | | | |  | |
| * Purpose of the study? | | | | | | Yes No | |
| * Expected duration of participation? | | | | | | Yes No | |
| * Procedures to be carried out? | | | | | | Yes No | |
| * Discomforts and inconveniences? | | | | | | Yes  No | |
| * Risks (including possible discrimination)? | | | | | | Yes  No | |
| * Random assignment to the trial treatments? | | | | | | Not applicable  Yes  No | |
| * Benefits to the participants? | | | | | | Yes  No | |
| * Alternative treatments/ procedures? | | | | | | Not applicable  Yes  No | |
| * Compensation and/or medical treatments in case of injury? | | | | | | Yes  No | |
| * Who to contact for pertinent questions and / or for assistance in a research- related injury? | | | | | | Yes  No | |
| * Refusal to participate or discontinuance at any time will involve penalty or loss of benefits to which the subject is entitled? | | | | | | Yes  No | |
| * Extent of confidentiality? | | | | | | Yes  No | |
| Is the informed consent written or presented in lay language that participants can understand?  Yes  No | | | | | | | |
| Does the protocol include an adequate process for ensuring that consent is voluntary?  Yes  No | | | | | | | |
| Do you have any other concerns? | | | | | | | |

**Recommendation:**   **Approved**

**Minor revisions required**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Major revisions required**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Disapproved**

**Reasons for disapproval:**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Name and Signature of Reviewer Review Date**