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| NEC LOGO  (no name) | **NATIONAL ETHICS COMMITTEE**  **STANDARD OPERATING PROCEDURES** | | |
| **REVIEWER’S WORKSHEET** | NEC Form No. | 4 |
| NEC SOP | 05 & 06 |
| Version No. | 2 |
| Version Date | 15 July 2014 |

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| Title of Study |  | | | | | |
| NEC Code | |  | Type of Review | |  | |
| Principal Investigator | |  | Institution | |  | |
| Reviewer | |  | | Primary reviewer | | Yes No |
| **Guide questions for reviewing the proposal / protocol** | | | | | | |
| Is/Are the proposal’s scientific question(s) reasonable?  Unable to Assess  Yes  No  If NO or UNABLE TO ASSESS, please explain. | | | | | | |
| Does the research need to be carried out with human participants? Unable to Assess Yes  No  If NO or UNABLE TO ASSESS, please explain. | | | | | | |
| Does the study involve individuals who belong to vulnerable groups? Unable to Assess Yes No  If YES or UNABLE TO ASSESS, please explain. | | | | | | |
| Are appropriate mechanisms in place to protect above individuals in vulnerable groups?  Unable to Assess Yes No  If NO or UNABLE TO ASSESS, please explain. | | | | | | |
| Are there probable risks to the human participants in the study? Unable to Assess Yes  No  If NO or UNABLE TO ASSESS, please explain. | | | | | | |
| Does the protocol adequately address the risk / benefit balance?? Unable to Assess Yes  No  If NO or UNABLE TO ASSESS, please explain. | | | | | | |
| Does the protocol adequately present informational background as to the result of previous studies prior to human experimentation?  Not applicable Yes  No | | | | | | |
| Are toxicological and pharmacological data adequate? Not applicable Yes  No | | | | | | |
| Is the informed consent procedure / form adequate and culturally appropriate?  Not applicable  Yes  No | | | | | | |
| Is/are the investigator/s adequately trained and do they have sufficient experience?  Unable to assess Yes  No | | | | | | |
| Are the research facilities adequate? Unable to assess Yes  No | | | | | | |
| Do you have any other concerns? | | | | | | |

**Recommendation:**  **Approved**

**Minor revisions required**

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**Major revisions required**

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**Disapproved**

**Reasons for disapproval:**

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**Name and Signature of Reviewer Review Date**