**PROTOCOL ASSESSMENT FORM**

|  |  |  |  |
| --- | --- | --- | --- |
| **DATE SUBMITTED** | Click or tap to enter a date. | **FIERC PROTOCOL CODE** | Click or tap here to enter text. |

|  |  |
| --- | --- |
| **PROTOCOL TITLE** | Click or tap here to enter text. |

|  |  |  |  |
| --- | --- | --- | --- |
| **PRINCIPAL INVESTIGATOR** | Click or tap here to enter text. | **INSTITUTION / DIVISION** | Click or tap here to enter text. |

|  |  |  |
| --- | --- | --- |
| **TYPE OF REVIEW** | [ ]  **FULL REVIEW**  | [ ]  **EXPEDITED REVIEW** |

|  |  |
| --- | --- |
| **INSTRUCTIONS****To the Principal Investigator:** | Please put 🗹 if the study protocol contains the specified assessment point and indicate page and paragraph number where it is found.  |
| **To the Primary Reviewer:** | Please evaluate how the assessment points below have been properly addressed by the study protocol, as applicable by confirming the submitted information indicate your comments in the space provided. Specify your action to be taken under “RECOMMENDED ACTION” and your conclusion under “SUMMARY OF RECOMMENDATION”. Please sign the space provided for the primary reviewer. |

|  |
| --- |
| **PROTOCOL DOCUMENT REVIEW** |

|  | **To be filled out by the PRINCIPAL INVESTIGATOR** | **To be filled out by the PRIMARY REVIEWER** |
| --- | --- | --- |
| **ASSESSMENT POINTS** | Indicate if the study protocol contains the specified assessment point | Page and paragraph where it is found | **REVIEWER’S COMMENTS** |
| 1. **SOCIAL VALUE**

*Review of relevance of the study to an existing social or health problem such that the results are expected to bring about a better understanding of related issues, or contribute to the promotion of well-being of individuals, their families, and communities (NEGHHR 2017)* | [ ]  **YES** | [ ]  **NO** | [ ]  **N/A** |  |  |
| 1. **SCIENTIFIC DESIGN**
 |  |  |  |  |  |
| * 1. **Objectives**

*Are the study objectives specific, measuarable, attainable, and reasonable? (2022 NEGRIHP page 343, item 2)* | [ ]  **YES** | [ ]  **NO** | [ ]  **N/A** |  |  |
| * 1. **Literature Review**

*Does the protocol present sufficient background information or results of previous studies prior to human experimentation. (2022 NEGRIHP 2022)*  | [ ]  **YES** | [ ]  **NO** | [ ]  **N/A** |  |  |
| * 1. **Research design**

*Review of appropriateness of design in view of objectives )UPMREB FORM 2(C)2012 24/01/2022)* | [ ]  **YES** | [ ]  **NO** | [ ]  **N/A** |  |  |
| * 1. **Sampling design**

*Review of appropriateness of sampling methods and techniques (UPMREB FORM2(C) 2012 24/01/2022)* | [ ]  **YES** | [ ]  **NO** | [ ]  **N/A** |  |  |
| * 1. **Sample size and site recruitment or accrual ceiling**

*Review of justification of sample size (UPMREB FORM2(C) 2012 24/01/2022)* | [ ]  **YES** | [ ]  **NO** | [ ]  **N/A** |  |  |
| * 1. **Data analysis plan**

*Review of appropriateness of statistical and non-statistical methods to be used and how participant data will be summarized (UPMREB FORM2(C) 2012 24/01/2022)* | [ ]  **YES** | [ ]  **NO** | [ ]  **N/A** |  |  |
| * 1. **Inclusion criteria**

*Review of precision of criteria both for scientific merit and safety concerns; and equitable selection (UPMREB FORM2 (C) 2012 24/01/2022)* | [ ]  **YES** | [ ]  **NO** | [ ]  **N/A** |  |  |
| * 1. **Exclusion criteria**

*Review of criteria precision both for scientific merit and safety concerns; and of justified exclusion (UPMREB FORM2(C) 2012 24/01/2022)* | [ ]  **YES** | [ ]  **NO** | [ ]  **N/A** |  |  |
| * 1. **Withdrawal criteria**

*Review of criteria precision both for scientific merit and safety concerns (UPMREB FORM2(C) 2012 24/01/2022)* | [ ]  **YES** | [ ]  **NO** | [ ]  **N/A** |  |  |
| 1. **CONDUCT OF STUDY**
 |  |  |  |  |  |
| **3.1 Data collectio plan***Review appropriateness of data collection, including description of personal data to be collected. For studies involving use of database, review of database management and role of personal data collector, as well as authority of investigator to assess data (UPMREB FORM2(C) 2012 24/01/2022)* | [ ]  **YES** | [ ]  **NO** | [ ]  **N/A** |  |  |
| **3.2 Specimen handing***Review of specimen storage, access, disposal, and terms of use, including appropriateness of biobank custodian and adherence to institutional guidelines for biobanking, including provision for sample and data removal and destruction for biobanked samples (UPMREB FORM2(C) 2012 24/01/2022)* | [ ]  **YES** | [ ]  **NO** | [ ]  **N/A** |  |  |
| **3.3 PrincipaI Investigator’s**  **qualifications***Review CV and relevant certifications to ascertain capability to manage study related risk (UPMREB FORM2(C) 2012 24/01/2022)* | [ ]  **YES** | [ ]  **NO** | [ ]  **N/A** |  |  |
| **3.4 Suitability of site***Review of adequacy of qualified staff and infrastructures (UPM REB FORM 2(C) 2012, 24/01/2022)* | [ ]  **YES** | [ ]  **NO** | [ ]  **N/A** |  |  |
| **3.5 Duration of participant** **Involvement***Review of length/extent of human participant involvement in the study (UPMREB FORM 2(C) 2012 24/01/2022)* | [ ]  **YES** | [ ]  **NO** | [ ]  **N/A** |  |  |
| 1. **ETHICAL CONSIDERATIONS**
 |  |  |  |  |  |
| * 1. **Transparency and Conflict of Interest**

*Review of management of conflict arising from financial, familial or proprietary considerations of the Principal Investigator, sponsor, or the study site* *(UPMREB FORM2(C) 2012 24/01/2022)* | [ ]  **YES** | [ ]  **NO** | [ ]  **N/A** |  |  |
| * 1. **Privacy, confidentiality, and data collection plan**

*Review of measures or guarantee to protect privacy and confidentiality of participant information and in compliance with the Data Privacy Act of 2012 as indicated by data collection methods including data protection plans including the steps to be taken so that all who have access to the data and the identities of the respondents can safeguard privacy and confidentiality (ex. Providing adequate instructions to research assistants, transcribers, or translator (NEGHHR 2017)* *Review of appropriateness of processing personal data, storage of data, access, disposal, and terms of use (NEGHHR 2017; Data Privacy Act of 2012 & UPMREB FORM2(C) 2012 24/01/2022)*  | [ ]  **YES** | [ ]  **NO** | [ ]  **N/A** |  |  |
| * 1. **Informed consent process**

*Review of application of the principle of respect for persons, who may solicit consent, how and when it will be done; who may give consent especially in case of special population like minors and those who are not legally competent to give consent, or indigenous people which require additional clearance use (UPMREB FORM 2 (C) 2012 24/01/2022)*  | [ ]  **YES** | [ ]  **NO** | [ ]  **N/A** |  |  |
| * 1. **Waiver of informed consent**

*Review of justification for waiver of informed consent or waiver of documentation of consent with considerations to potential risl to participants, collection of data, and mechanisms to ensure confidentiality and anonymity (UPMREB FORM2(C) 2012 24/01/2022)*  | [ ]  **YES** | [ ]  **NO** | [ ]  **N/A** |  |  |
| * 1. **Justification for the involvement of vulnerable groups**

*Review of involvement of vulnerable study populations. Vulnerable groups include the elderly, ethnic and racial minority groups, the homeless, prisoners, people with incurable disease, people who are politically powerless, or junior members of hierarchical group. Involvement of vulnerable groups must always be assessed in the context of the protocol and the participants (UPM REB FORM 2(C) 2012 24/01/2022)* | [ ]  **YES** | [ ]  **NO** | [ ]  **N/A** |  |  |
| * 1. **Assent for elderly**

*For adults who are not competent to consent (for example, elderly or adults with conditions that prevent appropriate consent), review feasibility of obtaining assent vis à vis incompetence to consent. (UPMREB FORM2(C) 2012 24/01/2022)*  | [ ]  **YES** | [ ]  **NO** | [ ]  **N/A** |  |  |
| * 1. **Assent for minors**

*Review of feasibility of obtaining assent vis à vis incompetence to consent; Review of applicability of the assent age brackets in children:**0-under 7: No assent**7-under 12: Verbal Assent**12-under15: Simplified Assent Form**15-under18:Co-sign informed consent form with parents**(UPMREB FORM2(C) 2012 24/01/2022)*  | [ ]  **YES** | [ ]  **NO** | [ ]  **N/A** |  |  |
| * 1. **Recruitment**

*Review of manner of recruitment including appropriateness of identified recruiting parties (UPMREB FORM2(C) 2012 24/01/2022)*  | [ ]  **YES** | [ ]  **NO** | [ ]  **N/A** |  |  |
| * 1. **Risks**

*Review of level of risk and measures to mitigate the risk (including physical, psychological, social, economic) including plans for adverse event management; Review of justification for allowable use of placebo as detailed in the Declaration of Helsinki (as applicable); Review of course of actions in case of breach of data (as applicable) (UPMREB FORM2(C) 2012 24/01/2022)*  | [ ]  **YES** | [ ]  **NO** | [ ]  **N/A** |  |  |
| * 1. **Benefits**

*Review of potential direct benefit to participants; the potential to yield generalizable knowledge about the participants’ condition/problem; non-material compensation to participant (health education or other creative benefits), where no clear, direct benefit from the project will be received by the participant (UPMREB FORM2(C) 2012 24/01/2022)*  | [ ]  **YES** | [ ]  **NO** | [ ]  **N/A** |  |  |
| * 1. **Safety monitoring plan**

*Review of appropriateness of measures to assess risk and burdens to the participants and precautions taken to minimize negative impact of the study on the well-being of the participants (UPMREB FORM2(C) 2012 24/01/2022)*  | [ ]  **YES** | [ ]  **NO** | [ ]  **N/A** |  |  |
| * 1. **Incentives or compensation**

*Review of amount and method of compensations, financial incentives, or reimbursement of study-related (UPMREB FORM2(C) 2012: 24/01/2022)*  | [ ]  **YES** | [ ]  **NO** | [ ]  **N/A** |  |  |
| * 1. **Compensation for study-related injuries**

*Review of amount and method of compensations for study-related injuries, including treatment entitlements, or certificate of insurance for clinical trials (UPMREB FORM2(C) 2012 24/01/2022)*  | [ ]  **YES** | [ ]  **NO** | [ ]  **N/A** |  |  |
| * 1. **Community considerations**

*Review of impact of the research on the community where the research occurs and/or to whom findings can be linked; including issues like stigma or draining of local capacity; sensitivity to cultural traditions, and involvement of the community in decisions about the conduct of study (UPMREB FORM2(C) 2012 24/01/2022)*  | [ ]  **YES** | [ ]  **NO** | [ ]  **N/A** |  |  |
| * 1. **Collaborative study terms of reference**

*Review of terms of collaborative study reference in case of multi-country / multi-institutional studies, including intellectual property rights, publication rights, information and responsibility sharing, transparency, and capability building (UPMREB FORM2(C) 2012 24/01/2022)*  | [ ]  **YES** | [ ]  **NO** | [ ]  **N/A** |  |  |
| * 1. **Dissemination / data sharing plan / statement**

*Review of appropriateness in the sharing research results which may have significant implications on the well-being of the participants and the community and in relation to achieving social value (UPMREB FORM2(C) 2012 24/01/2022)*  | [ ]  **YES** | [ ]  **NO** | [ ]  **N/A** |  |  |
| * 1. **Other Issues**

*Review of issues not subsumed in the protocol study (UPM REB FORM 2(C) 2012 ,24/01/2022)* | [ ]  **YES** | [ ]  **NO** | [ ]  **N/A** |  |  |
| **RECOMMENDED ACTION**[ ]  **APPROVE**[ ]  **MINOR REVISIONS REQUIRED**[ ]  **MAJOR REVISIONS REQUIRED**[ ]  **DISAPPROVED**

|  |
| --- |
| **SUMMARY OF RECOMMENDATIONS:****1.****2.****3.****4.****5.** |

|  |
| --- |
| **JUSTIFICATION FOR RECOMMENDED ACTION:****Overall Risk Benefit Assessment:**[ ]  **Favorable**[ ]  **Unfavorable** |

|  |  |
| --- | --- |
| **PRIMARY REVIEWER:**Click or tap here to enter text.**Signature over Printed Name** | Click or tap to enter a date.**Date:**  |

 |