

**IRB PROTOCOL EVALUATION FORM\* (Form 3.1)**

IRB Protocol Code: Date (D/M/Y):

Protocol Title: Sponsor:

Date of Submission:

Principal Investigator: Contact no./ Email

Adviser: Contact no./ Email

Study Coordinator/s: Contact no./ Email

Type of Study: Review Status:

() Intervention ( ) Epidemiology ( ) Observational study

( ) Document review ( ) Individual based ( ) Genetic

( ) Social Survey ( ) Others, specify

( ) Full Board

( ) Expedited

Description of the Study in brief: Mark whatever applies:

( ) Double blind ( ) Multicenter study ( ) Single blind ( ) Open label

( ) Sponsor Initiated ( ) Global protocol ( ) Investigator Initiated ( ) Vaccine ( ) Diagnostics

( ) Observational ( ) Questionnaire ( ) Use of Genetic Materials ( ) Medical Device

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **To be filled out by the Primary Reviewer** | | | | |
| **ASSESSMENT POINTS** |  | | | **REVIEWER’S FINDINGS/COMMENTS** | **REVIEWER’S RECOMMEND-ATIONS** |
| **1. SOCIAL VALUE** |  | | | | |
| **1.1** 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.  *(NEGRIHP 2022 page 15)* | * Clear | * Unclear |  |  |  |
| **2. SCIENTIFIC DESIGN** |  | | | | |
| **2.1 Objectives**  Are the objectives attainable, S.M.A.R.T.? | * Clear | * Unclear |  |  |  |
| **2.2 Literature review**  Does review of literature of describe previous studies in the Philippines/foreign countries show gaps in knowledge regarding the topic.  *NEGRIHP 2022 page 46)* | * Complete | * Incomplete |  |  |  |
| **2.3 Research design**  Can the objective be attained using the research design?  *(NEGRIHP 2022 page 108)* | * Clear | * Unclear |  |  |  |
| **2.4 Sampling design**  Is the sampling technique as describe in the research design appropriate?  *(ICH GCP 6.9.1)* | * Clear | * Unclear |  |  |  |
| **2.5 Sample size and site recruitment or accrual ceiling**  Review of justification of sample size.  *(ICH GCP 6.9.2)* | * Clear | * Unclear |  |  |  |
| **2.6 Procedures for recruitment**  Statement on who, when and how the recruitment process is done. If you are the caregiver of the participants, how are you going to recruit? | * Clear | * Unclear |  |  |  |
| **2.7 Process of securing Informed Consent**  Statement on who, when and how to secure the IC process. If you are the caregiver of the participants, how are you going to secure the IC? | * Clear | * Unclear |  |  |  |
| **2.8 Data analysis plan**  Review of appropriateness of statistical and non-statistical methods to be used and how participant data will be summarized.  *(NEGRIHP 2022 page 46)* | * Clear | * Unclear |  |  |  |
| **2.9 Inclusion criteria**  Review of precision of criteria both for scientific merit and safety concerns; and of equitable selection.  *(NEGRIHP 2022 page 46)* | * Clear | * Unclear |  |  |  |
| **2.10 Exclusion criteria**  Review of criteria precision both for scientific merit and safety concerns; and of justified exclusion.  *(NEGRIHP 2022 page 46)* | * Clear | * Unclear |  |  |  |
| **2.11 Withdrawal criteria**  Review of the withdrawal criteria whether it is precise both for scientific merit and safety concerns.  *(NEGRIHP 2022 page 108)* | * Clear | * Unclear |  |  |  |
| **3. CONDUCT OF STUDY** |  | | | | |
| **3.1 Data collection plan**  Review of appropriateness of data collection tool, (e.g chart review, survey, CRF) including description of personal data to be collected.  *(NEGRIHP 2022 page 46)* | * Clear | * Unclear |  |  |  |
| **3.2 Specimen handling**  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.  *(NEGRIHP 2022 page 231)* | * Clear | * Unclear |  |  |  |
| **3.3 PI qualifications**  Review of CV and relevant certifications to ascertain capability to manage study methods and study related risks. *(NEGRIHP page 32)* | * Qualified | * Unqualified |  |  |  |
| **3.4 Suitability of site**  Review of adequacy of qualified staff and infrastructures.  *(NEGRIHP 2022 page 51)* | * Suitable | * Not Suitable |  |  |  |
| **3.5 Duration of participant involvement**  Review of length/extent of human participant involvement in the study.  *(NEGRIHP 2022 page 108)* | * Clear | * Unclear |  |  |  |
| **4. ETHICAL CONSIDERATIONS** |  | | | | |
| **4.1 Transparency and Conflict of interest**  Review of management of conflict arising from financial, familial, or proprietary considerations of the PI, sponsor, or the study site.  *(NEGRIHP page 51)* | * Clear | * Unclear |  |  |  |
| **4.2 Privacy, confidentiality, and data protection plan**  Review of measures or guarantees 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 translators) *(NEGRIHP 2022)*; Review of appropriateness of processing personal data, storage of data, access, disposal, and terms of use. *(NEGRIHP 2022 page 50 Data Privacy Act of 2012)* | * Clear | * Unclear |  |  |  |
| **4.3 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 populations like minors and those who are not legally competent to give consent, or indigenous people which require additional clearances.  *(NEGRIHP 2022 page 46)* | * Clear | * Unclear | * N/A |  |  |
| **4.4 Waiver of informed consent**  Review of justification for waiver of informed consent or waiver of documentation of consent with considerations to potential risk to participants, collection of data, and mechanisms to ensure confidentiality and anonymity.  *(NEGRIHP 2022 page 134)* | * Clear | * Unclear | * N/A |  |  |
| **4.5 Justification for the involvement of vulnerable groups**  Review of involvement of vulnerable study populations and impact on informed consent. Vulnerable groups include the minors, elderly, ethnic and racial minority groups, the homeless, prisoners, people with incurable disease, people who are politically powerless, or junior members of a hierarchical group. Involvement of vulnerable groups must always be assessed in the context of the protocol and the participants.  *(NEGRIHP 2022 page 23)* | * No | * Yes | * N/A |  |  |
| **4.6 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.  *(NEGRIHP 2022 page 47)* | * No | * Yes | * N/A |  |  |
| **4.7 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:  •< 7 y/o- No need for assent  •7 to < 12 y/o- Verbal Assent  •12 to <15 y/o: Simplified written assent  •15 to < 18 y/o- the minor can co-sign the consent signed by the parents.  (NEGRIHP 2022 page 141) | * No | * Yes | * N/A |  |  |
| **4.8 Recruitment**  Review of manner of recruitment including appropriateness of identified recruiting parties.  *(NEGRIHP 2022 page 31)* | * Clear | * Unclear | * N/A |  |  |
| **4.9 Risks**  Review of level of risk and measures to mitigate these risks (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 action in case of breach of data (as applicable). *(NEGRIHP 2022 page 46; page 50)* | * Clear | * Unclear |  |  |  |
| **4.10 Are the provisions for the mitigation of risks in the ICF consistent with what is in the protocol?** | * Consistent | * Inconsistent |  |  |  |
| **4.11 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. *(NEGRIHP 2022 page 46; page 50)* | * Clear | * Unclear |  |  |  |
| **4.12 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.  *(NEGRIHP 2022 page 50)* | * Clear | * Unclear |  |  |  |
| **4.13 Post-trial access**  Description of post-study access to the study product or intervention that have been proven safe and effective, as applicable.  *(NEGRIHP 2022 page 71)* | * No | * Yes | * N/A |  |  |
| **4.14 Incentives, compensation or Reimbursement**  Review of amount and method of compensations, financial incentives, or reimbursement of study-related expenses. *(NEGRIHP 2022 page 26)* | * No | * Yes | * N/A |  |  |
| **4.15 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. *(NEGRIHP 2022 page 26, page 196)* | * No | * Yes | * N/A |  |  |
| **4.16 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.  *(NEGRIHP 2022 page 51)* | * No | * Yes | * N/A |  |  |
| **4.17 Collaborative study terms of reference**  Review of terms of collaborative study especially in case of multi-country/multi-institutional studies, including intellectual property rights, publication rights, information and responsibility sharing, transparency, and capacity building.  *(NEGRIHP 2022 page 47)* | * No | * Yes | * N/A |  |  |
| **4.18 Dissemination / data sharing plan/ statement**  Review of appropriateness and the practicability of the dissemination plan, as well as the suitability of the recipient(s) of the information to achieving social value. *(NEGRIHP 2022 page 15)* | * Clear | * Unclear |  |  |  |
| **4.19 Other issues**  Review of issues not addressed by item 1-4.18 |  |  |  |  |  |

SUMMARY OF FINDINGS:

SUMMARY OF RECOMMENDATIONS:

**DECISION:**

Approved Major Revisions Minor Revision Disapproved

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Date**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Name and Signature of Primary Reviewer**