**Informed Consent Assessment Form**

| **STUDY PROTOCOL INFORMATION** | |
| --- | --- |
| **Reference Number:[[1]](#footnote-0)** |  |
| **UPMREB Code:[[2]](#footnote-1)** |  |
| **Study Protocol Title:** |  |
| **Principal Investigator:** | <Title, Name, Surname> |
| **Study Protocol Submission Date:** | <dd/mm/yyyy> |

**INSTRUCTIONS**

| To the Principal Investigator: | Please indicate in the space provided below whether or not the specified element is addressed by the informed consent form (ICF). To facilitate the evaluation of the assessment point, indicate the page and paragraph where this information can be found. |
| --- | --- |
| To the Primary Reviewer: | Please evaluate how the elements outlined below have been appropriately addressed by the main informed consent form (ICF) and any additional ICFs, as applicable. Indicate, for each item, which ICF the comment is referring to and by confirming the submitted information and putting your comments in the space provided under “REVIEWER COMMENTS.” In your comments, ensure that **vulnerability, recruitment process, and process of obtaining informed** consent are always assessed in the context of the study protocol and the participant. Finalize your review by indicating your conclusions under “RECOMMENDED ACTION” and signing in space provided for the primary reviewer. |

|  | | **To be filled out by the PI** | | | | **To be filled out by the Primary Reviewer** | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Essential Elements**  **(as applicable to the study)** | | Indicate if the ICF has the specified element | | | Page and paragraph where element is found | **REVIEWER COMMENTS** | **REVIEWER RECOMMEND-ATIONS** |
| **YES** | | **N/A** |  |  |  |
| 1. Statement that the study involves research *(ICH GCP 4.8.10.a)* | |  | |  |  |  |  |
| 1. Statement describing the purpose of the study *(ICH GCP 4.8.10.b)* | |  | |  |  |  |  |
| 1. Study-related treatments and probability for random assignment *(ICH GCP 4.8.10.c)* | |  | |  |  |  |  |
| 1. Study procedures including all invasive procedures *(ICH GCP 4.8.10.d)* | |  | |  |  |  |  |
| 1. *Site-specific recruitment including appropriateness of identified recruiting parties (NEGRIHP 2022, page 31 item 1.4)* | |  | |  |  |  |  |
| 1. Responsibilities of the participant *(ICH GCP 4.8.10.e)* | |  | |  |  |  |  |
| 1. Expected duration of participation in the study *(ICH GCP 4.8.10.s)* | |  | |  |  |  |  |
| 1. Approximate number of participants in the study *(ICH GCP 4.8.10.t)* | |  | |  |  |  |  |
| 1. Study aspects that are experimental *(ICH GCP 4.8.10.f)* | |  | |  |  |  |  |
| 1. Foreseeable risks to participant/embryo/ fetus/nursing infant; including pain, discomfort, or inconvenience associated with participation including risks to spouse or partner; and integrating risks as detailed in the investigator’s brochure *(ICH GCP 4.8.10.g)* | |  | |  |  |  |  |
| 1. Risks from allowable use of placebo (as applicable) *(NEGRIHP 2022, page 17 item 12.5, pages 109-111, Use of Placebo)* | |  | |  |  |  |  |
| 1. Reasonably expected benefits; or absence of direct benefit to participants, as applicable *(ICH GCP 4.8.10.h)* | |  | |  |  |  |  |
| 1. Expected benefits to the community or to society, or contributions to scientific knowledge*(NEGRIHP 2022, page 17 item 12.6)* | |  | |  |  |  |  |
| 1. Description of post-study access to the study product or intervention that have been proven safe and effective, as applicable *(NEGHHR page 64 item 6.12)* | |  | |  |  |  |  |
| 1. Alternative procedures or treatment available to participant, as applicable *(NEGHHR page 155 item 16)* | |  | |  |  |  |  |
| 1. Anticipated payment, if any, to the participant in the course of the study; whether money or other forms of material goods, and if so, the kind and amount   *(NEGRIHP 2022, page 17 item 12.7)* | |  | |  |  |  |  |
| 1. Compensation (or no plans of compensation) for the participant or the participant’s family or dependents in case of disability or death resulting from study-related injuries *(ICH GCP 4.8.10.j)* | |  | |  |  |  |  |
| 1. Anticipated expenses, if any, to the participant in the course of the study *(ICH GCP 4.8.10.l)* | |  | |  |  |  |  |
| 1. Statement that participation is voluntary and may be withdrawn anytime without penalty or loss of benefit to which the participant is entitled *(ICH GCP 4.8.10.m)* | |  | |  |  |  |  |
| 1. For research involving children and adolescents, statement that consent will be obtained if the participant reaches legal age in the duration of the study, as applicable (*NEGHHR 2017 page 131 par. 2)* | |  | |  |  |  |  |
| 1. Applicable assent age brackets in children:   0-under 7: No assent  7-under 12: Verbal Assent  12-under15: Simplified Assent Form  15-under 18: Co-sign informed consent form with parents  *(NEGRIHP 2022, pages 141-142, Integrity of the child and respect for autonomy; and ICH GCP E11 R1 page 11, item 2.6.3)* | |  | |  |  |  |  |
| 1. Applicable assent for non-legally consenting adult   *(NEGRIHP 2022, page 16 item 8)* | |  | |  |  |  |  |
| 1. Statement that the study monitor(s), auditor(s), the UPMREB Ethics Review Panel, and regulatory authorities will be granted direct access to participant’s medical records for purposes **ONLY** of verification of clinical trial procedures and data *(ICH GCP 4.8.10.n)* | |  | |  |  |  |  |
| 1. Statement that the records identifying the participant will be kept confidential and will not be made publicly available, to the extent permitted by law; and that the identity of the participant will remain confidential in the event the study results are published; including limitations to the investigator’s ability to guarantee confidentiality *(ICH GCP 4.8.10.o)* | |  | |  |  |  |  |
| 1. Description of data protection plan and details about storage (including who has access to the study-related documents, how long identifying data will be stored, and manner of storage) *(NEGRIHP 2022, page 19 item 12.14)* | |  | |  |  |  |  |
| 1. Description of policy regarding the use of genetic tests and familial genetic information, as applicable, and the precautions in place to prevent disclosure of results to immediate family relative or to others without consent of the participant *(NEGRIHP 2022, page 198-202, ETHICAL GUIDELINES FOR GENETICS AND GENOMIC RESEARCH)* | |  | |  |  |  |  |
| 1. Possible direct or secondary use of participant’s medical records and biological specimens taken during clinical care or in the course of this study, as applicable. Plans for the destruction of collected biological specimens at the end of the designated storage period will be outlined. Alternatively, details regarding storage duration, facility type, location, access protocols, and potential future utilization will be provided. Participants retain the right to refuse future use, storage, or request the destruction of materials.   *(NEGRIHP 2022, page 19 item 12.15 and 12.16)* | |  | |  |  |  |  |
| 1. Plans to develop commercial products from biological specimens and whether the participant will receive monetary or other benefit from such development *(NEGRIHP 2022, page 19 item 12.17)* | |  | |  |  |  |  |
| 1. Statement that the participant or participant’s legally acceptable representative will be informed in a timely manner if information becomes available that may be relevant to willingness of the participant to continue to participation *(ICH GCP 4.8.10.p)* | |  | |  |  |  |  |
| 1. Foreseeable circumstances and reasons under which participation in the study may be terminated *(ICH GCP 4.8.10.r)* | |  | |  |  |  |  |
| 1. Sponsor, institutional affiliation of the investigators, and nature and sources of funds *(NEGRIHP 2022, page 19 item 12.12)* | |  | |  |  |  |  |
| 1. Statement whether the investigator is serving only as an investigator or as both investigator and the participant’s healthcare provider *(NEGRIHP 2022, page 20item 12.18)* | |  | |  |  |  |  |
| 1. Person(s) to contact in the study team for further information regarding the study and whom to contact in the event of study-related injury *(ICH GCP 4.8.10.q)* | |  | |  |  |  |  |
| 1. Statement that the UPMREB Ethics Review Panel (specify) has approved the study, and may be reached through the following contact for information regarding rights of study participants, including grievances and complaints:   **Name of UPMREB Panel Chair**  **Address:** Room 126, Ground Floor  National Institutes of Health, UP Manila  623 Pedro Gil St  Ermita 1000 Manila  **Email:** [upmreb@post.upm.edu.ph](mailto:upmreb@post.upm.edu.ph)  **Tel:** +63 2 8526-4346  *(NEGRIHP 2022, page 20 item 12.22.)* | |  | |  |  |  |  |
| 1. Comprehensibility of language used *(NEGRIHP 2022, page 16 item 12)* | |  | | | |  |  |
| **RECOMMENDED ACTION:** | | | | | | |  |
| * APPROVE | | | | | | |  |
| * MINOR MODIFICATIONS | | | | | | |  |
| * MAJOR MODIFICATIONS * DISAPPROVE * PENDING, IF MAJOR CLARIFICATIONS ARE REQUIRED BEFORE A DECISION CAN BE MADE | | | | | | |  |
| SUMMARY OF RECOMMENDATIONS:  1.  2.  3.  4.  5. | | | | | | | |
| **JUSTIFICATION FOR RECOMMENDED ACTION** | | | | | | | |
| **PRIMARY REVIEWER** | | | Signature | |  | | |
| Date: <dd/mm/yyyy> | | | Name | | <Title, Name, Surname> | | |

1. To be issued upon RGAO registration [↑](#footnote-ref-0)
2. To be issued upon initial processing by UPMREB [↑](#footnote-ref-1)