| **STUDY PROTOCOL INFORMATION** | |
| --- | --- |
| **Reference Number:[[1]](#footnote-0)** |  |
| **UPOU IREB Code:[[2]](#footnote-1)** |  |
| **Study Protocol Title:** |  |
| **Principal Investigator:** |  |
| **Study Protocol Submission Date:** |  |

**INSTRUCTIONS**

| To the Principal Investigator: | Does your research involve human participants?   * Yes * No   If yes, please proceed in accomplishing this form. 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 informed consent form (ICF), as applicable, 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 applying research ethics** 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** | | | |  |
| **Essential Elements**  **(as applicable to the study)** | | | | Indicate if the ICF has the specified element | | | Page and paragraph where element is found | **REVIEWER COMMENTS** |
| **YES** | **N/A** | |  |  |
| 1. Statement that the study involves research | | | |  |  | |  |  |
| 1. Statement describing the purpose of the study | | | |  |  | |  | 1. **Objectives**   *Review of viability of expected output*   * 1. **Research design**   *Review of appropriateness of design in view of objectives* |
| 1. Study-related treatments and probability for random assignment | | | |  |  | |  |  |
| 1. Study procedures including all invasive procedures | | | |  |  | |  |  |
| 1. Responsibilities of the participant | | | |  |  | |  |  |
| 1. Expected duration of participation in the study | | | |  |  | |  | 1. **Duration**   *Review of length/extent of human participant involvement in the study* |
| 1. Approximate number of participants in the study | | | |  |  | |  | * 1. **Sampling design**   *Review of appropriateness of sampling methods and techniques*   1. **Sample size**   *Review of justification of sample size*  ***Inclusion criteria***  *Review of precision of criteria both for scientific merit and safety concerns; and of equitable selection*  ***Exclusion criteria***  *Review of criteria precision both for scientific merit and safety concerns; and of justified exclusion*  ***Withdrawal criteria***  *Review of criteria precision both for scientific merit and safety concerns* |
| 1. Study aspects that are experimental | | | |  |  | |  |  |
| 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~~ | | | |  |  | |  |  |
| 1. ~~Risks from allowable use of placebo (as applicable)~~ | | | |  |  | |  |  |
| 1. Reasonably expected benefits; or absence of direct benefit to participants, as applicable | | | |  |  | |  | * 1. **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)* |
| 1. Expected benefits to the community or to society, or contributions to scientific knowledge (e.g. study products of clinical trials) | | | |  |  | |  | * 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*  ***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* |
| 1. ~~Description of post-study access to the study product or intervention that have been proven safe and effective~~ | | | |  |  | |  |  |
| 1. Alternative procedures or treatment available to participant | | | |  |  | |  |  |
| 1. Compensation or insurance or treatment entitlements of the participant in case of study-related injury | | | |  |  | |  | 1. **Incentives or compensation**   *Review of amount and method of compensations, financial incentives, or reimbursement of study-related expenses* |
| 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 | | | |  |  | |  |  |
| 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 | | | |  |  | |  |  |
| 1. Anticipated expenses, if any, to the participant in the course of the study | | | |  |  | |  |  |
| 1. Statement that participation is voluntary, and that participant may withdraw anytime without penalty or loss of benefit to which the participant is entitled | | | |  |  | |  |  |
| 1. Statement that the study monitor(s), auditor(s), the UPOU IREB, and regulatory authorities will be granted direct access to participant’s medical records for purposes **ONLY** of verification of ~~clinical trial procedures~~ and data | | | |  |  | |  |  |
| 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 | | | |  |  | |  | 1. **Privacy and confidentiality**   *Review of measures or guarantees to protect privacy and confidentiality of participant information as indicated by data collection methods including data protection plans* |
| 1. ~~Description of policy regarding the use of genetic tests and familial genetic information, and the precautions in place to prevent disclosure of results to immediate family relative or to others without consent of the participant~~ | | | |  |  | |  |  |
| 1. Possible direct or secondary use of participant’s medical records and biological specimens taken in the ~~course of clinical care or in the~~ course of this study | | | |  |  | |  |  |
| 1. Plans to destroy collected biological specimen at the end of the study; if not, details about storage (duration, type of storage facility, location, access information) and possible future use; affirming participant’s right to refuse future use, refuse storage, or have the materials destroyed | | | |  |  | |  |  |
| 1. ~~Plans to develop commercial products from biological specimens and whether the participant will receive monetary or other benefit from such development~~ | | | |  |  | |  |  |
| 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 | | | |  |  | |  |  |
| 1. Statement describing access of participant to the result of the study | | | |  |  | |  |  |
| 1. Statement describing extent of participant’s right to access his/her records (or lack thereof *vis à vis* pending request for approval of non or partial disclosure) | | | |  |  | |  |  |
| 1. Foreseeable circumstances and reasons under which participation in the study may be terminated | | | |  |  | |  |  |
| 1. Sponsor, institutional affiliation of the investigators, and nature and sources of funds | | | |  |  | |  | 1. **Conflict of interest**   *Review of management of conflict arising from financial, familial, or proprietary considerations of the PI, sponsor, or the study site* |
| 1. Statement whether the investigator is serving only as an investigator or as both investigator and the participant’s healthcare provider | | | |  |  | |  | 1. **PI qualifications**   *Review of CV and relevant certifications to ascertain capability to manage study related risks* |
| 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 | | | |  |  | |  |  |
| 1. Statement that the UPOU 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 UPOU IREC Chair**  **Address:** UPOU HQ  **Email:**  **Tel:**  **Mobile:** | | | |  |  | |  |  |
| 1. Comprehensibility of language used | | | |  | | | |  |
| 1. Other comments not addressed by items 1-34 | | | |  | | | |  |
| **RECOMMENDED ACTION:** | | | | | | | | |
| * APPROVE | | | | | | | | |
| * MINOR MODIFICATIONS | | | | | | | | |
| * MAJOR MODIFICATIONS * DISAPPROVE * PENDING, IF MAJOR CLARIFICATIONS ARE REQUIRED BEFORE A DECISION CAN BE MADE | | | | | | | | |
| **JUSTIFICATION FOR RECOMMENDED ACTION** | | | | | | | | |
| **PRIMARY REVIEWER** | |  | Signature | | |  | | |
| Date: <dd/mm/yyyy> | |  | Name | | | <Title, Name, Surname> | | |

1. To be issued upon RPC registration/submission [↑](#footnote-ref-0)
2. To be issued upon initial processing by UPOU IREC [↑](#footnote-ref-1)