**INFORMED CONSENT ASSESSMENT FORM**

**STUDY PROTOCOL INFORMATION**

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| **PSURERC Code:***(to be provided by the PSURERC Staff)* |  |
| **Study Protocol Title:** |  |
| **Principal Investigator/Lead Researcher:** |  |
| **Study Protocol Submission**  **Date:** |  |

**INSTRUCTIONS**

To the Principal Investigator/Researcher: To facilitate the evaluation of the assessment point, please indicate the page and line number/s where the pertinent 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 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 the space provided for the primary reviewer.

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| **Essential Elements**  **(as applicable to the study)** | Page and line numbers where the pertinent information can be found  (as applicable) | **REVIEWER’S COMMENTS AND RECOMMENDATIONS** |
| 1. Statement that the study involves research |  |  |
| 2. Statement describing the purpose of the  study |  |  |
| 3. Study-related treatments and probability for random assignment |  |  |
| 4. Study procedures and details of data  collection in which the participants will be  involved in. |  |  |
| 5. Responsibilities of the participant |  |  |
| 6. Expected duration of participation in the study |  |  |
| 7. Approximate number of participants in the  study |  |  |
| 8. Study aspects that are experimental |  |  |
| 9. All foreseeable risks to the participant, including pain, discomfort, or inconvenience associated with participation, including risks to spouse or partner, embryo/ fetus/nursing infant, and integrating  risks as detailed in the investigator’s brochure (if applicable), including protection strategies and mitigation measures for each risk |  |  |
| 10. Risks from allowable use of placebo (if  applicable) |  |  |
| 11. Reasonably expected benefits; or absence of direct benefit to participants, as applicable |  |  |
| 12. Expected benefits to the community or  society, or contributions to scientific  knowledge |  |  |
| 13. Description of post-study access to the study  product or intervention that has been proven safe and effective (if applicable) |  |  |
| 14. Alternative procedures or treatment available to participant (if applicable) |  |  |
| 15. Compensation, insurance, or treatment entitlements of the participant in case of study- related injury (if applicable) |  |  |
| 16. Anticipated payment or incentives, 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 |  |  |
| 17. 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(if applicable) |  |  |
| 18. Compensation, if any, for inconvenience, use of time, energy, and other resources by the partcipants due to participation, and if so, the kind and amount. |  |  |
| 19. Anticipated expenses, if any, that the participant will incur in the course of the study |  |  |
| 20. Statement that participation is voluntary, and  that participant may withdraw anytime without  penalty or loss of benefit to which the  participant is entitled |  |  |
| 21. Statement that the study monitor(s), auditor(s), the PSURERC, and regulatory authorities will be granted direct access to participant’s medical records for purposes **ONLY** of verification of clinical trial procedures and data (if applicable) |  |  |
| 22. 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; including description of how confidential data will be protected, duration of data archiving, and who will have access. |  |  |
| 23. 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 relatives or to others without  consent of the participant (if applicable). |  |  |
| 24. Possible direct or secondary use of participant’s medical records and biological specimens taken during clinical care or during this study (if applicable). |  |  |
| 25. Plans to destroy collected biological specimens 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 (if applicable). |  |  |
| 26. Plans to develop commercial products from  biological specimens and whether the participant will receive monetary or other benefits from such  development (if applicable). |  |  |
| 27. Statement that the participant or participant’s legally acceptable representative will be informed promptly if information becomes available that  maybe relevant to the willingness of the participant to continue to participate (if applicable). |  |  |
| 28. Statement describing participants' access to the results of the study. |  |  |
| 29. Statement describing the extent of the participant’s right to access his/her records (or lack thereof *vis à vis* pending request for approval of non or partial  disclosure) (if applicable). |  |  |
| 30. Foreseeable circumstances and reasons  under which participation in the study may be  terminated. |  |  |
| 31. Information about the sponsor, or funding agency, institutional affiliation of the investigators, and nature and sources of funds. |  |  |
| 32. Statement whether the investigator/researcher  serves only as an investigator/researcher or  as both the investigator/researcher and  the participant’s healthcare provider  (if applicable). |  |  |
| 33. Person(s) to contact in the study team for further information regarding the study, and whom to contact in case of study-related injury (if applicable). |  |  |
| 34. Statement that the PSURERC has approved the study, and may be reached through the following address and contact for information regarding the rights of study participants, including grievances, and complaints:  **Palawan State University Research Ethics Review Committee**  **Address:** Door 2, Ground Floor, Student Innovation Park Building**,** PSU Main Campus, Tiniguiban Heights, Puerto Princesa City  **Email:** [psurercsubmissions@psu.palawan.edu.ph](mailto:psurercsubmissions@psu.palawan.edu.ph) |  |  |
| 35. Comprehensibility of language used |  |  |
| 35. Other comments not addressed by items 1-35 |  |  |

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| **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: Name: |