

**INFORMED CONSENT EVALUATION FORM\* (Form 3.2)**

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

( ) Full Board

( ) Expedited

Protocol Title: Type of Review:

Principal Investigator: Sponsor:

Date of Submission:

**A. INFORMED CONSENT DOCUMENT REVIEW**

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|  | **To be filled out by the Primary Reviewer** | | | | |
| **Essential Elements**  **(as applicable to the study)** | **Indicate if the ICF has the specified element** | | | **REVIEWER’S FINDINGS/COMMENTS** | **REVIEWER’S RECOMMEND-ATIONS** |
| 1. Statement that the study involves research.  *(ICH GCP 4.8.10.a)* | * Yes | * No | * N/A |  |  |
| 2. Statement describing the purpose of the study. (ICH GCP 4.8.10.b) | * Clear | * Unclear |  |  |  |
| 3. Study-related treatments and probability for random assignment. *(ICH GCP 4.8.10.c)* | * Clear | * Unclear |  |  |  |
| 4. Procedures for recruitment  Statement on who, when and how the recruitment process is done. | * Clear | * Unclear |  |  |  |
| 5. Process of securing Informed consent Statement on who, when and how to secure the IC process. | * Clear | * Unclear |  |  |  |
| 6. Study procedures including all invasive procedures.  *(ICH GCP 4.8.10.d)* | * Clear | * Unclear |  |  |  |
| 7. Responsibilities of the participant.  *(ICH GCP 4.8.10.e)* | * Clear | * Unclear |  |  |  |
| 8. Expected duration of participation in the study. *(ICH GCP 4.8.10.s)* | * Clear | * Unclear |  |  |  |
| 9. Approximate number of participants in the study. *(ICH GCP 4.8.10.t)* | * Clear | * Unclear |  |  |  |
| 10. Study aspects that are experimental.  *(ICH GCP 4.8.10.f)* | * Yes | * No |  |  |  |
| 11. 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)* | * Clear | * Unclear |  |  |  |
| 12. Risks from allowable use of placebo (as applicable).  *(NEGRIHP 2022 page 108)* | * Clear | * Unclear |  |  |  |
| 13. Are the provisions for the mitigation of risks in the protocol consistent with what is in the ICF? | * Yes | * No |  |  |  |
| 14. Reasonably expected benefits; or absence of direct benefit to participants, as applicable. *(ICH GCP 4.8.10.h)* | * Clear | * Unclear |  |  |  |
| 15. Expected benefits to the community or to society, or contributions to scientific knowledge. *(NEGRIHP 2022 page 135)* | * Clear | * Unclear |  |  |  |
| 16. Description of post-study access to the study product or intervention that have been proven safe and effective, as applicable.  *(NEGRIHP 2022 page 71)* | * Yes | * No | * N/A |  |  |
| 17. Alternative procedures or treatment available to participant.  *(NEGRIHP 2022 page 225)* | * Yes | * No |  |  |  |
| 18. 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 71)* | * Clear | * Unclear |  |  |  |
| 19. 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)* | * Yes | * No |  |  |  |
| 20. Anticipated expenses, if any, to the participant in the course of the study. *(ICH GCP 4.8.10.l)* | * Clear | * Unclear |  |  |  |
| 21. 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)* | * Clear | * Unclear |  |  |  |
| 22. 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. *(NEGRIHP 2022 page 138)* | * Clear | * Unclear | * N/A |  |  |
| 23. Statement that the study monitor(s), auditor(s), the SPHI-IRB 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)* | * Yes | * No | * N/A |  |  |
| 24. 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)* | * Yes | * No | * N/A |  |  |
| 25. 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 26)* | * Clear | * Unclear |  |  |  |
| 26. 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 198-204)* | * Clear | * Unclear | * N/A |  |  |
| 27. Possible direct or secondary use of participant’s personal data, medical records and biological specimens taken in the course of clinical care or in the course of this study, as applicable. *(NEGRIHP 2022 page 19)* | * Yes | * No | * N/A |  |  |
| 28. Plans to destroy collected personal data, medical records, and biological specimen at the end of the specified storage period, as applicable; 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.  *(NEGRIHP 2022 page 19)* | * Yes | * No |  |  |  |
| 29. 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)* | * Yes | * No | * N/A |  |  |
| 30. 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)* | * Yes | * No |  |  |  |
| 31. Foreseeable circumstances and reasons under which participation in the study may be terminated  *(ICH GCP 4.8.10.r)* | * Yes | * No |  |  |  |
| 32. Sponsor, institutional affiliation of the investigator/researcher, and nature and sources of funds.  *(NEGRIHP 2022 page 19)* | * Yes | * No |  |  |  |
| 33. Statement whether the investigator/researcher is serving only as an investigator or as both investigator and the participant’s healthcare provider. *(NEGRIHP 2022)* | * Yes | * No | * N/A |  |  |
| 34. 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)* | * Yes | * No |  |  |  |
| 35. Comprehensibility of language used.  *(NEGHHR 2022)* | * Yes | * No |  |  |  |
| 36. Statement that the SPHI-IRB 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 SPHI-IRB Chair  Address: 4th Floor, Cancer Center Building, St. Paul’s Hospital of Iloilo, Inc.  Genral Luna St., Iloilo City  Email: sphirbresearch@gmail.com  Tel: 337-2742-29 local 7306  *(NEGRIHP 2022)* | * Yes | * No |  |  |  |
| 37. Other comments not addressed by items 1-36. |  |  |  |  |  |

**B. DECISION:**

Approval Minor Revision

Major Revisions Disapproval

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

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