**Informed Consent Assessment Form**

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| **STUDY PROTOCOL INFORMATION** |
| **MDH\_IRB Code:** |  |
| **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 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 space provided for the primary reviewer.

|  | **To be filled out by MDH IRB** |
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| **Essential Elements****(as applicable to the study)** | **REVIEWER COMMENTS**(Please use complete sentences when identifying issues for assessment) |
|  | **YES** | **NO** | **N/A** |  |
| 1. Is the language understandable?
 |[ ] [ ] [ ]   |
| 1. Is there a statement that this is a research/trial?
 | [ ]  | [ ]  |[ ]   |
| 1. Is the purpose of the study given?
 | [ ]  | [ ]  |[ ]   |
| 1. Are study procedures and treatments detailed? (randomization process, invasive procedures, etc.)
 | [ ]  | [ ]  |[ ]   |
| 1. Are responsibilities of the participant detailed?
 | [ ]  | [ ]  |[ ]   |
| 1. Are details of the study explained? (Duration of participation, number of participants, study aspects that are experimental)
 | [ ]  | [ ]  |[ ]   |
| 1. Are the foreseeable risks to the participant explained? Including possible fetal risks, breastfeeding risks and risks to spouse/partner? Are there risks from using the placebo?
 | [ ]  | [ ]  |[ ]   |
| 1. Are expected benefits detailed (or absence of benefit)? Are there community benefits/knowledge?
 | [ ]  | [ ]  |[ ]   |
| 1. Is participant informed of alternative treatments and procedures if available?
 | [ ]  | [ ]  |[ ]   |
| 1. Will the participant be paid or compensated for the study? What are the participants’ anticipated expenses?
 | [ ]  | [ ]  |[ ]   |
| 1. Will study-related injuries and expenses be covered?
 | [ ]  | [ ]  |[ ]   |
| 1. Is it explained that participation is voluntary, and that participant may withdraw anytime without penalty or loss of access to care.
 | [ ]  | [ ]  |[ ]   |
| 1. Are there appropriate types of consent forms (assent, LAR, etc.) to protect vulnerable participants?
 | [ ]  | [ ]  |[ ]   |
| 1. Are procedures and protocols for keeping privacy and confidentiality provided?
* Is there a statement that participant information will be kept with DPA?
 | [ ]  | [ ]  |[ ]   |
| 1. If there is a genetic component in the study? Is there a separate ICF that is given to the participant for future genetic use?
 | [ ]  | [ ]  |[ ]   |
| 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. Will the results of the study be made available to the participant? Is post-study or post-trial access described?
 | [ ]  | [ ]  |[ ]   |
| 1. Is/are the 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 stated?
 | [ ]  | [ ]  |[ ]   |
| 1. Statement that the MDH IRB 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 MDH IRB Chair****Address:**8th Floor Norberto Ty Medical Tower 2 Manila Doctors Hospital, T.M. Kalaw Street, Ermita, 1000 Manila**Email:** irb@maniladoctors.com.ph**Tel:** +63 2 8558-0888 local 4728 and Fax local 0579**Mobile:** +09159369505 | [ ]  | [ ]  |[ ]   |

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| **RECOMMENDED ACTION** |
| * EXEMPT
* APPROVAL
* MINOR MODIFICATIONS
* MAJOR MODIFICATIONS
* DISAPPROVAL
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| SUMMARY OF RECOMMENDATION: |
| 🞏 PRIMARY REVIEWER🞏 PRIMARY LAY REVIEWER 🞏 SECONDARY REVIEWER🞏 EXPERT REVIEWER | Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Name < Title, Name, Surname>Date Reviewed: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_<dd/mm/yyyy> |