**Informed Consent Assessment Form**

|  |
| --- |
| **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 the PI** | **To be filled out by MDH IRB** |
| --- | --- | --- |
| **Essential Elements****(as applicable to the study)** | **Indicate if the ICF has the specified element** | **Page and paragraph where element is found** | **REVIEWER COMMENTS**(Please use complete sentences when identifying issues for assessment) |
| **YES** | **N/A** |  |  |
| 1. Statement that the study involves research
 | [ ]  | [ ]  |       |  |
| 1. Statement describing the purpose of the study
 | [ ]  | [ ]  |       |  |
| 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. Approximate number of participants in the study
 | [ ]  | [ ]  |       |  |
| 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;
 | [ ]  | [ ]  |       |  |
| 1. Risks from allowable use of placebo (as applicable)
 | [ ]  | [ ]  |       |  |
| 1. Reasonably expected benefits; or absence of direct benefit to participants, as applicable
 | [ ]  | [ ]  |       |  |
| 1. Expected benefits to the community or to society, or contributions to scientific knowledge
 | [ ]  | [ ]  |       |  |
| 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. 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. For research involving children and adolescents, statement that consent will be obtained if the participant reaches legal age in the duration of the study
 | [ ]  | [ ]  |       |  |
| 1. Statement that the study monitor(s), auditor(s), the MDH IRB 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. 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) (*NEGHHR 2017)*
 | [ ]  | [ ]  |  |  |
| 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. **Data Privacy Issues (28-33) in compliance with the Data Privacy Act of 2012**
 | [ ]  | [ ]  |  |  |
| 1. Statement describing that consent for participation is time-bound
 | [ ]  | [ ]  |  |  |
| 1. Statement describing the data subject’s right to be informed that his/her personal data will be collected and processed
 | [ ]  | [ ]  |  |  |
| 1. Statement describing the data subject’s right to object or withhold consent to processing in case of changes or any amendment to the information supplied
 | [ ]  | [ ]  |  |  |
| 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. Compensation or insurance or treatment entitlements of the participant in case of study-related injury
 | [ ]  | [ ]  |  |  |
| 1. Statement describing access of participant to the result of the study including details on what data will be shared and available, duration, and access criteria for data sharing
 | [ ]  | [ ]  |  |  |
| 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. Statement whether the investigator is serving only as an investigator or as both investigator and the participant’s healthcare provider
 | [ ]  | [ ]  |  |  |
| 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 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 | [ ]  | [ ]  |       |  |
| 1. Comprehensibility of language used
 |  |  |  |  |

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