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| **THE MEDICAL CITY** |
| Ortigas Avenue, Pasig City, Philippines |
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| **INSTITUTIONAL REVIEW BOARD** |
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| **INFORMED CONSENT ASSESSMENT FORM** |
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| **PROTOCOL INFORMATION** |
|  |
| Protocol Title: | Protocol Title |
| IRB Registry No.: | IRB Registry Number | Protocol No.: | Protocol Number |
| Principal Investigator: | Principal Investigator | Field of Study: | Field of Study |
| Date Submitted: | Enter Date | Sponsor: | Sponsor |
|  |  |  |  |
|  |
| **INSTRUCTIONS:*****Principal Investigator/s:*** *Accomplish this form digitally. [Legend: Y-Yes; N-No; N/A-Not Applicable] If yes, write the page number.* |
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| **CRITERIA** | **PRINCIPAL INVESTIGATOR** | **TMC-IRB REVIEWER** |
| **Y****N****N/A** | **PAGE NO.** | **Y** | **N** | **N/A** | **COMMENT/S****(Please use the back page if needed)** |
| **1** | **INFORMED CONSENT FORM** |
| 1.1 | Are the participants provided with appropriate study information? |  |  |  |  |  |  |
| 1.2 | Is it stated that participation in the study is voluntary? |  |  |  |  |  |  |
| 1.3 | Are the measures for personal data protection based on the Data Privacy Act of 2012 clearly stated in the Informed Consent? |  |  |  |  |  |  |
| 1.4 | Are the people who have access to the data clearly indicated? |  |  |  |  |  |  |
| 1.5 | Is the purpose of the research indicated? |  |  |  |  |  |  |
| 1.6 | Is the expectation for the research participant clearly indicated? |  |  |  |  |  |  |
| 1.7 | Are the risks from the procedures well explained in the Informed Consent? |  |  |  |  |  |  |
| 1.8 | Is the monetary benefit / absence of monetary benefit clearly communicated? |  |  |  |  |  |  |
| 1.9 | Are the alternative treatments clearly described? |  |  |  |  |  |  |
| 1.10 | Is the compensation for injuries arising from the participation in the study indicated? |  |  |  |  |  |  |
| 1.11 | Is there clear statement that the research participant can withdraw anytime without loss of benefits? |  |  |  |  |  |  |
| 1.12 | Was it explicit in the Informed Consent that any new data that will affect their decision to participate in the study will be communicated to them and in a timely manner? |  |  |  |  |  |  |
| 1.13 | Does the informed consent form provide information regarding monitoring and handling of adverse events? |  |  |  |  |  |  |
| 1.14 | Are the mechanisms or statements that will inform participants and communities of the result of the research (this applies to non-clinical study or research)? |  |  |  |  |  |  |
| 1.15 | Are the number of participants and the duration of participation indicated in the participant information sheet? |  |  |  |  |  |  |
| 1.16 | Is the informed consent written or presented in non-technical language that participants can understand? |  |  |  |  |  |  |
| 1.17 | Is the name of the contact person and contact numbers, office address, etc., indicated in the informed consent? (Including TMC-IRB contact details)Contact Person:Carlo Emmanuel J. Sumpaico, M.D.TMC-IRB ChairTel. No.: (632) 8-988-1000 loc. 65254th Floor, Clinical Services Group, Podium Building, The Medical City |  |  |  |  |  |  |
| 1.18 | Are there provisions for the signature of **one (1) witness**? |  |  |  |  |  |  |
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| *I hereby pledge to uphold the integrity of this research and to protect human subjects in accordance with the Declaration of Helsinki, International Conference on Harmonization of Good Clinical Practice (ICH-GCP), Council for International Organizations of Medical Sciences (CIOMS), and the National Ethical Guidelines for Health Research (PHREB-DOST).* |
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|  |  | Name of Principal Investigator |  |  |
| Signature Over Printed Name / Date and Time |
| **PRINCIPAL INVESTIGATOR** |
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| **DO NOT FILL OUT THIS SECTION** |
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| **DECISION:** |
| [x]  Approved |
| [x]  Minor Revision Required |
| [x]  Major Revision Required |
| [x]  Pending (if clarification is required before a decision can be made) |
| [x]  Approval not Granted |
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|  |  |  |  |  |
| Signature Over Printed Name / Date and Time |
| **REVIEWER** |
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| **SUMMARY OF COMMENT/S (use the back page if needed):** |