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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** | | | | | | | | | | | | | | | |
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| 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 | | | |
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| **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 Chair  Tel. No.: (632) 8-988-1000 loc. 6525  4th 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:** | | | | | | | | | | | | | | | |
| Approved | | | | | | | | | | | | | | | |
| Minor Revision Required | | | | | | | | | | | | | | | |
| Major Revision Required | | | | | | | | | | | | | | | |
| Pending (if clarification is required before a decision can be made) | | | | | | | | | | | | | | | |
| 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):** | | | | | | | | | | | | | | | |