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| **THE MEDICAL CITY** |
| Ortigas Avenue, Pasig City, Philippines |
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| **INSTITUTIONAL REVIEW BOARD** |
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| **REVIEW OF MEDICAL DEVICES** |
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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 |
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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** | **DETERMINATION OF RISK** |
| 1.1 | Does the device fall under the Significant Risk Category? |  |  |  |  |  |  |
| 1.2 | Is it intended to be used as an implant and does it present a potential serious risk to the health, safety, or welfare of a subject? |  |  |  |  |  |  |
| 1.3 | Is it purported or represented to be used for supporting or sustaining human life and presents a potential serious risk to the health, safety, or welfare of a subject? |  |  |  |  |  |  |
| 1.4 | Does it have a substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject? |  |  |  |  |  |  |
| 1.5 | Does the device fall under the Non-Significant Risk Category? |  |  |  |  |  |  |
| **2** | **PRIOR INVESTIGATION** |
| 2.1 | Is there a report of prior investigations that includes all prior clinical, animal, and laboratory testing of the device? |  |  |  |  |  |  |
| 2.2 | Is it comprehensive and adequate to justify the proposed investigation? |  |  |  |  |  |  |
| 2.3 | Does it contain all results of publications, whether adverse or supportive, that are relevant to an evaluation of the safety and effectiveness of the device? |  |  |  |  |  |  |
| **3** | **INVESTIGATIONAL PLAN** |
| 3.1 | Are the name and intended use of the device and the objectives and duration of the investigation clearly stated? |  |  |  |  |  |  |
| 3.2 | Is there a written protocol describing the methodology to be used and an analysis of the protocol demonstrating its scientific soundness? |  |  |  |  |  |  |
| 3.3 | Is there a description and analysis of all increased risks to the research subjects and how these risks will be minimized; a justification for the investigation; and a description of the patient population including the number, age, sex, and condition? |  |  |  |  |  |  |
| 3.4 | Is there a description of each important component, ingredient, property, and principle of operation of the device and any anticipated changes in the device during the investigation? |  |  |  |  |  |  |
| 3.5 | Are there written procedures for monitoring the investigation? |  |  |  |  |  |  |
| 3.6 | Is there a description of the methods, facilities, and controls used for the manufacture, processing, packing, storage, and installation of the device? |  |  |  |  |  |  |
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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):** |