|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **THE MEDICAL CITY** | | | | | | | | | | | | | | | |
| Ortigas Avenue, Pasig City, Philippines | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | |
| **INSTITUTIONAL REVIEW BOARD** | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | |
| **RESEARCH PROTOCOL ASSESSMENT FORM** | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | |
| **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.* | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | |
| **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** | **SCIENTIFIC AND SOCIAL VALUE** | | | | | | | | | | | | | | |
| 1.1 | | Will the research result in any of the following: new knowledge about the disease, development of a new intervention - diagnostic preventive or therapeutic product, promotion or education, intervention program, or health system improvement? | | | |  |  | |  |  |  | |  | | |
| **2** | **SCIENTIFIC VALIDITY** | | | | | | | | | | | | | | |
| 2.1 | | Does the research question have clear P.I.C.O. (Population, Intervention, Control, and Outcome)? | | | |  |  | |  |  |  | |  | | |
| 2.2 | | Do the objectives answer the P.I.C.O.? | | | |  |  | |  |  |  | |  | | |
| 2.3 | | Do the chosen methodology appropriate to the objective? | | | |  |  | |  |  |  | |  | | |
| 2.4 | | Are the endpoints or indicator appropriate and adequately measured and analyzed? | | | |  |  | |  |  |  | |  | | |
| 2.5 | | Are the hypotheses clearly stated? (if applicable) | | | |  |  | |  |  |  | |  | | |
| 2.6 | | Is the use of placebo justified? (if applicable) | | | |  |  | |  |  |  | |  | | |
| 2.7 | | When applicable, is there a determination of adequate sample size? | | | |  |  | |  |  |  | |  | | |
| **3** | **POPULATION** | | | | | | | | | | | | | | |
| 3.1 | | Are vulnerable/special populations the subject of this study? | | | |  |  | |  |  |  | |  | | |
| 3.2 | | When applicable, is the use of vulnerable/special population in this study justifiable? | | | |  |  | |  |  |  | |  | | |
| 3.3 | | Does the inclusion criteria ensure that populations who will potentially enjoy the benefits of the research can participate in the study? | | | |  |  | |  |  |  | |  | | |
| 3.4 | | Does the criteria ensure that potential participants who may be higher risk of being harmed are excluded? | | | |  |  | |  |  |  | |  | | |
| 3.5 | | Will the consent be obtained from appropriate and eligible decision makers? | | | |  |  | |  |  |  | |  | | |
| 3.6 | | Is there a determination that it is morally acceptable for the subject to use contraceptive methods for the duration of the study? | | | |  |  | |  |  |  | |  | | |
| **4** | **MINIMIZE HARM/MAXIMIZE BENEFIT** | | | | | | | | | | | | | | |
| 4.1 | | Do the study procedure pose risk(s)? | | | |  |  | |  |  |  | |  | | |
| 4.2 | | Does the research design provide adequate measures to minimize the risks that the participants will be exposed to? | | | |  |  | |  |  |  | |  | | |
| 4.3 | | Are there expected adverse events? | | | |  |  | |  |  |  | |  | | |
| 4.4 | | Are there appropriate steps to be taken to address adverse events? | | | |  |  | |  |  |  | |  | | |
| 4.5 | | Are there appropriate criteria for withdrawing the participant from the study? | | | |  |  | |  |  |  | |  | | |
| 4.6 | | Do the benefits from the conduct of the study outweigh potential risks to the participants? | | | |  |  | |  |  |  | |  | | |
| 4.7 | | Does the study ensure that there will be benefits to participants and/or communities where the research will be conducted? | | | |  |  | |  |  |  | |  | | |
| 4.8 | | In the case of clinical trials contributing to licensure data, are there any provisions for providing the availability of the effective drug identified from the study participants, or community where the study will be done? | | | |  |  | |  |  |  | |  | | |
| **5** | **INDEPENDENCE/INVESTIGATOR’S QUALIFICATION** | | | | | | | | | | | | | | |
| 5.1 | | Does Principal Investigator’s specialization match the requirements of the protocol procedure? Have an updated Curriculum Vitae and Good Clinical Practice (GCP) certificate? | | | |  |  | |  |  |  | |  | | |
| 5.2 | | Is the number of studies the investigator is handling justified? No apparent disproportionate time devoted to the research? | | | |  |  | |  |  |  | |  | | |
| 5.3 | | Do you have any conflict of interest with the protocol/study being reviewed? | | | |  |  | |  |  |  | | **Principal Investigator:** If YES, please specify: Please specify  **Reviewer:** if YES, please specify: | | |
|  | |  | | | |  |  | |  |  |  | |  | | |
|  | | | | | | | | | | | | | | | |
| *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).* | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | |
|  | | |  | | Name of Principal Investigator | | | | | | | | |  |  |
| Signature Over Printed Name / Date and Time | | | | | | | | | | | | | | | |
| **PRINCIPAL INVESTIGATOR** | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | |
| **DO NOT FILL OUT THIS SECTION** | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | |
| **DECISION:** | | | | | | | | | | | | | | | |
| Approved | | | | | | | | | | | | | | | |
| Minor Revision Required | | | | | | | | | | | | | | | |
| Major Revision Required | | | | | | | | | | | | | | | |
| Pending (if clarification is required before a decision can be made) | | | | | | | | | | | | | | | |
| Approval not Granted | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | |
|  | | |  | |  | | | | | | | | |  |  |
| Signature Over Printed Name / Date and Time | | | | | | | | | | | | | | | |
| **REVIEWER** | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | |
| **SUMMARY OF COMMENT/S (use the back page if needed):** | | | | | | | | | | | | | | | |