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| **THE MEDICAL CITY** |
| Ortigas Avenue, Pasig City, Philippines |
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| **INSTITUTIONAL REVIEW BOARD** |
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| **APPLICATION FORM FOR INITIAL REVIEW** |
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|  | **\*THIS SECTION IS TO BE FILLED OUT BY THE IRB SECRETARIAT ONLY\*** |  |
|  |  |  |
|  | **ACTION TAKEN:** |  | **IRB STAMP** |  |  |
|  | * Level of Review
 |  |  |  |
|  | [x]  Full Review |  |  |  |
|  | [x]  Expedited Review |  |  |  |
|  | [x]  Exempted from Review |  |  |  |
|  |  |  |  |  |
|  | * Name of assigned reviewers:
 |  |  |  |
|  | Primary: |  |  |  |  |  |
|  | Alternate: |  |  |  |  |  |
|  | ICF: |  |  |  |  |  |
|  |  |  |  |  |
|  | * If full review, date of IRB review:
 |  |  |  |
|  |  |  |  |  |  |  |
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|  |  |  |
|  |  | GEMINN LOUIS C. APOSTOL, M.D., M.B.A. |  | CARLO EMMANUEL J. SUMPAICO, M.D. |  |  |
|  |  | Signature Over Printed Name / Date and Time |  | Signature Over Printed Name / Date and Time |  |  |
|  |  | **PANEL SECRETARY****TMC - INSTITUTIONAL REVIEW BOARD** |  | **CHAIR****TMC - INSTITUTIONAL REVIEW BOARD** |  |  |
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| **PROJECT INFORMATION** |
|  |
| 1. **Title of Research Protocol:**
 | Title of Research Protocol |
|  |
| 1. **Date of Application:**
 | Date of Application |
|  |
| 1. **Have other ethical review boards reviewed this protocol before its submission to TMC-IRB?**
 |
| [x]  Yes (Submit a copy of the board’s decision on the protocol) |
| [x]  No |
|  |
| 1. **What type of research is this?**
 |
| * 1. WITH Direct Involvement of Human Subjects:
 |
| [x]  Research using any treatment procedure, protocol, or intervention. Specify: Please specify |
| [x]  Research using any diagnostic method, protocol, or intervention. Specify: Please specify |
| [x]  Research involving biological specimen collection. Specify: Please specify |
| [x]  Research solely using surveys interviews, focus groups, observations, or other similar methods |
|  |
| * 1. WITHOUT Direct Involvement of Human Subjects:
 |
| [x]  Research solely using human data and biological specimen, already collected, or in a tissue bank |
| [x]  Research only using medical records |
|  |
| * 1. Others: Please specify
 |
|  |
| 1. **Will drugs, biologics, devices, or procedures be used in this project?**
 |
| [x]  YES; a licensed drug, biologic, or device will be used. Specify: Please specify |
| [x]  YES; an unlicensed drug, a new medicine or biologic will be used. Specify: Please specify |
| [x]  NO; no drug, biologic, or device will be used |
| [x]  Off-label drug use or registered with FDA for another indication |
| [x]  Surgical procedure or experimental |
|  |
| 1. **To what health or disease category does this research belong (if applicable)?**
 |
| [x]  Communicable Disease | [x]  Quality Improvement |
| [x]  Non-communicable Disease | [x]  Health System Research |
| [x]  Others: Please specify |
|  |
|  |
| **FUNDING** |
|  |
| 1. **Is this research study funded?**
 |
| [x]  Yes *(Provide a copy of your grant proposal/contract with the application)* |
| [x]  No *(Proceed to Conflict of Interest section)* |
|  |
| 1. **Provide the name and mailing address of the internal and external sources of funding.**
 |
| * 1. Name of Sponsor:

Name of Sponsor | * 1. Mailing Address of Sponsor:

Address of Sponsor |
|  |
| 1. **Is the funding agency providing the research intervention (e.g., drug, device, etc.) free of charge?**
 |
| [x]  Yes |
| [x]  No |
|  |
| 1. **Has the funding agency agreed to pay for the direct costs of managing study-related injuries?**
 |
| [x]  Yes |
| [x]  No |
|  |
| 1. **Is the funding agency requiring full review?**
 |
| [x]  Yes |
| [x]  No |
|  |
|  |
| **CONFLICT OF INTEREST** |
|  |
| 1. **Principal Investigator’s Conflict of Interest Statement**
 |
|  | **YES** | **NO** |
| * 1. Do you have any stocks, shares, or equity interests in your sponsor?
 | [x]  | [x]  |
| * 1. Do you prepare or deliver lectures on behalf of the research sponsor?
 | [x]  | [x]  |
| * 1. Do you receive regular compensation from the sponsor, e.g., benefit in the form of equipment, retainers, or honoraria?
 | [x]  | [x]  |
|  |
| 1. **Do any of the co-investigators, key research personnel (e.g., research associates and assistants), and/or their spouses or dependent children have a conflict of interest (COI), associated with this research (e.g., have significant financial investment related to the study)?**
 |
| [x]  Yes. Explain: Please specify |
| [x]  No |
|  |
| 1. **Does** **The Medical City have an ownership or royalty interest in any intellectual property related to this study?**
 |
| [x]  Yes. Explain: Please specify |
| [x]  No |
|  |
|  |
| **STUDY PARTICIPANTS** |
|  |
| 1. **Choose ALL categories of participants who will be involved in the study.**
 |
| [x]  Children (individuals under 18 years old) | [x]  Pregnant Women |
| [x]  Fetuses, Neonates, fetal material in vitro fertilization | [x]  Prisoners |
| [x]  Healthy Adults (18 to 60 years old) | [x]  Senior Citizens (60 years old and above) |
| [x]  HIV-Positive Individuals | [x]  Students |
| [x]  Indigenous Groups | [x]  The Medical City Employees |
| [x]  Indigent Persons (i.e., impoverished) | [x]  Women of Reproductive Potential at the Time of This Research |
| [x]  Individual with a Mental or Decisional Impairment |
| [x]  Patients (persons receiving medical treatment) | [x]  Others: Please specify |
|  |
| 1. **Will any of the participants be currently enrolled, employed, or managed as a patient by any member of the research team?**
 |
| [x]  Yes. Describe measures to avoid participant coercion and undue influence: Please specify |
| [x]  No |
|  |
| 1. **Will a control group of participants be used?**
 |
| [x]  Yes |  |
| * 1. If yes, please choose:
 |
| [x]  Placebo Control |
| [x]  Standard Therapy Control |
| [x]  Others: Please specify |
| [x]  No |
|  |
| 1. **Is the research a blind (masked) study, e.g., the participant is unaware of the variable or treatment that he or she is exposed to?**
 |
| [x]  Yes. Explain: Please specify |
| [x]  No |
|  |
|  |
| **RECRUITMENT** |
|  |
| 1. **Indicate the types of recruitment that will be done for this research. Choose all that apply.**
 |
| [x]  Newspaper/Magazine Advertisements *(Attach copies of materials to be used).* |
| [x]  Radio/Television Advertisements *(Attach copies of the materials/verbal scripts to be used).* |
| [x]  Letters/Emails/Telephone Calls to Potential Participants *(Attach copies of the materials/oral scripts to be used).* |
| [x]  Flyers/Posters/Brochures *(Attach copies of materials to be used).* |
| [x]  Website *(Attach copies of documents to be used).* |
| [x]  Face-to-Face or Verbal Approach  |
| [x]  Others: Please specify |
|  |
| 1. **Will investigators access education/medical/assessment records and/or school/hospital/clinic databases for recruitment and selection purposes?**
 |
| [x]  Yes | [x]  No *(Skip to Question #22)* |
|  |
| 1. **Has permission to access information been requested from the hospital or institution holding these records?**
 |
| [x]  Yes *(Provide a copy of the written request or authorization to release/access information)* |
| [x]  No |
|  |
| 1. **Explain how potential participants’ contact information are to be obtained.**
 |
| Please specify |
|  |
|  |
| **INFORMED CONSENT** |
|  |
| 1. **WHO will be responsible for obtaining informed consent/assent form participants?**
 |
| Please specify |
|  |
| 1. **WHEN exactly will the participants be approached for obtaining informed consent/assent?**
 |
| Please specify |
|  |
| 1. **WHERE exactly will the informed consent/assent be obtained from the participants?**
 |
| Please specify |
|  |
| 1. **What type of consent will be obtained? Choose all that apply.**
 |
| [x]  Signed consent/assent - participant and/or Legally Authorized Representative (LAR) will sign the consent form |
| [x]  Implied consent - participant will not sign consent form (e.g., mail survey, email, online survey) |
| Justify: Please specify |
| [x]  Verbal consent - participant gives permission verbally (e.g., in-person interview, telephone interview) |
| Justify: Please specify |
| [x]  Passive/Opt-Out consent - participant only required to act if they do not want to participate |
| Justify: Please specify |
| [x]  Complete waiver of informed consent |
| Justify: Please specify |
| [x]  Others: Please specify |
|  |
| 1. **Participants MUST receive a copy of the informed consent form with the approval box/statement on it. Describe how participants will receive a copy of the informed consent form to keep for their records.**
 |
| Please specify |
|  |
| 1. **Does the study involve giving false information to participants or withholding information from them?**
 |
| [x]  Yes. Justify the use of deception: Please specify |
| [x]  No |
|  |
|  |
| **RISKS AND BENEFITS** |
|  |
| 1. **List all the potential discomforts and risks (physical, psychological, legal, social, or economic) of participation in the study. Describe the likelihood and seriousness of the risk and how it will be mitigated.**
 |
|  |
|  | **Risks/Discomfort** | **Seriousness** | **Likelihood** | **Mitigation Plan** |  |
|  |  | Minimal Risk[[1]](#footnote-1) | Low or High |  |  |
|  |  | Moderate Risk[[2]](#footnote-2) |  |  |  |
|  |  | High Risk[[3]](#footnote-3) |  |  |  |
|  |
| 1. **Will medical or psychological care be available for participants who may require it because of the study?**
 |
| [x]  Yes. Describe and identify the source of medical or psychological care available: Please specify |
| [x]  No |
|  |
| 1. **Is it possible investigators will discover a condition previously unknown to the participant (e.g., disease, wrong paternity) because of study procedures?**
 |
|  |
| [x]  Yes. Explain how and when such a discovery would be handled: Please specify |
| [x]  No |
|  |
| 1. **What are the potential DIRECT benefits to the study participants? If there are none, state “no benefits.”**

*Note: Payment or compensation for participation is not considered a benefit.* |
| Please specify |
|  |
| 1. **What are the potential benefits to society and/or to the scientific and medical community?**
 |
| Please specify |
|  |
|  |
| **CONFIDENTIALITY AND PRIVACY** |
|  |
| 1. **Describe the provisions made to maintain confidentiality of the data. Select all that apply:**
 |
| [x]  Password protected computer files | [x]  Locked offices |
| [x]  Locked file cabinets  | [x]  Use of identification code, numbers, and pseudonyms |
| [x]  Others: Please specify |  |
|  |
| 1. **Who will have access to the raw data?**
 |
| Please specify |
|  |
| 1. **Will identifiers be disclosed to a sponsor or to collaborators at another institution?**
 |
| [x]  Yes. List the identifiers that will be disclosed and explain why this is necessary: Please specify |
| [x]  No |
|  |
| 1. **Will a list or document linking the code (i.e., code numbers, pseudonyms) and participants' identity be used in this study?**
 |
| [x]  Yes. |
| [x]  No. *(Skip to Question #41)* |
|  |
| 1. **Where will the document linking the code to participants' identity be stored and how will it be secured?**
 |
| Please specify |
|  |
| 1. **Who will have access to the document linking the code to participants' identity?**
 |
| Please specify |
|  |
| 1. **Will the document linking the code to participants' identity be destroyed eventually?**
 |
| [x]  Yes. When will the document be destroyed? Please specify |
| [x]  No |
|  |
| 1. **What will happen to the research records when the research has been completed? Choose ONE only.**
 |
| [x]  Stored indefinitely with identifiers removed. Please specify |
| [x]  Stored indefinitely with identifiers attached. |
| List the identifiers that will be attached to the data: Please specify |
| Explain why the data must be stored indefinitely with identifiers: Please specify |
| [x]  Destroyed after several years. Specify the number of years: Please specify |
| [x]  Others: Please specify |
|  |
| 1. **Could the information being collected for this study have adverse consequences for participants or be damaging to their financial standing, employability, insurability, or reputation?**
 |
| [x]  Yes. Explain: Please specify |
| [x]  No |
|  |
|  |
| *As the Principal Investigator on this research study, I assure that this application accurately reflects the nature and extent of all procedures involving human participants and related information.* *I will obtain approval from The Medical City – Institutional Review Board (TMC-IRB) before initiating any changes to the approved study protocol, including changes in procedures, personnel, documents, instruments, etc., except where necessary to eliminate apparent immediate hazards to participants.**I am familiar with and will comply with all pertinent institutional and national regulations and policies regarding research ethics with human participants.**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.* |
|   |
|   |
|   |
|  |  | Name of Principal Investigator |  |  |
| Signature Over Printed Name / Date and Time |
| **PRINCIPAL INVESTIGATOR** |

1. **Low/Minimal Risk** - The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. [↑](#footnote-ref-1)
2. **Medium/Moderate Risk** - Risks are recognized as being greater than minimal, but are not considered high. There is a medium to a high probability of a moderate-severity event occurring because of study participation (e.g., reversible worsening of a non-fatal disease such as seasonal allergy while receiving placebo or pneumonia from a bronchoscopy), but there are adequate surveillance and protections to identify adverse events promptly and to minimize their effects. [↑](#footnote-ref-2)
3. **High Risk** - If the study can lead to an unexpected/unplanned loss of life, or permanent impairment of quality of life, or may lead to serious legal action against Principal Investigators and/or institution. The study risk is greater than a moderate risk study due to the increased probability for generating serious adverse events. There is a high probability of an event that is serious and prolonged or permanent occurring because of study participation. [↑](#footnote-ref-3)