**APPLICATION FORM**

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| SECTION I: APPLICATION INFORMATION | | | | |
| 1. **Study Protocol Code:** | 1.1 MCU-FDTMF IRB CODE: | | |  |
| 1.2 SPONSOR CODE | | |  |
| 1. **Type of Submission:** | □ | 2.1 Initial Review | | |
| □ | 2.2 Resubmission *(responses to initial review recommendations or submission of studies with investigator-initiated changes prior to ethical approval)* ***NOTE****: version and date of version must be inserted as document footer for all resubmissions* | | |
| □ | 2.3 Protocol Amendments | | |
| □ | 2.4 Continuing Review | | |
| □ | 2.5 Protocol Termination | | |
| □ | 2.6 Final Report | | |
| 1. **Date of Submission:** |  | | | |
| 1. **Study Category:** | □ | 4.1 Research involving human participants | | |
| □ | 4.2 Research involving non-human living vertebrates | | |
| □ | 4.4 Others (indicate): | | |
| 1. **Type of Study:** | □ | 5.1 Pre-clinical Research | | |
| □ | 5.2 **Non-clinical trial**, specifically (*choose one*): | | |
|  | □ | 5.2.1 Diagnostics | |
|  | □ | 5.2.2 In vitro study | |
|  | □ | 5.2.3 Genetic or genomic research | |
|  | □ | 5.2.4 Stem cell research | |
|  | □ | 5.2.5 Herbal research | |
|  | □ | 5.2.6 Complementary and Alternative Medicine Research | |
|  | □ | 5.2.7 Research on Assisted Reproductive Technology | |
|  | □ | 5.2.8 Research on Indigenous Materials | |
|  | □ | 5.2.9 Review of medical records | |
|  | □ | 5.2.10 Epidemiological study | |
|  | □ | 5.2.11 Socio behavioral research | |
|  | □ | 5.2.12 Health informatics | |
|  | □ | 5.2.13 Operations/process research | |
| □ | 5.3 **Clinical Trial Type 1** (*drug or pharmaceutical trials, diagnostic trials, trials on devices and other therapy trials*) intended for marketing registration | | |
| □ | 5.4 **Clinical Trial Type 2** (*drug or pharmaceutical trials, diagnostic trials, trials on devices and other therapy trials*) **NOT** intended for marketing registration | | |
| □ | 5.5 **Post Marketing Surveillance** | | |
| □ | 5.6 OTHERS, please indicate: | | |
| 1. **Category of Principal Investigator:** | □ | 6.1 MCU-FDTMF Consultants/Faculty | | |
| □ | 6.2 MCU-FDTMF: | | |
|  | □ | 6.2.1 Residents-in-training | |
|  | □ | 6.2.2 Fellows-in-training | |
|  | □ | 6.2.3 Residents/fellows graduated completing research requirements | |
|  | □ | 6.2.4 Other researchers (please specify): | |
| □ | 6.3 NON-MCU-FDTMF (**NOTE***: This category requires completion of PART III: AUTHORIZATION AND ACKNOWLEDGEMENT OF REVIEW below*) | | |
| □ | 6.4 Others, please specify: | | |
| 1. **Purpose of the study:** | □ | 7.1 Academic requirement | | |
| □ | 7.2 Independent research work | | |
| □ | 7.3 Multi-institutional or multi-country collaboration | | |
| □ | 7.4 Others (indicate): | | |
| 1. **Study duration:** |  | | | |
| 1. **Use of special population or vulnerable groups:** | □ | 9.1 Children (under 18) | | |
| □ | 9.2 Indigenous People | | |
| □ | 9.3 Elderly | | |
| □ | 9.4 People on welfare/social assistance | | |
| □ | 9.5 Poor and unemployed | | |
| □ | 9.6 Patients in emergency care | | |
| □ | 9.7 Homeless persons | | |
| □ | 9.8 Refugees or displaced persons | | |
| □ | 9.9 Patients with incurable diseases | | |
| □ | 9.10 Others (indicate): | | |
| □ | 9.11 Not applicable | | |
| 1. **Endorsing Department / Institution:** | □ | 10.1 MCU-FDTMF: | | |
|  | □ | 10.1.1 Department of Family and Community Medicine | |
|  | □ | 10.1.2 Department of Medicine | |
|  | □ | 10.1.3 Department of Obstetrics and Gynecology | |
|  | □ | 10.1.4 Department of Ophthalmology | |
|  | □ | 10.1.5 Department of Otolaryngology | |
|  | □ | 10.1.6 Department of Pathology | |
|  | □ | 10.1.7 Department of Radiology | |
|  | □ | 10.1.8 Department of Surgery | |
|  | □ | 10.1.9 Others (indicate): | |
| □ | 10.2 Non-MCU-FDTMF (local): Manila Central University College of Medicine- Department of Family and Community Medicine | | |
| □ | 10.3 Non-MCU-FDTMF (foreign institution): <name of institution> | | |
| 1. **Study site:** | □ | 11.1 MCU-FDTMF | | |
| □ | 11.2 Non-MCU-FDTMF with local IRB/ERC/ERB | | |
| □ | 11.3 Non-MCU-FDTMF without local IRB/ERC/ERB | | |
| 1. **Funding Agency:** | 12.1 **(NAME): Principal Investigator Funded** | | | |
| **Type of funding** | | | |
| □ | 12.1 MCU-FDTMF | | |
| □ | 12.2 Investigator | | |
| □ | 12.3 Philippine government/entity/agency | | |
| □ | 12.4 Multilateral agency (UN agencies and other governmental agencies) | | |
| □ | 12.5 Private company or other non-governmental organization (NGO) | | |
| □ | 12.5 Others (indicate): | | |
| 1. **Study Budget:** |  | | | |
| 1. **Protocol Title:** |  | | | |
| 1. **Principal Investigator:** |  | | | |
| 1. **PI Address:** |  | | | |
| 1. **PI Telephone Number:** |  | | | |
| 1. **PI Facsimile** |  | | | |
| 1. **PI Email:** |  | | | |
| 1. **Institute/Department:** |  | | | |
| 1. **Sponsor:** |  | | | |
| 1. **Conflict of interest declaration (*Relationship with sponsor*)** | □ YES  □ NO  □ NA | | | 12.1 Are you a regular employee of the sponsor? |
| □ YES  □ NO  □ NA | | | 12.2 Did you do consultancy or part time work for the sponsor? |
| □ YES  □ NO  □ NA | | | 12.3 In the past year, did you receive P250, 000 or more form the sponsor? Other ties with the sponsor? |
| 1. **Other investigators with corresponding task description** *(add additional rows as applicable):* | Co-Investigator:  Task description: | | | |
| Co-Investigator:  Task description: | | | |
| 1. **Submitted by:** |  | | | |
| Study Designation: | | |  |
| 1. **PI Signature** |  | | | |

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| SECTION II: SCIENTIFIC/TECHNICAL REVIEW APPROVAL ENDORSEMENT  *This section should be signed by the Chair/Head of the Scientific/Technical Review committee/office that reviewed the scientific soundness of the study and issued the appropriate approval. Alternatively, results of Scientific/Technical Review disposition may be appended to this application, instead of completing this section, provided that the information required below had been appropriately addressed.* | | | | | | |
| **STUDY PROTOCOL TITLE:** | |  | | | | |
| **Principal Investigator** | |  | | | | |
| I confirm that the (**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**) has reviewed and approved the following study protocol-related information: Objectives/Expected output supported by literature review; overall research design; sampling design, sample size, Inclusion/exclusion/ withdrawal criteria; data collection plan and specimen collection, processing, and storage as applicable; data analysis plan including statistical design/framework, as applicable. | | | | | | |
| **Issuing committee/office:** | | |  | | | |
| **Head of committee/office:** | | |  | | | |
| **Signature:** |  | | | **Date:** | |  |
| SECTION III: INSTITUTIONAL ENDORSEMENT  *This section should be signed by the head of unit (administrative authority legally empowered to sign on behalf the unit such as Dean, Director, Chair, and the like) of the Principal Investigator. This section is required only for initial submission,* ***provided there are no changes in study protocol information below****.* | | | | | | |
| **STUDY PROTOCOL TITLE:** | |  | | | | |
| **Principal Investigator:** | |  | | | | |
| I confirm that I have read this Application and that the research will be implemented under the oversight of this Department/Institution in accordance with the conditions of approval by the *MCU – Filemon D. Tanchoco, Sr. Medical Foundation Inc. Institutional Review Board*. I also confirm that the Principal Investigator has a regular appointment in this institution. | | | | | | |
| **Issuing Unit/Department** | |  | | | | |
| **Head of committee/office:** | |  | | | | |
| **Signature:** |  | | | **Date:** | |  |
| SECTION IV: AUTHORIZATION AND ACKNOWLEDGEMENT OF REVIEW  *This section should be completed by the signatory official who can sign on behalf of the institution that has oversight on the research site,* ***IF the research site is OUTSIDE the scope of authority of MCU-FDTMF and the PI is non MCU-FDTMF personnel****. If not applicable, put N/A in all fields. This section is required only for initial submission, provided there are no changes in study protocol information below. In case regional IRB will opt not to review, attach letter of endorsement.* | | | | | | |
| **STUDY PROTOCOL TITLE:** | |  | | | | |
| **Principal Investigator:** | |  | | | | |
| This is to certify that the <NAME OF RESEARCH SITE>:  1) Has no local Institutional Review Board/ Ethics Review Committee; and  2) Authorizes and acknowledges the ***MCU – Filemon D. Tanchoco, Sr. Medical Foundation, Inc. Institutional Review Board (MCU-FDTMF IRB)***, located at the *2nd Floor Graduate Pharmacy Laboratories, Manila Central University, Samson Road, EDSA, Caloocan City*, to perform the ethical review of the above mentioned study protocol. in accordance with international ethical standards and national regulatory requirements, and oversee the conduct of the research study which includes progress monitoring, adverse event monitoring, and site visits. | | | | | | |
| **Name of Research Site:** | | |  | | | |
| **Address of Research Site:** | | |  | | | |
| **Signatory Official** | | |  | | | |
| **Position of Official:** | | |  | | | |
| **Signature:** |  | | | | Date: |  |
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