**CHECKLIST**

|  |  |  |
| --- | --- | --- |
|  | **Submission Date** |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **MCU-FDTMF PROTOCOL CODE** |  | **Sponsor Protocol Number** |  |

|  |  |
| --- | --- |
| **Protocol Title** |  |

|  |  |
| --- | --- |
| **Principal Investigator(s)** |  |
| **Sponsor** |  |

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| --- |
| **Documents to be Submitted:** |
|  |  |  |  |
|  |  |  | Full Protocol |
|  |  |  |  |
|  |  |  | Checklist Form (*MCU-FDTMF IRB Form 2.8-2020*) |
|  |  |  |  |
|  |  |  | Application Form for Protocol Review (*MCU-FDTMF IRB Form 2.1-2019*) |
|  |  |  |  |
|  |  |  | Protocol Summary Sheet (*MCU-FDTMF IRB Form 2.2-2019*) |
|  |  |  |  |
|  |  |  | Protocol Document Evaluation Form (MCU-FDTMF IRB Form 2.3-2020) |
|  |  |  |  |
|  |  |  | Informed Consent Document Evaluation Form (MCU-FDTMFIRB Form 2.4-2020) |
|  |  |  |  |
|  |  |  | Document Receipt Form (MCU-FDTMF IRB Form 2.9-2020) |
|  |  |  |  |
|  |  |  | Budget |
|  |  |  |  |
|  |  |  | Informed Consent Form in English (for studies with human participants) |
|  |  |  |  |
|  |  |  | Informed Consent Form in local language (for studies with human participants) |
|  |  |  |  |
|  |  |  | Assent Form in English (for studies involving minors and relevant populations deemed |
|  |  |  | incompetent to sign an informed consent) |
|  |  |  |  |
|  |  |  | Assent Form in local language (for studies involving minors and relevant populations deemed |
|  |  |  | incompetent to sign an informed consent) |
|  |  |  |  |
|  |  |  | Informed consent form for Genetic Studies in English and Local Language |
|  |  |  |  |
|  |  |  | Data Collection Forms (including CRFs) |
|  |  |  |  |
|  |  |  | Investigators’ Brochure (for clinical trials phase I, II, III) or Basic Product Information Document |
|  |  |  | (for Phase IV clinical trials) |
|  |  |  |  |
|  |  |  | Recruitment Advertisement, if applicable |
|  |  |  |  |
|  |  |  | Other information or documents for participants (such as diaries, etc.) |
|  |  |  |  |
|  |  |  | Curriculum Vitae of PI and Study team members |
|  |  |  |  |
|  |  |  | Good Clinical Practice (GCP) Training Certificate of PI, Co-Investigator and the rest of the study team |
|  |  |  |  |
|  |  |  |  |
|  |  |  | Journal Reports and Literature Review (for fellows-in-training, residents-in-training, nurses and other allied personnel) |
|  |  |  |  |
|  |  |  |  |
|  |  |  | Declaration of Conflict of Interest signed by the PI (*MCU-FDTMF IRB Form 2.1-2019:* |
|  |  |  | *Application for Protocol Review*) |
|  |  |  |  |
|  |  |  | Ethical Considerations: description / statement of compliance with ethical principle |
|  |  |  | (*MCU-FDTMF IRB Form 2.2-2019: Protocol Summary Sheet*) |
|  |  |  |  |
|  |  |  | Technical Review Board approval signed and dated, if applicable |
|  |  |  |  |

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| --- | --- | --- | --- |
| **Principal Investigator’s Signature** |  | **Date** |  |

**Note:**

1. Cover page of the folder must contain the following information:
	* Protocol Title
	* Protocol Number
	* Sponsor
	* Principal Investigator
	* Site Name
2. Follow the below sequence, starting from the 2nd page to the succeeding pages:
* Technical Review Board Approval signed and dated, if applicable
* MCU-FDTMF IRB above documents
* Table of Contents
* Study Protocol (Include a footer (in all pages) that indicates both the **DATE** and **VESION NUMBER.**
1. All documents submitted should be labelled or tabbed, signed by PI as indicated, submit to MCU-FDTMF IRB Secretariat at 2nd Floor, Graduate Pharmacy Building, Manila Central University, Samson Road, EDSA, Caloocan City.
2. Submit study protocol and related documents in data file folder or in PVC binders for clinical trials. For fellows-in-training, residents-in-training, students and other allied personnel **use folders for the 9 copies and one (1) PVC binder** for the original document submission.