

Protocol Application Requirements and Initial Review Checklist

A. STUDY PROTOCOL INFORMATION

MMERC Code:	
Study Protocol Title:	
Principal Investigator:	
Study Protocol Submission Date: <i>(to be accomplished by MMERC Staff)</i>	
Verified Complete by: <i>(to be accomplished by MMERC Staff)</i>	
Classification of Review: <i>(to be accomplished by MMERC Staff)</i>	<input type="checkbox"/> EXPEDITED <input type="checkbox"/> FULL BOARD <input type="checkbox"/> EXEMPTED
Classified by the: <input type="checkbox"/> CHAIR <input type="checkbox"/> VICE CHAIR <input type="checkbox"/> MEMBER SECRETARY	

B. A COMPLETE PROTOCOL PACKAGE INCLUDES THE FOLLOWING:

- ☐ 1. MMERC Application Form 2.1 – completely filled, signed and dated by PI
- ☐ 2. Full protocol with the informed consent form (if no ICF, waiver of consent)
- ☐ 3. Executive protocol summary that follows research project proposal format and contains a ManilaMed ERC Protocol Summary Sheet (MMERC Form 2.2)
- ☐ 4. Protocol Evaluation Form 2.3
- ☐ 5. Informed Consent Form 2.4
- ☐ 6. Declaration of conflict of interest
- ☐ 7. Data collection form/s
- ☐ 8. Informed Consent form (English and local dialect)
- ☐ 9. Assent form if applicable (English and local dialect)
- ☐ 10. CV of the PI and co-investigators, GCP Certificate (as necessary but mandatory for sponsor-initiated studies), PRC license (updated)
- ☐ 11. GANTT Chart (as necessary)
- ☐ 12. Ads for recruitment, if applicable
- ☐ 13. Technical approval document
- ☐ 14. Insurance
- ☐ 15. Budget
- ☐ 16. For researches involving access to medical records of ManilaMed:
- ☐ 17. Consent of ManilaMed Director for access of records
- ☐ 18. Data Sharing Agreement Form of ManilaMed.
- ☐ 19. Memorandum of Agreement between ManilaMed and other institutions if applicable
- ☐ 20. Bill of Rights in Health Research, Studies and Clinical Trials

Chair, MMERC

Signature over Printed Name/ Date