Republic of the Philippines
Department of Health
Center for Health Development 2
REGION II TRAUMA AND MEDICAL CENTER

Review Checklist

STUDY PROTOCOL INFORMATION

R2TMC-IRB Code:[1]	
Study Protocol Title:	
Principal Investigator:	
Study Protocol Submission Date: *(to be accomplished by R2TMC-IRB Staff)*	
Verified Complete by: *(to be accomplished by R2TMC-IRB Staff)*	Signature over Printed Name
Classification of Review: *(to be accomplished by R2TMC-IRB)*	☐ **EXPEDITED** ☐ **FULL BOARD**
Classified by the: **R2TMC-IRB CHAIR**	(Signature over Printed Name)

Basic Documents (must submit)

- ☐ Review Checklist **(R2TMC-IRB FM-PS00-TD05-02-01)**
- ☐ Technical Review Clearance for R2TMC- Funded Research
- ☐ Printed Registration and Application Form**(R2TMC-IRB FM-PS00-TD 05-02-02)**
- ☐ Study Assessment Form **(R2TMC-IRB FM-PS 00-TD 05-02-04)**
- ☐ Study Protocol
- ☐ Data collection forms (including CRFs)
- ☐ Diagrammatic workflow
- ☐ CV of PI and study team members
- ☐ Electronic copy of study protocol,
- ☐ Proof of payment of ethics review fee (as applicable)

Republic of the Philippines
Department of Health
Center for Health Development 2
REGION II TRAUMA AND MEDICAL CENTER

Study-specific Documents (submit as needed)

- ☐ Investigator's Brochure (for clinical trials phase I, II, III) or Basic Product Information Document (for clinical trials phase IV)
- ☐ 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 form)
- ☐ Assent form in local language (for studies involving minors and relevant populations deemed incompetent to sign an informed consent form)
- ☐ Good Clinical Practice (GCP) Training Certificate of PI, Co-I and the rest of the study team (for clinical trials)
- ☐ Recruitment advertisements (as needed by the study protocol)
- ☐ Other information or documents for participants (such as diaries, etc.)
- ☐ Material Transfer Agreement (for any research involving transfer of biological specimens)
- ☐ Memorandum of Agreement (for collaborative studies)
- ☐ Endorsed Clinical Trial Agreement (for clinical trials done in Veterans Regional Hospital; processed separately by the R2TMC Legal Office and to be submitted to MCC upon receipt of notification of ethical approval from R2TMC- **R2TMC-IRB**)
- ☐ Site Resources Checklist for Clinical Trial Outside R2TMC By R2TMC Personnel
  Site Resources Checklist for Clinical Trial outside R2TMC By non-R2TMC Personnel previous ethical review approvals/clearances (for students/personnel of foreign universities researching in the Philippines or those with prior ethical review)
- ☐ National Commission for Indigenous People (NCIP) Clearance (for studies with indigenous populations; can be processed while **R2TMC-IRB** review is ongoing)
- ☐ Clearance or permit from respective regulatory authorities (such as FDA approval for clinical trials and DENR local transport permit, as applicable)