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PROTOCOL PACKAGE CHECKLIST (Form 2.6.1)

Protocol Title:_____
_____
_____

PROTOCOL CODE:_____
PRIMARY INVESTIGATOR:_____
Date of Submission: _____

Basic Documents *(ALL must be submitted)*

- ☐ Protocol package checklist *(Form 2.6.1)*
- ☐ Application form for Protocol Review *(Form 2.6.2)*
- ☐ Protocol Evaluation Review *(Form 2.6.3)*
- ☐ Protocol Summary Sheet *(Form 2.6.4)*
- ☐ Study Protocol
- ☐ Diagrammatic work flow
- ☐ Gantt Chart for Schedule of activities
- ☐ Supplementary Documents (if applicable)
    - ☐ Questionnaire
    - ☐ Data Collection Forms
    - ☐ Product Brochure
    - ☐ Investigator's Brochure (for clinical trials phase I, II, III) or Basic Product Information Document (for Phase IV clinical trials)
    - ☐ Philippine FDA Marketing Authorization or Import License
    - ☐ Permit/s for Special Population (please specify)

      _____
- ☐ Informed Consent Form
  ☐ English ☐ Tagalog ☐ Others
- ☐ Assent Form (if applicable)
  ☐ English ☐ Tagalog ☐ Others
- ☐ Technical Review Certificate
- ☐ Good Clinical Practice (GCP) Training Certificate of PI, Co-I and the rest of the study team: updated at least within THREE (3) years (for clinical trials)
- ☐ Curriculum Vitae for all members of the Study Team

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- ☐ Non-Disclosure Agreement <Principal Investigator> *(Form 2.6.5)*
- ☐ Study Protocol Assessment Form *(Form 2.12.1)*
- ☐ Informed Consent Assessment Form *(Form 2.12.2)*

Study Specific Documents *(submit as needed particularly for externally originated studies and sponsored studies)*

- □ 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)
- □ Site Resources Checklist for Clinical Trial Outside BATMC By BATMC Personnel
- □ Site Resources Checklist for Clinical Trial Outside BATMC By non-BATMC 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 BATMC-RERC review is ongoing)
- □ Clearance or permit from respective regulatory authorities (such as FDA approval for clinical trials and DENR local transport permit, as applicable
- ☐ Contracts and/or Approval of relevant offices / regulatory authorities (Written review agreement / Authorization and Acknowledgement of review)

WHO Templates for Informed Consent and Assent Forms *(use as Guide only)*

- ☐ WHO TEMPLATE: Informed Consent form in English and Local language (for studies involving adult human participants) *(Use as Guide : WHO Form ICF-1)*
- ☐ WHO TEMPLATE: Informed Consent form for Co-signature in English and Local language (for studies involving minors ages more than or equal to 15 years up to less than 18 years of age and relevant populations deemed incompetent to execute decision and signing of informed consent form) *(Use as Guide : WHO Form ICF-1)*
- ☐ WHO TEMPLATE: Assent form in English and Local language (for studies involving minors less than or equal to 12-15 years of age and relevant populations deemed incompetent to sign an informed consent form*(Use as Guide : WHO Form ICF-2)*
- ☐ WHO TEMPLATE: Informed Parental Consent for Research Involving Children (Qualitative Studies) *(Use as Guide : WHO Form ICF-3)*
- ☐ WHO TEMPLATE: informed Consent for Storage and Future Use of Unused Sample *(Use as Guide : WHO Form ICF-4)*
- ☐ WHO TEMPLATE: Informed Consent for Qualitative Studies -research interventions that use questionnaires, in-depth interviews or focus group discussions *(Use as Guide : WHO Form ICF-5)*

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APPLICATION FORM FOR PROTOCOL REVIEW (Form 2.6.2)

		RERC Protocol Number:	
Sponsor Protocol Number		Submission Date:	
Type of Submission:	☐Initial Review ☐Continuing Review ☐Resubmission for re-review ☐Protocol Termination ☐Protocol Amendments ☐Final Report		
Protocol Title:			
Principal Investigator			
Telephone Number		Fax:	
E-mail		Preferred Contact:	☐ Phone ☐Fax ☐Email
Institute:			
Sponsor:			
Conflict of Interest Declaration (Relationship with sponsor)	Are you a regular employee of the sponsor? ☐ Yes ☐ No Did you do consultancy or part time work for the sponsor? ☐Yes ☐No In the past year, did you receive any monetary		

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	remuneration from the sponsor? ☐Yes ☐No Other ties with the sponsor ☐Yes ☐No
PI Signature:	
Verified Complete by: *(to be accomplished by BATMC-RERC staff)*	
Classification of Review: *(to be accomplished by BATMC-RERC staff)*	☐ EXPEDITED ☐ FULL-BOARD
Assigned Primary Reviewers :	
Independent Consultant to be Invited	
Classified by the: ☐ BATMC-RERC CHAIR ☐ BATMC-RERC SECRETARY	

PROTOCOL EVALUATION FORM (FORM 2.6.3)

BATMC-RERC CODE:		**DATE:**
NAME OF PRIMARY INVESTIGATOR		
PROTOCOL TITLE		
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 ethics approval.) NOTE: version and date of version must be inserted as a document footer for all submissions. ☐Continuing Review/Progress Report ☐Protocol Termination ☐Protocol Amendments ☐Final Report	
2.Date of Submission		
3. Study Category	☐4.1 Research involving human participants	

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4. Type of Study	☐5.1 Pre – clinical Research ☐5.2 Non-clinical trial, specifically (choose one): ☐5.2.1 Diagnosis ☐5.2.2 In vitro study ☐5.2.3 Stem Cell Research ☐5.2.4 Herbal Research ☐5.2.5 Complementary and Alternative Medicine Research ☐5.2.6 Review of medical records ☐5.2.7 Epidemiological study ☐5.2.8 Socio-behavioral research ☐5.2.9 Health Informatics ☐5.2.10 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

6. Category of Investigator	☐6.1 BATMC Research Center initiated study ☐6.2 BATMC ☐6.2.1 Active and; Associate-Active, Visiting Consultants ☐6.2.2 Residents-in-training ☐6.2.3 Fellows-in-training ☐6.2.4 Residents/Fellows graduated completing research requirements ☐6.2.5 Nursing ☐6.2.6 Other Researches (administrative etc,) please specify: ☐6.3 Non-BATMC ☐6.3.1 Active and; Associate-Active, Visiting Consultants ☐6.3.2 Residents-In-Training

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	☐6.3.3 Fellows-In-training ☐6.3.4 Residents/Fellows graduated completing research requirements ☐6.3.5 Nursing ☐6.3.6 Other Researches (administrative etc) please specify;
7. Proposed Study	☐7.1 Academic requirements (Thesis, Dissertation, Training Requirement ☐7.2 Independent research work ☐7.3 Multi-institutional or multi-country collaboration ☐7.4 Others (indicate):
8. PI Fascimile/CONTACT NUMBER/ EMAIL ADDRESS	
9. Classification of REVIEW	☐EXPEDITED REVIEW
(FOR RERC ONLY)	☐FULL BOARD REVIEW
	☐EXEMPTED from REVIEW
10. Assigned Primary Reviewers	
11. Independent Consultant	

PROTOCOL SUMMARY SHEET (FORM 2.6.4)

Date:_____

RERC Protocol NO:	Title

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Principal Investigator	Sponsor
Rationale	
Objectives	
Study Design/ Methodology	
Inclusion Criteria	
Exclusion Criteria	
Data Analysis Plan	
Study Outcomes	