NATIONAL CENTER FOR MENTAL HEALTH
RESEARCH ETHICS COMMITTEE

FORM 2.1
APPLICATION FOR INITIAL REVIEW

		REC Protocol No.	<to be filled up by REC Staff>
Sponsor Protocol No.	<to be filled up by REC Staff>	Submission Date	<to be filled up by REC Staff>
Protocol Title			
Type of Research	☐ Biomedical studies ☐ Clinical Trials ☐ Public Health Research ☐ Social Research ☐ Health Operations Research ☐ Others(specify): _____		
Principal Investigator			
Study Duration			
Sponsor			
Telephone No.		Fax No.	
E-mail Address		Preferred means of contact	☐ Phone ☐ Email
Institution			

Are you an 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 ₱250,000 or more from the sponsor?	☐ Yes	☐ No
Other ties with the sponsor:		

Ethical Responsibility and Conflict of Interest (COI) Statement

I hereby pledge to address all forms of COI that I may have and perform my tasks objectively, protect the scientific integrity of the study, protect all human participants and comply with my ethical responsibilities as Investigator.

Principal Investigator Signature	

FORM 2.1
APPLICATION FOR INITIAL REVIEW

- **Basic Documents must be submitted: (check the documents applicable to your proposal for submission)**

☐ Application for Initial Review (Form 2.1)
☐ Protocol Summary Sheet (Form 2.2)
☐ 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 (if applicable)
☐ Philippine FDA Marketing Authorization or Import License (if applicable)
☐ Permit/s for Special Population (please specify)
_____ (if applicable)

☐ Informed Consent Form
☐ English ☐ Tagalog ☐ Others
☐ Assent Form (if applicable)
☐ English ☐ Tagalog ☐ Others
☐ Technical Review Committee/Department Approval
☐ **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), **GRP, BRET, RCR** or any **Ethics Training** for Non-Clinical Trials
☐ Curriculum Vitae for all members of the Study Team

- **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.)
☐ Memorandum of Agreement (for collaborative studies)
☐ Non-NCMH researcher or with sponsor
☐ NCMH researcher is funded by a sponsor
☐ Previous ethical review approvals/clearances (for students/personnel of foreign universities researching in the Philippines or those with prior ethical review)
☐ 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)

Received by:_____ _____
REC Staff Date