

	Reference No.: BatStateU-FO-BERC-002	Effectivity Date:	Revision No.: 00
APPLICATION FOR ETHICS REVIEW OF A NEW PROTOCOL			

Instructions to the Researcher: Please accomplish this form and ensure that you have included in your submission the documents that you checked in Section 3 Checklist of Documents.

1. General Information			
Title of the Study			
BERC Code (To be Provided by BERC)		Study Site	
Name of Researcher		Contact Information	Tel No:
			Mobile Number
			Fax No:
Co-Researcher (if any)			Email:
Institution			
Address of Institution			
Type of Study	☐ Clinical Trial (Sponsored) ☐ Clinical Trials (Researcher- initiated) ☐ Health Operations Research (Health Programs and Policies) ☐ Social/ Behavioral Research ☐ Public Health/ Epidemiologic Research ☐ Others _____ ☐ Biomedical research (Retrospective' Prospective and diagnostic studies) ☐ Stem Cell Research ☐ Genetic Research ☐ Others _____		
	☐ Multicenter ☐ Multicenter (National) ☐ Single Site (International)		
Source of Funding	☐ Self-funded ☐ Government-Funded ☐ Scholarship/Research Grant ☐ Sponsored by a Pharmaceutical Company Specify: _____ ☐ Institution-Funded ☐ Others _____		
Duration of the Study	Start date: End date:	No. of Study Participants	
Has the Research undergone a Technical Review?		☐ Yes (please attach technical review results)	

Tracking No. _____

	☐ No	
Has the research been submitted to another BERC?	☐ Yes	☐ No
2. Brief Description of the Study		
3. Checklist of Documents		
Basic Requirements		Supplementary Documents
☐ Letter request for review		☐ Questionnaire (if applicable)
☐ Endorsement/Referral Letter		☐ Data Collection Forms (if applicable)
☐ Full proposal/study protocol		☐ Product Brochure (if applicable)
☐ Technical Review Approval		☐ Philippine FDA Marketing Authorization or Import License
☐ Certificate of Completion (e.g, RCR/BRET/GCP)		
☐ Curriculum Vitae of Researcher/s		
☐ Informed Consent Form (if applicable)		☐ Permit/s for special populations (please specify)
☐ English version ☐ Filipino version		
☐ Others_____		
☐ Assent Form (if applicable)		☐ Others (please specify)
☐ English version ☐ Filipino version		
☐ Others_____		
Accomplish		

Signature		
Date submitted		
-----To be filled by the BERC secretariat-----		
Completeness of Document	☐ Complete ☐ Incomplete	
Remarks		
Date Received		
Received by		