**APPLICATION FORM FOR ETHICAL REVIEW OF STUDY PROTOCOL**

**General Instruction**

Please accomplish this application form and attach them to copies of the proposal package submitted for review.

Protocol Code\* Date of Submission\*

Initial Submission Ammendment/SAE/SUSAR

 Resubmission Progress Report

 Continuing Review Terminal/Final Report

Type of Submission:

Study Protocol Title:

Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Position: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Contact Numbers: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Email address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Researcher/ Principal Investigator:

Basic Research

Clinical Trials

Social and Observational Research

Health Research

Others \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Undergraduate Thesis

Masteral Thesis

Doctoral Dissertation

GIA and GAA Funded Research

Others \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Nature and

Type of Study

 Research from the University Research outside the University

Ethics Review Fee\* Official Receipt No.

Signature of Researcher/Principal Investigator Received by:\*

Note: (\*) to be filled out by URERB Secretariat

**CHECKLIST ON THE REQUIREMENTS FOR ETHICS REVIEW**

To be filled out by URERB Secretariat

Basic Documents

* + Application Form (URERB Form 4)
	+ Cover Letter (Request letter addressed to the Chairperson)(URERB Form 5)
	+ Endorsement Letter/Certificate by the research or advisory committee (URERB Form 6)
	+ Research protocol (The protocol must include the title, objectives of the study, significance of the study, literature review, methodology and procedures, description of the study population, exclusion/inclusion criteria, ethical considerations, data analysis plan)
	+ Informed Consent Document (ICD) URERB Form 9 or Assent Document (for studies involving minors and relevant populations deemed incompetent to sign an informed consent form)
	+ Study tools (These include survey questionnaires, interview guide, case report form, posters/advertisements for recruitment, etc.)
	+ Curriculum vitae of researcher/principal investigator

Additional Documents (as needed)

* + Study Protocol Assessment Form (URERB Form 7)
	+ Informed Consent Assessment Form (URERB Form 8)
	+ Study drug/medical device information (These include investigator brochures/ published literature/ medical device manufacturer’s design, if relevant)
	+ Information regarding funding, sponsors, institutional affiliations, other potential conflicts of interest;(if applicable)
	+ Contracts and approval of relevant offices (if applicable)
	+ Memorandum of Agreement (MOA) if study is collaborative in nature; Materials Transfer Agreement (MTA), Intellectual Property approval, Investigational Device Exemption (IDE), when relevant; (if applicable)
	+ Study/protocol budgetary requirements.

For Resubmissions/Post Approval Submissions

* + Revised Study Protocol with study tools and ICD
	+ Revision Form for the Study Protocol (URERB Form 10 )
	+ Revision Form for the Informed Consent (URERB Form 11)
	+ Others \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Verified the completeness of the study protocol package by: Endorsed by:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Staff Secretariat Member Secretary

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Review Classification:

* Full Review
* Expedited Review \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* Exempt Review Chair, URERB