CRERC FORM 3.3
PROTOCOL FORMAT CHECKLIST

To be filled by investigator

CRERC Protocol No:	Title

Principal Investigator	Sponsor & Sponsor's Protocol No.;

	PAGE Number	**AVAILABLE (/)**
I. **TITLE PAGE**		
-Research Title		
-Institution		
-List of Investigators		
-Primary Investigators or Primary Author		
-Consultant Co-Authors		
-Month/Year		
II. **INTRODUCTION**		
-What is known about the research topic?		
-Are there local studies?		
-What is not yet known about the research topic?		
-What makes your study different from the ones conducted elsewhere?		
-A statement on rationale and justification of doing the research proposal.		
-Overall objective or goal of the research proposal.		
III. **REVIEW OF RELATED LITERATURE**		
IV. **RESEARCH QUESTION**		
V. **SIGNIFICANCE OF THE STUDY**		
VI. **OBJECTIVES OF THE STUDY**		
-General Objectives		
-Specific Objectives		
VII. **DEFINITION OF TERMS**		
VIII. **METHODOLOGY**		
-Research Design		
-Study Setting		
-Inclusion and Exclusion Criteria		
-Sampling Design or Sampling Frame		
-Sample Size Estimation		
-Data Collection Procedures *(provide a detailed description)*		

-Manner by which the data will be collected.		
-Description of the tool or instrument *(if applicable)*		
-Description of interventions for clinical trials and other forms of experimentation *(if applicable)*		
-Outcome Measures		
-Primary Outcome		
-Secondary Outcome/s *(if applicable)*		
-Data Handling, Management, and Analysis		
-Describe the encoding process		
-Describe the types of data that will be collected		
-Describe how the different types of data will be analyzed		
-Descriptive Statistics		
-If applicable, analytical statistics *(state hypothesis and other forms of statistical assumptions)*		
IX. ETHICAL CONSIDERATIONS		
-Ethics Review Process		
-State where to seek for approval		
-Informed Consent		
-Describe the process		
-Describe the timing of eliciting the research proposal's informed consent		
-Describe the venue where the informed consent process will take place		
-Disclosure of Study Objectives		
-Disclosure of Procedures		
-Disclosure of Study Benefits or Advantages		
-Disclosure of Harms and Risks		
-Serious Adverse Events		
-Serious Unexpected Serious Adverse Reaction		
-Others *(e.g. Psychological Harm, etc.)*		
-Options to Withdraw and Alternation Options		
-Privacy		
-Confidentiality		
-Compensation, Remuneration, and Reimbursement		
-Extent of Use of the Study		
-Authorship		
-Complete name of the Primary Author/s		
-Complete name of the Secondary Author/s		
-Contributorship		
-Complete name of the Contributing Author/s (e.g. Statistician)		
-Declaration of Conflict of Interest		
-Source of Funding		
-Is this an investigator-initiated study?		
-Is this a sponsor-initiated study?		
-Contact Details		

-Primary Author/s		
-Office Address		
-Mobile Phone Number		
-Landline Number		
-E-mail Address		
-Secondary Author/s		
-Office Address		
-Mobile Phone Number		
-Landline Number		
-E-mail Address		
-CRERC Chair		
-Office Address		
-Mobile Phone Number		
-Landline Number		
-E-mail Address		
X. DUMMY RESULTS AND TABLES		
-Provide dummy results and how the data will be presented		
-Label tables accordingly		
XI. REFERENCES		
-Please refer to https://www.nlm.nih.gov/bsd/uniform_requirements.html for syntax of various reference citations.		
XII. RESEARCH BUDGET		
-Itemize research budgetary requirements		
XIII. RESEARCH TIMELINE (Use Gantt Chart)		
XIV. APPENDIX		
-Informed Consent Forms (All Versions)		
-Other tables		
-Equations, Solutions		
-Figures		
-Pictures		
-Others: Please specify		