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Appendix 6. General outline for a study protocol/research project for IRB No. application at RHIH

Study title, Principal investigators and collaborators as well as their institutions/department affiliation.

Summary of the study to be submitted in RHIH Research and ethical review committee for IRB N°. application.

1. Executive summary (Not more than 250 words) *must be on a separate sheet*
2. Introduction -Background/rationale of the study
3. Statement of the problem
4. Aim and objectives
   4.1 Main objective
   4.2. Specific objectives
   4.3. Research questions or hypothesis
   4.4. Justification of the study
   4.5. Significance of the study
   4.6. Key literature summary of critical review and research gap identified from current and past relevant studies done and justify the novel of the current protocol.
5. **Methodology**
   5.1. Study description
   5.2. Research study design
   5.3. Research study approach
   5.4. Research study site setting/area
   5.5. Study population
   5.6. Proposed intervention if interventions study
   5.7. Description of theoretical framework: Model or theory name selected related to the research topic name selected (Why do you select to use this model?)

5.8. Conceptual framework (Main exposures and/or confounders and /or outcomes to be measured).

6. Selection of study population

6.1. Inclusion criteria

6.2. Exclusion criteria

6.3. Research study sample size calculation

6.4. Research study sampling technique/strategy ***

6.5. Randomization if randomized trial

7. Study procedures

7.1. Procedures at enrollment

7.2. Follow up if cohorts study or trial

7.3. Measurements of exposures and confounders

7.4. Measurement of outcomes

7.5. Laboratory methods if the study has a lab component

7.6. Data collection instruments or tools

7.7. Validity and reliability of data collection instrument or tool

7.8. Recruitment and training of field assistance (if any).

7.9. Data collection procedures(Administration procedures)

7.10. Data management

7.11. Proposed statistical methods of data analysis

What research methods will you use? Give a **brief non-technical explanation**.

Include study design, statistical analysis methods, sample size, and power analysis

8. Ethical considerations issues and how you propose to deal with them

8.1. Confidentiality

8.2. Informed consent

8.3. Ethical approval

8.4. Risks and benefits

8.5. Data storage

9. Expected Outcome/Results

10. Plan of dissemination of results

11. List of references using Havard referencing style (Both in-text and reference list)

12. Work plan and Gantt chart

13. Logistics/Budget

13.1. Distribution of responsibilities in study protocol

13.2. Timetable

13.3. Budget in details for full study protocol and source of funds

14. Appendices (Questionnaire, Consent forms, Invitation letter requesting the participation in research etc… and their translation in language of study participants such as Kinyarwanda etc…)