

General outline for a study protocol:

Study title, principal collaborators and institutions

Summary of study = synopsis

1. Background
2. Aim and objectives
 - 2.1. Aims
 - 2.2 Objectives
3. Methods
 - 3.1.1. Study description
 - 3.1.2. Study design
 - 3.1.3. Study site
 - 3.1.4. Study population
 - 3.1.5. Proposed intervention if interventions study
 - 3.1.6. Main exposures and/or confounders and/or outcomes to be measured
4. Selection of study population
 - 4.1. Inclusion criteria
 - 4.2. Exclusion criteria
 - 4.3. Sampling
 - 4.4. Randomization if randomized trial
5. Study procedures
 - 5.1. Procedures at enrolment
 - 5.2. Follow-up if cohorts study or trial
 - 5.3. Measurement of exposures and confounders
 - 5.4. Measurement of outcomes
 - 5.5. Laboratory methods if the study has a lab component
 - 5.6. Sample size
 - 5.7. Data Management
 - 5.8. Proposed analysis
6. Ethical considerations
 - 6.1. Confidentiality
 - 6.2. Informed consent
 - 6.3. Ethical approval
7. Logistics
 - 7.1. Distribution of responsibilities
 - 7.2. Timetable
 - 7.3 Budget
8. References
9. Appendices