

OUTLINE FOR BIOMEDICAL/CLINICAL TRIAL STUDY PROTOCOL

The research protocol should contain the following:

Format for research proposal

- Font Size 12, 1.5 line spacing
- Pages numbered.
- Table of content
- List of abbreviations where applicable
- List of table(s) and figure(s)

PLEASE NOTE THAT ARRANGEMENTS OF THE PROTOCOL SHOULD FOLLOW THE SEQUENCE PROVIDED IN THE OUTLINE BELOW.

Outline for research proposal

1. Ghana specific Protocol (if study is a multi-centre and original protocol is Generic)
2. Project summary
3. General Information
4. Background rationale
5. Literature review
6. Study goals and objectives
7. Study design
8. Study population
9. Study area(s)
10. Methodology
11. Ethical and Safety Considerations (Problems anticipated and solutions proposed)
12. Plans for Follow-up (s)
13. Data management considerations and statistical analysis
14. Quality assurance
15. Expected Outcomes of the study
16. Dissemination of results
17. Duration of the Project
18. Project Management
19. Informed-Consent Form
20. Budget
21. Funding source(s)
22. References
23. Collaborators (Include letter of support)

24. Curriculum Vitae of PI and co PIs
25. Abridged Curriculum Vitae of Supervisors for student protocols
26. Profile on Previous study (If study is in Phases)
27. Insurance cover for participants
28. Material Transfer Agreement (if specimen has to be transported outside Ghana)
29. Indicate if samples will be stored (where and for how long)
30. Membership of Data Safety Management Board (DSMB), CVs, and Charter of Work
31. GCP certificates for PI and Co PIs
32. Registration with clinical trials registry
33. NB: Regulatory approval from FDA required before study can start

OUTLINE FOR SOCIAL SCIENCE STUDY PROTOCOL

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Outline for research proposal

1. Project summary
2. Background rationale
3. Literature review
4. Study design
5. Study goals and objectives
6. Study population
7. Study area
8. Methodology
9. Data management and statistical analysis
10. Expected Outcomes of the study
11. Dissemination of results and publication policy

12. Duration of the Project
13. Problems anticipated
14. Project Management
15. Ethical Considerations
16. Informed-Consent Documents
17. Budget
18. Funding source(s)
19. References
20. Collaborators (include letter of support)
21. Curriculum Vitae of each Investigator
22. Abridged Curriculum Vitae of Supervisors for student protocols
23. Profile on Previous study (If study is in Phases)