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GHANA HEALTH SERVICE ETHICAL REVIEW COMMITTEE

Research & Development Division
Ghana Health Service
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REQUIREMENTS FOR SUBMISSION OF NEW PROTOCOLS FOR REVIEW

A
Requirement for submission of Clinical Trial Protocols

Thirteen (13) sets of (bounded new Protocol) must be submitted to the **GHANA HEALTH SERVICE ETHICAL REVIEW COMMITTEE** for consideration, **ONE MONTH** before the scheduled meeting date. Each set of the Protocol must include copies of the following:

1. Principal Investigator's Application for submission.
2. Current CVs of Principal Investigators & Co-Investigators
3. Cover letter from head of the Principal Investigator's Institutions i.e. (Institutional Support letter for the Study.)
4. Current Certificate of Training in Good Clinical Practices (GCP) for PI(s)
5. Full Protocol and Executive summary
6. Signatory page of Key persons of the Collaborative institutions involved in the study i.e.
   i. Investigator Agreement (PI's responsibility) Page duly signed, with name and date.
   ii. Sponsor Signatory Approval (Sponsor responsibility) Page duly signed, with date.

7Profile on previous study i.e. Phase 1 & Phase II studies (if applicable)
8 Written Informed Consent form plus translations into the local language
9. Written Parental Consent form & Assent form for older children (if study is for Minor)
10. Field guide i.e. questionnaire, enrolment forms, tools
11. Completed ERC checklist (copy attached)
12. Confirmation letter from Participating/Collaborative institution involved in the study
13. Scientific Review Approval
14. Material Transfer Agreement (MTA) for shipment of Specimen/Biological materials
15. Insurance Cover Note for Study Participants
16. Administrative Information on Sponsors of the study
17. Detailed Budget for the Study.
18. Principal Investigator (s) current Certificate of training in GOOD CLINICAL PRACTICES (GCP).
19. Investigational Product Brochure for the study
20. Data Safety Management Board (DSMB) membership and Charter of Work/Current CVs.
21. Referral forms for Treatment
22. Any other information deemed necessary to facilitate the review process.
23. Food and Drugs Board approval letter for Usage of the Investigational Product (This should be submitted after ERC approval).
24. Signed Agreement between Sponsor and Principal Investigator (If applicable)

CONTACT PERSONS

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B

Requirements for Submission of Basic & Social Science study Protocols

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Thirteen (13) sets of (bounded new Protocol) must be submitted to the **GHANA HEALTH SERVICE ETHICAL REVIEW COMMITTEE** for consideration, **ONE MONTH** before the scheduled meeting date. Each set of the Protocol must include copies of the following:

1. Principal Investigator's Application for submission.
2. Current CVs of Principal Investigators & Co-Investigators
3. Cover letter from head of the Principal Investigator's Institutions i.e. (Institutional Support letter for the Study.)
4. Full Protocol plus Scientific justification/ Executive summary
5. Signatory page of the Key persons of the Collaborative institutions involved of the study
6. Written Informed Consent form plus translations into the local language
7. Written Parental Consent form & Assent form for older children (if study is for Minor)
8. Field guide i.e. questionnaire, enrolment forms, tool
9. Completed ERC checklist (copy attached)
10. Confirmation letters from Participating/Collaborative institution involved in the study
11. Copy of letter asking permission to conduct the study in a particular institution
12. Copy of Permission letter granting permission for the study to be conducted in a particular institution
13. Administrative Information on Sponsors of the study
14. Agreement between Sponsors and Investigator (s) i.e. PI and Sponsor's Responsibilities
15. Institutional Review approval or Scientific Review approval (if applicable)
16. Referral forms for Treatment (if applicable)
17. Detailed Budget for the Study.
18. Material Transfer Agreement (MTA) if samples have to be taking outside for analyses
19. Any other additional information deemed necessary to facilitate the review process.
20. Data Safety Management Board (DSMB) membership and Charter of Work/Current CVs. (if applicable)
20. Food and Drugs Board approval letter (if applicable). This should be submitted after ERC approval).
21. Signed Agreement between Sponsor and Principal Investigator (If applicable)

Submit Applications to the following:

Postal Address
The Chairman
GHS-Ethical Review Committee
P. O. Box MB 190
Accra-GHANA
Adabraka Polyclinic

Location
The Chairman
GHS-Ethical Review Committee
Research and Development Division
How independent in composition of research

Opposite Accra Psychiatric Hospital
Cathedral Square, Castle Road, Accra

CONTACT PERSONS

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Nana Abena Kwaa

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C

Requirement for Submission of PhD Student's Project work Protocols

Thirteen (13) sets of (bounded new Protocol) must be submitted to the **GHANA HEALTH SERVICE ETHICAL REVIEW COMMITTEE** for consideration, at least **ONE-MONTHS** before the scheduled meeting date. Each set of the Protocol must include copies of the following:

1. Principal Investigator's Application for submission.
2. Current CVs of Principal Investigators & Co-Investigators
3. Cover letter from head of the Principal Investigator's Institutions i.e. (Institutional Support letter for the Study.)
4. Letter from Student's School/ Supervisor
5. Letter from Student's Local Supervisor (if PI is International Student)
4. 4. Full Protocol plus Scientific justification/ Executive summary
5. Signatory page of Principal Investigators (PI's) Project Supervisor, with name and date.
6. Written Informed Consent form plus translations into the local language (if study is for Adults)
7. Written Parental Consent form & Assent form for older children (if study is for Minor)
8. Field guide i.e. questionnaire, enrolment forms, and tools.
9. Completed ERC checklist (copy attached).
10 Confirmation letter from Participating/Collaborative institution involved in the study.
11. Institutional Review approval or Scientific Review approval (if applicable).
12. Copy of letter asking permission to conduct the study in a particular institution
13. Copy of letter from proposed study site granting permission for the study to be conducted there
14. Administrative Information on Sponsor (s) for the study.
15. Material Transfer Agreement (MTA) if samples/data have to be taking outside for analyses
16. Referral forms for Treatment (if applicable)
17. Detailed Budget for the Study.
18. Any other additional information deemed necessary to facilitate the review process
19. Food and Drugs Board approval letter for usage of a particular product (if applicable). This should be submitted after ERC approval).
20. Signed Agreement between Sponsor and Principal Investigator (If applicable)

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D

Requirement for Submission of Masters Student Project work Protocols (Basic and Social Science Study) MSc, MPhil, MPH etc.

Six (6) sets of (bounded new Protocol) must be submitted to the **GHANA HEALTH SERVICE ETHICAL REVIEW COMMITTEE** for consideration**, ONE MONTH** before the scheduled meeting date. Each set of the Protocol must include copies the following:

1. Principal Investigator's Application for submission.
2. Current CVs of Principal Investigators & Co-Investigators
3. Cover letter from head of the Principal Investigator's Institutions i.e. (Institutional Support letter for the Study.)
4. Letter from Student's School/ Supervisor
5. Letter from Student's Local Supervisor (if PI is International Student)
4. Full Protocol plus Scientific justification/ Executive summary
5. Signatory page of Principal Investigators (PI's) Project Supervisor, with name and date.
6. Written Informed Consent form plus translations into the local language (if study is for Adults)
7. Written Parental Consent form & Assent form for older children (if study is for Minor)
8. Field guide i.e. questionnaire, enrolment forms, and tools.
9. Completed ERC checklist (copy attached).
10 Confirmation letter from Participating/Collaborative institution involved in the study.
11. Institutional Review approval /Scientific Review approval (if applicable).
12. Copy of letter asking permission to conduct the study in a particular institution
13. Copy of letter from proposed study site granting permission for the study to be conducted there
14. Administrative Information on Sponsor (s) for the study.
15. Material Transfer Agreement (MTA) if samples have to be taking outside for analyses
16. Referral forms for Treatment (if applicable)
17. Detailed Budget for the Study.
18. Any other additional information deemed necessary to facilitate the review process
19. Food and Drugs Board approval letter for usage of a particular product (if applicable). This should be submitted after ERC approval).
20. Signed Agreement between Sponsor and Principal Investigator (If applicable)

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