Information on Ethical Clearance for the Conduct of Research in the Ghana Health Service

Research and Development Division

GHS Ethics Committee Meeting Schedule for 2010

The GHS Ethics Committee meets on the last Wednesday of every other month.

The scheduled meetings for the year 2010 will fall on:

1. 27th January
2. 31st March
3. 26th May
4. 28th July
5. 29th September
6. 24th November

Proposals for consideration at a meeting should be received at least TWO weeks before the scheduled meeting date, otherwise it will be scheduled for review at the next meeting.

Expedited review may be considered under exceptional circumstances, but never for clinical trials.

REQUIREMENTS FOR SUBMISSION FOR ETHICAL CLEARANCE

1. Completed checklist (copy attached)
2. 13 copies of full Protocol each with completed checklist attached
3. 13 copies Executive Summary of the full Protocol
4. 13 copies of the Consent form
5. 13 copies of the questionnaires/tools
3. CVs. of Investigators with a cover letter signed by the Principal Investigator
4. Institutional support letter from PI's Mother organization affirming the organization's awareness and approval to the study.

GHANA HEALTH SERVICE
ETHICAL REVIEW COMMITTEE ON RESEARCH INVOLVING HUMAN SUBJECTS (ERCRIHS)
(CHECKLIST)

PI NAME:
Project ID (To be given by the Secretariat

Title of Project:			**PI TO COMPLETE**		
			Yes	**No**	**N/A**
	Vulnerable/High Risk Group				
1	Is a vulnerable population being studied?		☐	☐	☐
	If yes, tick the vulnerable population being studied?				
	☐ Pregnant women ☐ Adolescents Children	☐Elderly ☐Refugees ☐Those who cannot give consent (unconscious)	Prisoners Persons with mental or Behavioural disorders Others		
2	Is the justification for studying this vulnerable population adequate?		☐	☐	☐
3.	Have adequate provisions been made to ensure that the vulnerable population is not being exploited?		☐	☐	☐
Responsible Technical Officer's Comments:					
Scientific and Technical Issues					
1.	Is the rational for the study clearly stated in the context of present knowledge?		☐	☐	☐
2.	Is the hypothesis to be tested fully explained?		☐	☐	☐
3.	Is the project design scientifically sound?		☐	☐	☐
4.	Where present, is the control arm adequate?		☐	☐	☐
5.	Are the inclusion and exclusion criteria complete and appropriate?		☐	☐	☐
6.	Are the types and methods for subject allocation appropriate?		☐	☐	☐
7.	Are the procedures for participant recruitment, admission, follow up and completion appropriate?		☐	☐	☐
8.	Are the drugs and/or devices to be used fully described?		☐	☐	☐
9.	Does the project design include appropriate criteria for stopping and discontinuing the research?		☐	☐	☐
10.	Are the clinical procedures to be carried out fully described and appropriate?		☐	☐	☐
11.	Are the laboratory tests and other diagnostic procedures fully described and appropriate?		☐	☐	☐
12	Is the Statistical basis for the study design appropriate and is the plan for analysis of the data appropriate?		☐	☐	☐
R**esponsible Technical Officer's Comments:**					

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		Yes	**No**	**N/A**
Informed Consent, Decision-making & Confidentiality				
1.	Is the information sheet free of technical terms, written in laypersons' language, easily understandable, complete & adequate?	☐	☐	☐
2.	Does it make it clear that the proposed study is research?	☐	☐	☐
3.	Does it explain why the study is being done and why the subject is being asked to participate	☐	☐	☐
4.	Does it clearly state the duration of the research**?**	☐	☐	☐
5.	Does it provide participants with a full description of the nature, sequence and frequency of the procedures to be carried out?	☐	☐	☐
6.	Does it explain the nature and likelihood of anticipated discomfort or adverse effects, including psychological and social risks, if any-and what has been done to minimize these risks, and the action to be taken if they occur?	☐	☐	☐
7.	Does it outline the possible benefits, if any, to the research participants	☐	☐	☐
8.	Does it outline the possible benefits, if any, to the community or to society?	☐	☐	☐
9	If confidentiality is not possible due to the research design, has this been conveyed to all relevant persons?	☐	☐	☐
10	Does it inform the research participants that their participation is voluntary and refusal to participate (or discontinue participation) will involve no penalty or loss of medical benefits to which the participant was otherwise entitled?	☐	☐	☐
11.	Does it describe the nature of any compensation or reimbursement to be provided?	☐	☐	☐
12	Does it provide the alternatives to participation?	☐	☐	☐
13.	Does it provide the name and contact information of a person who can provide more information about the research project at any time?	☐	☐	☐
14.	Has provision been made for subjects incapable of reading and signing the written consent form (e.g. illiterate patients)? (Please attach)	☐	☐	☐
15	Does it conclude with a statement such as ''I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any question I have asked have been answered to my satisfaction. I consent voluntarily to participate as a subject in this study and understand that I have the right to withdraw from the study at any time without in any way it affecting my further medical care''	☐	☐	☐

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		Yes	No	N/A
16.	Does it provide information to the research participants on the costs to the participants involved in terms or time, travel, man-days lost from work, etc. and reimbursements, if any?	☐	☐	☐
17.	Has provision been made for subjects incapable of giving personal consent (e.g. for cultural reasons, children or adolescents less than the legal age for consent in the country in which research is taking place, subjects with mental illness, etc)? (Please attach).	☐	☐	☐
18.	Does it outline the procedure that will be followed to keep participants informed of the progress and outcome of the research?	☐	☐	☐
Responsible Technical Officer's Comments:				
Other materials, documents and study instruments (Patient recruitment material, Questionnaires				
1	Is the Participant Recruitment Material (e.g. advertisements, notices, media articles, transcripts of radio messages) provided both in English and in the local language?	☐	☐	☐
2.	Do these materials make claims that may not be true?	☐	☐	☐
3.	Do they make promises that may be inappropriate in the research setting (e.g. provide undue incentives or emphasize remuneration?	☐	☐	☐
4.	Does the study involve questionnaires, diaries, study instrument?	☐	☐	☐
5.	Are these attached to the proposal (In English and local language)?	☐	☐	☐
6.	Are the questionnaires written in lay language and easily understood?	☐	☐	☐
7.	Are the questionnaires relevant to answer the research question?	☐	☐	☐
8.	Are the questionnaires worded sensitively?	☐	☐	☐
9.	Does the consent information and form describe the nature and purpose of the questions to be asked?	☐	☐	☐
10.	If applicable, does the consent information and form make it clear that some of the questions may prove embarrassing for the participant?	☐	☐	☐
11.	Does the proposal describe how confidentiality of the questionnaires will be maintained (i.e. will they be coded or anonimized)?	☐	☐	☐
12.	Does the consent information and form state that the participant is free to not answer any question?	☐	☐	☐
13.	Where applicable, does the informed consent form make it clear that the in-depth interview or focus group discussion is likely to be audio or video taped?	☐	☐	☐
14.	Where applicable, does the consent form mention how and for how long these tapes are going to be stored?	☐	☐	☐
Responsible Technical Officer's Comments:				

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		Yes	No	N/A
Clinical Trials				
1.	Is this a new drug or vaccine trial?	☐	☐	☐
2.	If applicable, is clearance from the national drug regulatory authority attached? *	☐	☐	☐
3.	Is the Investigator's Brochure (including safety information) attached?	☐	☐	☐
4.	Is the Adverse Drug Reaction/Adverse Event Reporting form attached?	☐	☐	☐
5.	Has a Data Safety Monitoring Board been established	☐	☐	☐
6.	Are the names of the chairperson and members of the DSMB available for the records?	☐	☐	☐
Responsible Technical Officer's Comments:				
Human Biological Materials				
1,	Will human biological materials (tissues, cells, fluids, genetic material or genetic information) be collected as part of the research?	☐	☐	☐
2.	Does the consent information and form fully described the nature, number and volume of the samples to be obtained and the procedures to be used for obtaining them?	☐	☐	☐
3.	Does the consent information and form indicate if the procedures for obtaining these materials are routine or experimental and if routine, are more invasive than usual?	☐	☐	☐
4.	Does the consent information and from clearly describe the use to which these samples will be put?	☐	☐	☐
5.	Does the consent information and form include the provision for the subject to decide on the use of left-over specimens in future research of a restricted, specified or unspecified nature?	☐	☐	☐
6.	Does the consent information and form cover for how long such specimens can be kept and how they will be finally destroyed?	☐	☐	☐
7.	Does the proposal describe how specimens will be coded/anonimized	☐	☐	☐
8.	Where applicable, does the consent form mention that genetic testing/genomic analysis will be carried out on the human biologic materials?	☐	☐	☐
Responsible Technical Officer's Comments:				