APPLICATION FORM FOR ETHICAL CLEARANCE OF NEW PROPOSAL

NOTES:

The protocol is to demonstrate to the UCCIRB how the proposed study will be conducted ethically. By this, the applicant must show that the research statement (gap) is unique, the proposed science and methods are appropriate and may not lead to incorrect conclusions. The safety of researcher(s) and research participants is ensured, and so are the anonymity and confidentially of participants. Avoid the definition of terms in the write-up. Where necessary, this should be done in the section for the definition of terminologies.

INSTRUCTIONS:

1. Applicants are to complete all sections of the form before it will be considered for review. **Send the soft copy of your work for pre-review** before you submit one (1) **neatly comb-bound** hard copy of the protocol to the UCCIRB Office. A soft copy must be sent to irb@ucc.edu.gh.
2. The proposal and other documents should be paged separately as done in the form.
3. Use very clear font sizes such as Times New Roman 11pt / 12pt, Arial 11pt, and Calibri 12pt.
4. The paper size should be A4
5. Margins of 2.5 × 1.0× 2.0 × 1.5cm
6. Maintain the header and footer of this form
7. Attach the following documents to your proposal to make a complete protocol.
    a. An application letter for ethical clearance by the Principal Investigator (PI)
    b. Support letters from
        i. Supervisor and Head of PI's College/School/Faculty/Department (for students).
        ii. Collaborator(s) from a different institution(s) should be added (non-students).
    c. Complete and attach the consent form(s) and checklist
    d. Add data collection instrument(s) *if any*
    e. Add similarity report of proposal
    f. Abridged Curriculum Vita of the applicant(s), and that of the Supervisor (for Student Investigator(s) should be added as an attachment. *- use the attached format*
8. For further information, contact UCCIRB at 0558093143/0508878309/ OR Email: irb@ucc.edu.gh

IMPORTANT INFORMATION

I. Please send the soft copy of ***every completed document*** for a pre-review and wait for further directives before you print the hard copy.

II. The applicant will be provided with periodic updates by the UCCIRB Secretariat on their application or you may call on the contacts provided above.

III. Research Investigators who have started or already gathered their primary data are NOT eligible to apply for Ethical Clearance from the UCCIRB. The UCCIRB will withdraw an

approved Ethical Clearance or suspend or cancel the review of an application if this is detected.

IV. **The protocol for submission must contain the original application letters**

V. Application letter(s) with a **date(s) more than a month old at the time of submitting the hard copy will not be accepted**.

VI. Research Investigators who do not respond to comment(s) on their reviewed protocol(s) within a month (1) will have their applications withdrawn by the UCCIRB.

VII. All protocols will be subjected to a similarity check of not more than 15%.

A. BACKGROUND INFORMATION

Title of Research: .....

Principal Investigator: (Name, Qualification (Specialty), Department, Postal Address, Telephone, Fax number, email address)

Co-Principal Investigator(s): (Name, Qualification (Specialty), Department, Postal Address, Telephone, Fax number, email address)

Name of Supervisor (Students Only)

Source(s) of Funding: .....

Type of Research: (Biomedical/Social/Behavioural/Physical etc)

B. FORMAT FOR PRESENTING PROPOSAL

DETAILS OF PROPOSAL: This should be the format of the full proposal

Executive summary (**Not more than 200 words**) *must be on a separate page*

Introduction/Rationale/Background (Not more than 400 words)

Statement of the Problem (Not more than 200 words)

Justification/Significance of the study (Not more than 100 words)

Aim(s) and or Objective(s) of study (Not more than 100 words)

Research Questions and or Hypothesis (not more than 100 words)

Methods (Not more than 1000 words)

- Study design
- Study site
- Population
- Sample and sampling procedure
- Inclusion and Exclusion criteria
- Instruments (provide a brief of what the instrument covers)
- Recruitment and training of field assistants (indicate whether you will use or not. Do not leave this section blank or delete it).
- Data collection/ Experimental procedures
- Data analysis (justify the proposed methods of analysis)
- Data management (should cover sampling storage and transportation if any)
- Ethical Considerations
    1. Ethical issues
    2. How you propose to deal with them
    3. Procedure for administering the consent form
    4. Demonstrate how the findings will be reported ethically

Expected Outcome/Results (not more than 100 words)

References (for cited works only)

Work Plan (provide a table)

Budget (provide a table)

Definition of key terminologies (where necessary)

C1. INFORMED CONSENT FORM FOR ADULT

PART I: INFORMATION SHEET **(NB: Avoid the use of technical language or jargon)**

Title: [*Name of research project*]

Principal Investigator: [*Name*]

Address: [*Name of institution/company and complete address*]

General Information about Research

(A brief introduction of the researcher or the research team. State the objective of the research in easily-understood words. There must be a statement that the study involves research, an explanation of the purpose of the research and the expected duration of the participant's participation, a description of the procedures to be followed and the identification of any procedures which are experimental and what the participant(s) is/are supposed to do. All information about the research must be stated)

Procedures

To find answers to the questions in the [name of instrument], we invite you to take part in this research project. If you accept, you will be required to:

(the following applies only to focus group discussions) take part in a discussion with 7-8 other persons with similar experiences. This discussion will be moderated by [name of moderator] or myself.

(the following applies only to in-depth interviews) participate in an interview with [name of interviewer] or myself.

(the following applies only to questionnaire surveys) fill out a survey which will be provided by [name of a distributor of blank surveys] and collected by [name of the collector of completed surveys].

[Explain the reasons why a particular person is being selected to take part in the study]

(e.g. You are being invited to take part in this discussion because we feel that your experience as a social worker can contribute much to this discussion).

[Explain the type of questions that the participants are likely to be asked in the FGD or interviews or in the survey]

(***The following applies only to focus group discussions***) During this discussion, however, we do not wish you to tell us your personal experiences, but give us your opinion on the questions that we will pose to the group based on your personal experiences and your experience within your community. If you do not wish to answer any of the questions or take part in any part of the discussion, you may say so and keep quiet. The discussion will take place in [location of the FGD], and no one else but the people who take part in the discussion and the moderator or myself will be present during this discussion. The entire discussion will be tape-recorded, but **no-one will be identified by name on the tape**. Additionally, the tape will be kept [explain how the tape will be stored]. The information recorded is considered confidential, and no one else except [name of person(s) with access to the tapes] will have access to the tapes.

(***The following applies only to interviews***) If you do not wish to answer any of the questions posed during the interview, you may say so and the interviewer will move on to the next question. The interview will take place in [location of the interview], and no one else but the interviewer will be present. The information recorded is considered confidential, and no one else except [name of person(s) with access to the information] will have access to the information documented during your interview.

(***The following applies only to surveys***) If you do not wish to answer any of the questions included in the survey, you may skip them and move on to the next question. [Describe how the survey will be distributed and collected]. The information recorded is considered confidential, and no one else except [name of person(s) with access to the information] will have access to your survey.

(***The following applies to all instruments***)

The expected duration of the [discussion, interview or survey] is about [length of discussion, interview, or survey] (e.g. 40-75 minutes).

Possible Risks and Discomforts

(Description of any reasonably foreseeable risks or discomfort to the participant in partaking or responding to the instrument. Include physical, social and psychological risk if anticipated.)

Possible Benefits

(*Specific statement about benefit(s) to individual(s) – researcher and participants) and/or society that can be reasonably expected)*

Alternatives to Participation

(Disclosure of appropriate alternatives of treatment, if any, which might be advantageous to the respondents must be indicated).

(This does not apply to all studies and is usually used for intervention studies)

Confidentiality

(A statement describing the extent, if any, to which secrecy of records identifying the respondents will be maintained. For example, "We will protect information about you to the best of our ability. You will not be named in any reports. Some staff of [list all groups that may access the research records] may sometimes look at your research records").

Compensation

(*If there are any reward packages either in cash or kind available for participants; they must be spelt out in terms of the actual amount to be given or gift to be given, conditions for receiving the package and when it will be made available to participants). Usually, compensation should be given at the end of the study*

Additional Cost

(Any additional cost to the participant that may result from participation in the research should be stated). **This does not apply to all studies**

Staying in the Research

(*If the research method is to be used with another method, list conditions of use and any exceptions to the exclusive use requirements).* (**This does not apply to all studies**)

Voluntary Participation and Right to Leave the Research

(*A statement that the research is voluntary and the participant can withdraw without penalty)*

Termination of Participation by the Researcher

(Any anticipated circumstances under which the participant's participation may be terminated by the investigator without regard to the participant's consent must be specified). **(This does not apply to all studies)**

Notification of Significant New Findings

(A statement that significant new findings developed during the course of the research that may relate to the participant's willingness to continue participation will be provided to the participant). **(This does not apply to all studies)**

Contacts for Additional Information

(Give an explanation of whom to contact for answers to pertinent questions about the research and whom to contact in case of research-related injury. Give names and mobile numbers that are accessible to the participant). For students include the contact of your supervisor.

Contact of Ethical Review Board

This research has been reviewed and approved by the Institutional Review Board of the University of Cape Coast (UCCIRB). If you have any questions about your rights as a research participant you can contact the Administrator at the IRB Office between the hours of 8:00 am and 4:30 p.m. through the phone lines 0558093143/0508878309 or email address: irb@ucc.edu.gh.

PART II: VOLUNTEER'S AGREEMENT

The above document describing the benefits, risks and procedures for the research title ***(title of research)*** has been read and explained to me. I have been given an opportunity to have any questions about the research answered to my satisfaction. I agree to participate as a volunteer.

OR

I have read the above document describing the benefits, risks and procedures for the research title ***(title of research)***. I have been given an opportunity to ask any question about the research and this has been answered to my satisfaction. I agree to participate as a volunteer.

Volunteer's Name: ……....

Volunteer's Signature/Thumbprint……..

Date: **……**

If volunteer cannot read the form themselves, a witness must sign here:

I was present while the benefits, risks and procedures were read to the volunteer. All questions were answered and the volunteer has agreed to take part in the research.

Witness's Name: …….

Witness's Signature/Thumbprint: ……

Date: ……..

I certify that the nature and purpose, the potential benefits, and possible risks associated with participating in this research have been explained to the above individual.

Researcher's Name: ……...

Researcher's Signature/Thumbprint…….

Date: **……..**

C2. CHILD ASSENT FORM (APPLICABLE IF MINORS ARE INVOLVED IN THE STUDY)

PART I: INFORMATION SHEET **(NB: Avoid the use of technical language or jargons)**

Introduction

My name is *[name of researcher]* and I am a *[qualification, status or position, department and institution]*. I am conducting research entitled *[research title]*. I am asking you to take part in this study because I am trying to learn more about *[purpose and should include the justification for the invitation]*.

Procedure

If you accept to be in this study, you will be asked to *[insert a detail description of the main research procedure such as completion of survey, body measurements, drug intake, sample collection etc]*. This will take *[insert length of participation]*.

Possible Benefits

Your participation in this study will result *[insert benefits and compensation]*.

Possible Risks and Discomforts

The risks associated are *[enumerate all associated risks]*. *However, this will be addressed [describe how you will address them]*.

Voluntary Participation and Right to Leave the Research

You are free to join this study and you can stop participating at any time if you feel uncomfortable. No one will be angry with you or punish you if you do not want to participate or stop participating. Please talk about this study with your parents before you decide whether or not to participate. I will also ask permission from your parents before you are enrolled into the study. Even if your parents/guardian say "yes" you can still decide not to participate.

Confidentiality

Indicate the procedures to ensure safety of the data [information or samples] retrieved and how you will make volunteers anonymous.

Contacts for Additional Information

You may ask me any questions about this study. You can call me at any time *[your contact information]* or talk to me the next time you see me. You may also contact *[any other person involved in the study; Co-PI, supervisor, sponsor etc.]*

Contact of Ethical Review Board

This research has been reviewed and approved by the Institutional Review Board of University of Cape Coast (UCCIRB). If you have any questions about your rights as a research participant you can contact the Administrator at the IRB Office between the hours of 8:00 am and 4:30 p.m. through the phone lines 0558093143/0508878309 or email address: irb@ucc.edu.gh.

PART II: VOLUNTEER'S AGREEMENT

By making a mark or thumb printing below, it means that you understand and know the issues concerning this research study. If you do not want to participate in this study, please do not sign this assent form. You and your parents will be given a copy of this form after you have signed it.

The information which describes the benefits, risks and procedures for the research titled *[research title]* has been read and or explained to me. I have been given an opportunity to ask any questions about the research answered to my satisfaction. I agree to participate.

Child's Name: ……..

Child's Mark/Thumbprint……..

Date: ……..

Witness for volunteer must sign here:

I was present while the benefits, risks and procedures were read and explained to the volunteer. All questions were answered and the volunteer has agreed to take part in the research.

Witness's Name: ……

Witness's Signature/Thumbprint…….

Date: ……

I certify that the nature and purpose, the potential benefits, and possible risks associated with participating in this research have been explained to the above volunteer in the presence of the witness *[name of witness]*.

Researcher's Name: ……...

Researcher's Signature/Thumbprint…….

Date: ……..

INFORMED CONSENT FORM FOR THOSE SEEKING INFORMATION FROM RECORDS

PART I: INFORMATION SHEET **(NB: Avoid the use of technical language or jargons)**

Title: [*Name of research project*]

Principal Investigator: [*Name*]

Address: [*Name of institution/company and complete address*]

General Information about Research

(A brief introduction of the researcher or the research team. State clearly the objective of the research in easily-understood words. There must be a statement that the study involves research, an explanation of the purpose of the research and the expected duration of the participant's participation, a description of the procedures to be followed and the identification of any procedures which are experimental and what the participant(s) is/are supposed to do. All information about the research must be stated)

Procedures

To find answers to the questions, *we* seek your permission to access the records of [specify the group] your outfit for this research project. If permission is granted, you will be required to make available records on [specify the group].

[Explain the reasons why a particular institution or group is being selected to take part in the study]

The data search will take place in [location of the institution], and no one else but the people who take part in the data search and the moderator or myself will be present during this data search.

The information obtained is considered confidential, and no one else except [name of person(s) with access to the information] will have access to the records. The expected duration of the data search is about (40-75 minutes).

Possible Benefits

(*Specific statement about benefit(s) to individual(s) – researcher and participants) and/or society that can be reasonably expected)*

Confidentiality

(A statement describing the extent, if any, to which secrecy of records identifying the respondents will be maintained. For example, "We will protect information about you to the best of our ability. You will not be named in any reports. Some staff of [list all groups that may access the research records] may sometimes look at your research records").

Contacts for Additional Information

(Give an explanation of whom to contact for answers to pertinent questions about the research and whom to contact in case of research-related injury. Give names and mobile numbers that are accessible to the participant). For students include the contact of your supervisor.

Contact of Ethical Review Board

This research has been reviewed and approved by the Institutional Review Board of University of Cape Coast (UCCIRB). If you have any questions about your rights as a research participant you can contact the Administrator at the IRB Office between the hours of 8:00 am and 4:30 p.m. through the phone lines 0558093143/0508878309 or email address: irb@ucc.edu.gh.

PART II: AGREEMENT OF OFICER-IN-CHARGE

I have read the above document describing the procedures, benefits and usage of the data to be taken for the research title ***(name of research)***. I have been given an opportunity to ask any question about the research and this has been answered to my satisfaction. I permit you to access the needed information/documents.

Name of officer-in-charge: …….

Signature……..

Date: **…….**

I certify that the nature and purpose, the potential benefits, and possible risks associated with participating in this research have been explained to the above individual.

Researcher's Name: ……...

Researcher's Signature: …….

Date: …….

D. CHECKLIST

Name of Principal Investigator: ……..

Title of Proposal:		**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 ☐ Incarcerated / Prisoners	☐Elderly (above 60yrs) ☐Refugees ☐Those who cannot give consent (sick or unconscious)	☐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?	☐	☐	☐
Comment(s) of reviewer:				
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 participant 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?	☐	☐	☐
Comment(s) of reviewer:				

Name of Principal Investigator: ……

.		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 participant 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 or other 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 participants 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 respondent 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''	☐	☐	☐
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 respondents' 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, respondents 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?	☐	☐	☐
Comment(s) of reviewer:				
Other materials, documents and study instruments (Patient recruitment material, Questionnaires)				
.		**Yes**	**No**	**N/A**
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 anonymised)?	☐	☐	☐
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?	☐	☐	☐
Comment(s) of reviewer:				
Clinical Trials		**YES**	**NO**	**N/A**
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?	☐	☐	☐
Comment(s) of reviewer:				

Human Biological Materials		**YES**	**NO**	**N/A**
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 describe 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 form clearly describe the use to which these samples will be put?	☐	☐	☐
5.	Does the consent information and form include the provision for the respondents 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 or anonymised?	☐	☐	☐
8.	Where applicable, does the consent form mention that genetic testing/genomic analysis will be carried out on the human biologic materials?	☐	☐	
Comment(s) of reviewer:				

ABRIDGED CURRICULUM VITAE

Name:

Address:

Telephone (s):

Mobile

Fax

Email:

Educational Background:

Employment Records:

Major Research Projects Undertaken:

Recent Publications:

Membership of Professional Body(ies)

Note: should not be more than two (2) pages

ARRANGEMENTS OF PROTOCOL FOR SUBMISSION

APPLICATION LETTER(S) *(PI, SUPERVISOR'S CONSENT LETTER, COVER LETTER from Dept COLLABORATING SUPPORT LETTER from INSTITUTION OR INDIVIDUAL)*

BACKGROUND INFORMATION

PROPOSAL

INFORMED CONSENT FORM(S)

CHECKLIST

RESEARCH INSTRUMENT(S)

ABRIDGED CV(S) OF INVESTIGATOR(S) AND THE SUPERVISOR (for student)

SIMILARITY REPORT

Please Note: All documents must be paged separately and put together as **one word document** for submission. Thank you