FINAL REPORT

TRAINING CHILDREN TO ASSIST IN INSTITUTIONAL REVIEW BOARD: A PILOT STUDY IN CAPE COAST, GHANA

December, 2024

This project is supported by the Oxford-Johns Hopkins Global Infectious Disease Ethics Collaborative (GLIDE). GLIDE is supported by the Wellcome Trust [221719].

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DISCLAIMER:

THE VIEWS EXPRESSED IN THIS 'TRAINING CHILDREN TO ASSIST IN INSTITUTIONAL REVIEW BOARD: A PILOT STUDY IN CAPE COAST, GHANA' PUBLICATION, ARE SOLELY THE AUTHORS' AND DO NOT NECESSARILY REFLECT THE VIEWS OF THE OXFORD–JOHNS HOPKINS GLOBAL INFECTIOUS DISEASE ETHICS COLLABORATIVE (GLIDE) OR THE WELLCOME TRUST

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1.0 INTRODUCTION

1.1 Project Background

The United Nations Convention on the Rights of the Child states that children have a right to be heard in all things that affect them and that children's views should be considered in conformity with their age and maturity (UNICEF, 1989). As a result, there has been a gradual shift from a paternalistic attitude toward children to respect for their autonomy to some extent. Consequently, there is a growing recognition that children's views and experiences should be included, and they should be consulted in matters that will affect them especially where their interests and rights are concerned (Archard, 2018).

In the domain of pediatric treatment, for instance, there has been an increasing attempt to empower and give pediatric patients due weight to their views according to their maturity. Some have argued that a teenager (e.g., fourteen years old, although the exact age associated with the ability is a matter of disagreement) can make health decisions and provide informed consent to medical procedures, and their autonomy should be respected (American Academy of Pediatrics Committee on Bioethics, 1995; Baker, 2013).

In the conduct of empirical research, children and teenagers have been mostly involved in data collection and, in some instances, as co-researchers. One question that is yet to be explored in-depth is whether children can play a role in Institutional Review Board (IRBs) activities. This body has the primary mandate to provide an independent, competent, and timely review of the ethics and methods of proposed research studies. The members of IRBs are composed of scientific, technical, and community experts (Lidz et al., 2012). Currently, IRBs comprise adult members with limited or no expert support services from children during reviews of pediatric research. However, adults are not always capable of representing children's views and interests, and many ethical issues in pediatric research could be better approached if children's perspectives are taken into consideration.

Following the present guidelines for engaging children in society's decision-making processes and activities that affect them, we argue that including competent children's perspectives in an IRB's ethical decision process in pediatric research has significant benefits with no correspondingly significant harms. This idea has been developed by Owusu and Passos-Ferreira in the manuscript "Licensing competent children to assist Institutional Review Boards", currently under review in the Journal of Medical Ethics. The present pilot study is an attempt to test the hypothesis formulated in this manuscript.

This pilot research study was conducted to explore how children's views can be incorporated into the decisions of IRBs. It was also implemented to serve as an empirical basis to assess the feasibility or otherwise of incorporating children's views into IRB reviews and serve as a framework for identifying competent children who could be engaged to support IRBs.

1.2 Implementation Questions

This pilot study sought answers to the following questions:

1. What are the core required abilities of children who are capable of supporting the ethics review activities of IRBs?
2. What are the main resources that would be required to train competent children to effectively support the ethics review activities of IRBs?
3. What are the key ethical issues that would be involved in the recruitment and training of children to support the ethics review activities of IRBs?
4. How feasible is it to incorporate the views of children into the ethics review activities of IRBs?

2.0 METHODOLOGY

2.1 Implementation Design

We adopted the *input-process-output-outcome model* to guide the implementation design. using the University of Cape Coast Institutional Review Board (UCCIRB) in Ghana to implement this pilot study. This model is one of the most common models used by project implementers to:

- assemble resources (data, information, technology, personnel, capital, expertise, materials) that would be required to implement a project successfully;
- define how these resources would be used in the process; and
- determine the desired results expected to be derived from the process.

2.2 Input

The implementation of this 'pioneer' study required varied resources, information, materials, and personnel. Concerning information, we relied on the views of key stakeholders, including members of the research community and IRB practitioners on the justification and acceptability of including children's views in the ethical review processes. We gathered this information through feedback from informal interactions, workshops, and conference presentations.

We also needed children who could be trained to understand the essentials of research ethics and the ethics review activities of IRBs. Based on our earlier argument to justify the competence of children in moral decisions, we recruited nine children between 14 and 18 years old who are enrolled in public senior high schools in the Cape Coast Metropolis and also resided in Cape Coast. The inclusion criteria comprised equitable gender representation, the ability to make basic health decisions and give valid assent to participate in research as well as the willingness and consent of parents/guardians. Besides, we relied on the support of the broader University of Cape Coast administration for assistance in the use of training venues and computer-based logistics for online training.

Another critical input was suitable training materials. Being mindful of the non-existence of these materials, we developed a training manual and facilitators' guide that were used to implement the project. The manual has an introductory section that details basic background information about research, and other sections that explain research ethics principles and information about the activities of IRBs such as research protocol review processes. We will share copies of the Manual and Guide with the University of Oxford GLIDE Project team once the materials are finalised and published.

Funding was a major driver in facilitating the mobilisation of the inputs and implementation of the pilot study. The project received its main funding from the University of Oxford in the United Kingdom (Grant Number CSR00350) through the GLIDE network/funding.

Process

To attain our goal of exploring how children's views can be incorporated into the decisions of IRBs, we implemented various activities that enabled us to transform our inputs into the intended output/outcome. Firstly, we secured the approval of the UCCIRB as the partner institution and Board to implement this study; having secured the ethics approval from the UCCIRB (ethics approval number UCCIRB/EXT/2023/31). Furthermore, we obtained consent and approval from the Cape Coast Metropolitan Directorate of Education to allow the public schools selected to participate in the project. Subsequently, the schools responded to our request and gave us approval to train the selected children. The final permission was sought from the parents of the children selected as well as the children for consent and assent respectively.

All the children were interviewed before the commencement of the training session to assess their understanding of research, research ethics, experiences as research participants, awareness of the conduct of unethical research, and the roles children can play to support the activities of IRBs in their ethical review of padiatric research protocols as well as their expectations from the pilot study. The data also served as baseline information. The non-residential training was conducted on weekends so that the academic activities of the children would not be interfered with.

Each child was picked from their residence to the training site at the University of Cape Coast and transported back to their respective places after each training session. Before the pick-up and sending of the children, the respective parents were informed, and permission was sought and granted. Training sessions (see Annex 1 for the timetable). centred on the basics of research methods, research ethics, and research protocol review processes using a mix of child-centered facilitation methodologies. The training sessions ended with a review of the pediatric research protocols provided by the UCCIRB. Each child reviewed the protocol individually. They identified and documented various ethical comments, after which the comments were consolidated and categorised based on broad ethical themes– risk, assent, and justice. The children made their decisions on the protocol based on their ethical assessment and review comments. The final stage of the process was the presentation of the children's review comments to the UCCIRB Members (see Annex 2).

Finally, post-training interviews were conducted to assess the project in general, and the training and capacity development of the children regarding research and pediatric research protocol review.

1.4. **Output**

Evidence from the review comments, presentation to the UCCIRB as well as the pre and post-training data and information suggest the following:

1. The children can review pediatric research protocols in social sciences;
2. Preliminary feedback from the UCCIRB indicates that the Members have identified;
    a. some administrative modifications that have to be done in their ethics application documents; and
    b. new areas to focus their ethics reviews, deficient capacities, and training needs relative to the ethics review comments by the children regarding pediatric research protocols.

1.5 **Outcome**

The outcome of the project is the overarching aim of this pilot study – the inclusion of trained children on IRBs to review pediatric research protocols. We feel convinced that the UCCIRB would accept to include children in this review process partly based on the feedback from the children that indicates that they have become aware of some ethical issues like potential research risks and harms, such as privacy and confidentiality, which their colleague students often breach. While this aim is yet to be fully realised, the following are other intended outcomes:

1. the formation of *Research Ethics Clubs* at the participating schools led by the children;
2. use the pilot project as a model to upscale and replicate it in other schools in the country.

In the medium to long term, we anticipate that IRBs will adopt the views of expert children in their decision-making process of reviewing a protocol before they ethically approve proposed pediatric research.

Preliminary informal feedback from the UCCIRB indicates that the Members have identified some administrative modifications that have to be in their ethics application documents, new areas to focus their ethics reviews, deficient capacities, and training needs relative to the ethics review of proposed pediatric research protocols. Ultimately, this pilot study has provided empirical baseline evidence to

justify the need to involve children's views in the ethical protocol review process and justified the need for IRBs to explore and engage competent children who will assist them in their ethical reviews. There is a need to extend the implementation of this pilot study to other IRBs to replicate the intervention and assess its scalability.

2.4 Ethical applications

The key ethical applications that were associated with this pilot study bordered on justice in the selection of the participants, parental/guardian consent, assent of the children, confidentiality, and beneficence. Regarding the selection of the research participants (justice), we relied on the recommendation of the school authorities to identify eligible participants based on our inclusion and exclusion criteria.

We also recruited the children after going through systematic and comprehensive ethical approval/permission processes from the UCCIRB, educational authorities, parents/guardians, and the children. The educational authorities and the school management provided official permission letters, while the parents and children provided valid written consent and assent respectively. Our informed consent (Annex 3) and Child Assent form (Annex 4) provided detailed information on the background of the pilot study, eligibility criteria, nature/structure of the training sessions, as well as information on benefits, harms, compensation, and voluntary participation.

During all the training sessions, the children were provided with snacks and lunch which the children preferred. We adopted an open communication system that allowed the children to send us regular written and oral feedback on the content of each module and facilitation strategies, as well as their views on the logistics and general administrative arrangements.

To ensure confidentiality, all the data gathered through the implementation of this pilot study, including personal details of the children and their parents, videos, pictures, interview transcripts, presentation slides, and protocol review comments, have been saved in a secured Dropbox folder and shared only among the investigators, the children, and the UCCIRB. No personal identifiers have been used in our reports and public presentations.

3.0 CONCLUSION AND RECOMMENDATIONS

In conclusion, the pilot study shows the importance and feasibility of including children's perspectives in the ethical review processes of IRBs. By training competent children and engaging them in the review of pediatric research protocols, the pilot study has demonstrated the potential for a more inclusive and representative ethical decision-making process. While challenges such as resource allocation remain, the initial findings provide a strong foundation for future exploration and scaling of this approach. Involving children in IRB activities could enhance the relevance and fairness of pediatric research, ensuring that the voices of those directly impacted are meaningfully included.

We, therefore, recommend the training of children to support IRBs in the review of pediatric research protocols. Additionally, and with the support of other collaborators, we will scale this pilot study up to include IRBs in Ghana and other global sites.

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ANNEXES

ANNEX 1: TRAINING TIMETABLE

UNIVERSITY OF CAPE COAST
DIRECTORATE OF RESEARCH, INNOVATION AND CONSULTANCY
& INSTITUTIONAL REVIEW BOARD

TRAINING CHILDREN TO ASSIST IN INSTITUTIONAL REVIEW BOARD:
A PILOT STUDY IN CAPE COAST, GHANA

DRAFT TRAINING TIMETABLE

DATE	TIME	ACTIVITY	FACILITATOR
Saturday, 18th May 2024	10:00am – 10:45am	Conduct of pre-training interviews	Dr. Samuel Asiedu Owusu/ Prof. Kobina Esia-Donkoh
	10:45am – 11:00am	**Welcome Ceremony** • Welcome message – Moderator • Introductory messages – Facilitators • Self Introductions and Selection of Course Representatives • Administrative Announcements – Moderator	Dr. Samuel Asiedu Owusu
	11:00am – 11:15am	Snack Break/Group Photograph	Course Representatives
	11:15am – 12:15pm	Session 1: Introductory module	Dr. Samuel Asiedu Owusu
	12:15pm – 13:45pm	Session 2 – Concept of research & types of research.	Prof. Kobina Esia-Donkoh
	13:45pm – 14:00pm	Lunch and Closing	Course Representatives
Saturday, 25th May 2024	10:00am – 10:40am	Session 3: Recap of Session 2	Prof. Kobina Esia-Donkoh
	10:40am – 11:00am	Snack Break	Course Representatives
	11:00am – 13:00pm	Session 4: Doing research & the steps in conducting research	Dr. Samuel Asiedu Owusu
	13:00pm – 14:00pm	Lunch and Closing	Course Representatives
Saturday, 1st June 2024	10:00am – 10:40am	Session 5: Recap of Session 4	Prof. Kobina Esia-Donkoh
	10:40am – 11:00am	Snack Break	Course Representative
	11:00am – 13:00pm	Session 6: Introduction to Research Ethics	Prof. Kobina Esia-Donkoh
	13:00pm – 14:00pm	Lunch and Closing	Course Representatives
Saturday, 8th June 2024	10:00am – 10:40am	Session 7: Recap of Session 6	Dr. Samuel Asiedu Owusu
	10:40am – 11:00am	Snack Break	Course Representatives
	11:00am – 13:00pm	Session 8: Principles of Research Ethics	Prof. Claudia Passos-Ferreira
	13:00pm – 14:00pm	Lunch and Closing	Course Representatives

Saturday, 15th June 2024	10:00am – 10:40am	Session 9: Recap of Session 8	Prof. Kobina Esia-Donkoh
	10:40am – 11:00am	Snack Break	Course Representatives
	11:00am – 13:00pm	Session 10: Application of ethics in research (Case Studies)	Samuel Asiedu Owusu
	13:00pm – 14:00pm	Lunch and Closing	Course Representatives
Saturday, 22nd June 2024	10:00am – 10:40am	Session 11: Recap of Session 9	Prof. Kobina Esia-Donkoh
	10:40am – 11:00am	Snack Break	Course Representative
	11:00am -13:00pm	Session 12: Research Protocol Review Process	Prof. Kobina Esia-Donkoh
	13:00pm – 14:00pm	Lunch and Closing	Course Representatives
Saturday, 29th June 2024	09:00am – 09:40am	Session 13: Recap of Session 12	Dr. Samuel Asiedu Owusu
	09:40am – 10:00am	Snack Break	Course Representative
	10:00am – 12:00pm	Session 14: Research Protocol Review Process (Practical exercises)	Dr. Samuel Asiedu Owusu

ANNEX 2: CONSOLIDATED REVIEW COMMENTS

UNIVERSITY OF CAPE COAST
INSTITUTIONAL REVIEW BOARD

Title of research: Using Creative Arts Technologies to improve Academic Performance of Children with Writting Challenges in a Municipality in Ghana.

HOW THE PROTOCOL WAS REVIEWED

- Members read the protocol individually but severally for clarity.
- Members sought the meanings of some key terms used in the protocol.
- Members made comments based on the provisions in the protocol.
- Members categorised the comments based on some key ethical themes.
- Members compared some of their comments with the contents of the training manual to ensure accuracy and consistency.
- Members made a decision based on their assessment of the protocol.

STRENGTHS OF THE PROPOSED RESEARCH

1. The aim of the research is clear and focused.
2. The use of quantitative methods will provide valuable data-driven insights.
3. Some ethical issues like privacy and confidentiality have been identified.
4. The use of pseudonyms to mask the identity of the participants is very commendable
5. Limits on access to the data are also commendable.
6. To ensure the ethical conduct of the research, training sessions for the teachers who will serve as research assistants are very important.

REVIEW COMMENTS

1. Informed assent form:
    a. The research involves the participation of minors (from kindergarten one to basic three learners.). This means that the consent of the parents is needed and the assent of the child is important as well. The researcher has been able to provide the necessary information concerning the research, however, the choice of words and the method of explanation is too complex for the children to comprehend.
    b. Kindergarteners may not have the cognitive ability to understand the research and provide informed assent.
    c. The child assent form provided is not age-appropriate since the selected subjects cannot comprehend fully the concepts on the form.
    d. The indication of the name of the children on the assent form can breach confidentiality.
    e. In the ethical issues section, you stated that "respondents will have to agree to participate in the survey since anonymity and confidentiality were ensured." This presupposes that you are not giving them the right to choose what they like.
    f. The use of the word 'ensured' suggests that the study has already been conducted. Why are you now applying for ethical clearance?

2. Confidentiality:
    a. The researcher makes it known that pseudonyms will be used to ensure the anonymity of participants. A pseudonym refers to a fictitious name. The use of a fictitious name is dangerous. Given that the researcher has sampled 50 volunteers, a pseudonym used could be affiliated with a non-participant. It can also be linked to someone else. Hence this can lead to falsification of information about a person who is not involved in the research and it breaches the person's right to confidentiality and even privacy.

b. Are the children going to sign the assent form? If yes, do they know how to sign?
c. How the data collected will be transmitted has not been indicated. This may allow third parties to have access to the data.
d. How sure are we that the supervisor will not disclose the information to third parties?
e. Who will keep the keys to the drawer containing the hard copies?

3. Risks: Although the researchers stated that there are no associated risks for participating in this research, but:
    a. The researcher indicated that data collection will take up to 2 months. However, s/he didn't clearly state where the selected pupils will be undergoing the experimentation.
    b. The researcher also didn't indicate the time of the day the research will be conducted and whether it will be during the vacation or not. If this study is conducted during the normal teaching and learning periods, it will affect the learning of the children and the teaching of the professional teachers.
    c. The researcher also did not indicate if the activities that will be implemented by the experimental group will be integrated into their curriculum and not hinder any academic activity.
    d. The researcher also didn't indicate the fact that an unforeseen risk could show itself and how he/she would protect the child.
    e. Children with dysgraphia may be more vulnerable to emotional distress or stigma.
    f. The researcher should provide a stronger support system (counselor/psychologist) for the participants who are likely to require them especially since tests are not pleasant for children.
    g. Some participants may experience frustration or anxiety during the creative arts sessions and may feel discouraged if they struggle with their tasks.
    h. Thirty minutes have been allocated for the learners to respond to the test items but what will happen if this duration will not be favourable for dysgraphia students? This can be very discomforting for the children. This breaks the principle of non-maleficence. The number of days of the two months that this will last was not stated by the researcher. This might affect the academic work of the participants because they will miss some lessons in school
    i. Why compensate only the team members with refreshments? The children not going to participate in this refreshment constitutes an injustice
    j. Where will the study be conducted and what safeguards will be provided to ensure the safety of the children?
4. Fair subject selection:
    a. The researcher is conducting the research in two out of 80 schools in the Ga West Municipality. Why is the researcher choosing Ga West Municipality out of many municipalities in the Greater Accra Region since the researcher indicated that there is no record of students with dysgraphia in Ghana? Is it due to convenience or accessibility? This appears as an injustice to the other 78 schools.
    b. The researcher should have administered questionnaires to teachers in all the schools in the Municipality so that he/she would be able to identify the children with the neurological condition and suitable for the research so that the selection of the participants would have been fair and compliant with the ethical principle of justice and scientific value in the conduct of research.
    c. Why is the researcher choosing to do it in the Greater Accra Region? What about the other regions in Ghana? Why did he choose 2 schools out of 80? This could lead to an inequitable distribution of burdens and benefits that are associated with the implementation of this research.
    d. Why is he selecting 50 participants only? Are the participants going to be equally distributed by gender and class? Will the participants equally be from both the control

and experimental groups? How the 50 students would be sampled was not stated and this could be assumed as unfair and discriminating
   e. Why did he/she select children ranging from kindergarten 1 to basic 3?
   f. What methods will the researcher use to be able to recruit average children of dysgraphia to have an effective research size?
   g. The adopted method is not fair and inclusive. The researcher should ensure the inclusive selection of participants from a justified study site.
   h. The researcher did not indicate the criteria used in selecting the two schools as well as the criteria for selecting the 50 students.
   i. No provision has been made for participants with dysgraphia who may also have other special educational needs.
   j. Why did the researcher limit the participants from Kindergarten to Basic 3? What about the other classes? Don't we have dysgraphia students in the other classes?
   k. What procedure was adopted by the researcher to choose the experiment?
   l. In case the school(s) disagree, what will you do?

5. Recruitment and Training of Field Assistants:
   a. The researcher did not indicate how he/she will evaluate the teachers before they are found suitable to participate in the research.
   b. The researcher didn't clearly state the roles of the professional teachers he/she is going to recruit nor the basis for declaring the teachers professional.
   c. The researcher has indicated that there will be three training sessions for the research staff, each lasting two hours, to develop the necessary skills to conduct the research successfully. How sure are the researchers that the two hours will not affect their instructional hours since they will be professional teachers? When will the training sessions take place?
   d. The researcher did not indicate how the assistants will be evaluated to determine if they are abreast of research ethics issues before they are allowed to assist in the implementation of the research

6. Respect for autonomy
   a. They may not be able to make decisions to participate or withdraw from the research if they feel uncomfortable.

7. Data collection procedure
   a. The means of data collection in this proposal is not the right one to be used. For such a proposed study and considering the ages of the children and their neurological conditions, the use of a questionnaire for kindergarten pupils with dysgraphia is not an appropriate means of collecting such data. The test and the questionnaire will stress the children.
   b. The researcher did not indicate that permissions will be south of the Ghana Education Service. This may breach the principle of respect for persons.
   c. If after receiving your letter the headteachers accept that the study will be conducted in their schools. How will you receive their feedback? If they call you, who will pay for their call credit?

8. Compensation
   a. Although the children will take part in research that may benefit them in another way, they should be compensated to motivate them to participate in the study.

9. Budget
   a. Some of the cost items like the amount for photocopying and printing as well as for data

analysis have been over-budgeted.

b. You did not budget for accommodation.
c. GHC500.00 has been allocated for transportation but there is no information indicating the distances between the selected schools. What informed this cost estimate?

10. Data management
    a. The researcher did not indicate how long the data will be kept until disposal and the mechanism for the disposal according to provisions in Ghana's Data Protection Act.

11. Other observations
    a. Kindergarteners' writing skills are still emerging making it challenging to identify dysgraphia. They are still developing their fine motor skills and may not have the cognitive ability to express writing difficulties.
    b. The inclusion of kindergartners should be properly justified to indicate how their inclusion in the study will contribute to the attainment of the objectives.
    c. The researcher has not considered the negative effects of creative arts on the academic performance of students.
    d. Children, as they are growing up find it difficult to grasp learning materials so here dysgraphia should not be considered as an issue, or children who cannot write well should not be considered as dysgraphia patients.

Decision

Decision	**Number**	
Revised and Submit	7	
Defer	2	

ANNEX 3: INFORMED CONSENT FORM FOR PARENTS/GUARDIANS

PART I: INFORMATION SHEET

Title: Training children to assist in institutional review board: a pilot study in cape coast, Ghana
Principal Investigator: [Dr. Samuel Asiedu Owusu]
Address: Directorate of Research, Innovation and Consultancy, University of Cape Coast, Cape Coast, Ghana.

General Information about Research

Hello, I am Dr. Samuel Asiedu Owusu. I work at the University of Cape Coast as a social science health researcher. I have also worked at the University of Cape Coast Institutional Review Board where we review all documents related to proposed research to ensure that research participants are protected from harm that may be caused by research investigators. Together with my colleagues Prof. Kobina Esia-Donkoh and Prof. Claudia Passos-Ferreira, we have observed that even though children actively take part in the conduct of research and that they are also knowledgeable in some of the issues that directly affect them, they are not involved in the review of the research documents that are submitted by research investigators to the Board for ethical reviews. We think that children who are knowledgeable in research should also be allowed to actively participate in the ethical review processes. It is because of this that we want to engage your ward to take part in our research where we will find out if such children can help the Board in its decision-making processes.

Procedures

We are therefore requesting that you allow your ward to join 14 other children in our research. If you agree, we will also inform your ward about our research and ask him/her to decide or decline to participate. If your ward agrees, we will train him or her in basic issues in research, research ethics and the research protocol review processes. The training will be facilitated by myself, Kobina and Claudia (virtual participant) and it will take place at the University of Cape Coast Faculty of Social Sciences Conference Room. The entire training session will span for 4 months, but it will be conducted on Saturdays so that it will not seriously affect your wards academic work. After the training, the participants will be asked to review a research ethics protocol and present their report to members of the UCCIRB. We will first interview your ward about his/her knowledge in research and research ethics at our first meeting. The findings will help us to structure our facilitation techniques. We will conduct the same interviews after the training to find out the new knowledge and skills that your ward has gained. If your ward does not wish to answer any of the questions posed during the interview, he/she may say so to enable us to move to the next question. The information recorded is considered confidential, and no one else except the three facilitators, your ward, and the UCCIRB will have access to the information documented during the interview. The expected duration of the interview is about 30 minutes.

Possible Risks and Discomforts

The scheduling of the training sessions on weekends (Saturdays) may conflict with other activities of your ward including participation in schools' extracurricular activities. It may also interfere with his or her routine academic activities scheduled for Saturday afternoons. These may constitute *harm* to your ward. As we have already indicated, we will recruit participants only after receipt of consent from their school authorities and you (parents/guardians) as well as assent from your ward.

Possible Benefits

This research work is novel in the global practice of research ethics reviews. The benefit that your child or ward will derive from participating in this research is that it will broaden his/her understanding of research and research ethics issues. These will directly support him or her in his academic pursuit. This pilot research study will also benefit the UCCIRB and other IRBs in Ghana and elsewhere since it will provide a model or serve as the foundation on which future initiatives to involve children in research ethics review processes will revolve. It will also inform some policy formulation and implementation as

they relate to the administration of pediatric research ethics.

Alternatives to Participation
Not applicable

Confidentiality
To ensure the confidentiality of your ward during and after his or her participation in this research project, all data files will be password-protected and shared only among the investigators, your ward and the UCCIRB. Furthermore, all hand-written notes will be transcribed and saved electronically on a password-protected laptop which is owned by the principal investigator. The hard copies of the data will be shredded as well. No personal identifiers will be used in our reports but will be presented using pseudonyms. The Investigators will continue to adopt measures that will conform to appropriate research ethics standards as and when they unfold in the data collection process. Data transfer via the Internet will be secured with passwords.

Compensation
We cannot compensate your ward for his or her contribution in time, knowledge, and skills for this research project. We will recognise this as one of his or her major contributions to knowledge generation and strengthening of the research ethics administration procedures in the world.

Additional Cost
Commuting to the training site will involve some transportation costs to your ward which may be referred to as harm or discomfort to you or your ward. To prevent this potential harm, the investigators have made adequate budget allocations that will cater for the commuting and other logistical needs of your ward while taking part in the research project. Furthermore, we will ensure that neither you, your child, or your ward will incur any financial cost for participation in this study. We will also provide meals and water at every training session to ensure that participants do not spend money on food and water while taking part in this research.

Staying in the Research
Not applicable

Voluntary Participation and Right to Leave the Research
Your child or ward's participation in this research is voluntary and refusal to participate (or discontinue participation) will involve no penalty or loss of academic opportunities or other benefits to which he or she is otherwise entitled.

Termination of Participation by the Researcher
Not applicable

Notification of Significant New Findings
Not applicable

Contacts for Additional Information
If you wish to raise any questions or seek further clarification on this study, you may contact me, Dr. Samuel Asiedu Owusu at sowusu@ucc.edu.gh, +233244207814

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 a.m. 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 titled **Training children to assist in Institutional Review Board: a pilot study in Cape Coast, Ghana** 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 that my child or ward can participate in the proposed pilot research project.

Parent/Guardian Name: ……

Parent/Guardian Signature/Thumbprint……. Date : **……**

If the volunteer cannot engage in the declared method of consenting, a witness must sign here:

I was present while the benefits, risks and procedures were read to the Parent/Guardian. 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:……..…

ANNEX 4: CHILD ASSENT FORM

PART I: INFORMATION SHEET

Introduction

My name is Dr. Samuel Asiedu Owusu and I am a researcher at the University of Cape Coast Directorate of Research, Innovation and Consultancy. I am conducting research entitled *Training Children to assist in Institutional Review Board: a pilot study in Cape Coast, Ghana*. I am asking you to take part in this study because I am trying to learn more about how children can contribute to the ethical review of research protocol processes by members of the University of Cape Coast Institutional Review Board.

Procedure

If you accept to be in this study, you will be asked to join 14 other children in our research. That we will train you in basic issues in research, research ethics, and the research protocol review processes. The training will be facilitated by myself, Kobina, and Claudia, and it will take place at the University of Cape Coast Faculty of Social Sciences Conference Room. The entire training session will span for 4 months, but it will be conducted on Saturdays so that it will not seriously affect your academic work. After the training, the participants will be asked to review a research ethics protocol and present their report to members of the UCCIRB. We will first interview you about your knowledge of research and research ethics at our first meeting. The findings will help us to structure our facilitation techniques. We will conduct the same interviews after the training to find out the new knowledge and skills that you have gained. If you do not wish to answer any of the questions posed during the interview, you may say so to enable us to move to the next question. The information recorded is considered confidential, and no one else except you, the three facilitators, and the UCCIRB will have access to the information documented during your interview. The expected duration of the interview is about 30 minutes.

Possible Benefits

This research work is novel in the global practice of research ethics reviews. It will broaden your understanding in research and research ethics issues. These will directly support you in your academic pursuit. This pilot research study will also benefit the UCCIRB and other IRBs in Ghana and elsewhere since it will provide a model or serve as the foundation on which future initiatives to involve children in research ethics review processes will revolve. It will also inform some policy formulation and implementation as they relate to the administration of paediatric research ethics.

Possible Risks and Discomforts

The scheduling of the training sessions on weekends (Saturdays) may conflict with your other activities including participation in schools' extracurricular activities. It may also interfere you're your other routine weekend academic activities. These may constitute *harm* to you. As we have already indicated, we will only ask you to participate after you, your parents/guardian, and your school have consented to your participation.

Additional Cost

Commuting to the training site will involve some transportation costs which may be referred to as harm or discomfort to you. To prevent this potential harm, the investigators have made adequate budget allocations that will cater for your commuting and other logistical needs while taking part in the research project. Furthermore, we will ensure that you will not incur any financial cost for participation in this study. We will also provide meals and water at every training session to ensure that participants do not spend money on food and water while taking part in this research.

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 in the study. Even if your parents/guardian say "yes" you can still decide not to participate.

Confidentiality

To ensure your confidentiality during and after participation in this research project, all data files will be password-protected and shared only among the investigators, you, and the UCCIRB. Furthermore, all hand-written notes will be transcribed and saved electronically on a password-protected laptop which is owned by the principal investigator. The hard copies of the data will be shredded as well. No personal identifiers will be used in our reports but will be represented using pseudonyms. The Investigators will continue to adopt measures that will conform to appropriate research ethical standards as and when they unfold in the data collection process. Data transfer via the Internet will be secured with passwords.

Contacts for Additional Information

You may ask me any questions about this study. You can call me at any time on +233244207814 or talk to me the next time you see me. You may also contact Prof. Kobina Esiah-Donkoh (+233244769566).

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 **Training Children to assist in Institutional Review Board: a pilot study in Cape Coast, Ghana** 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 signature……..

Date: ……..……..