Application 1: Factors influencing the uptake of voluntary counselling and testing services for HIV/AIDS in the Lower Manya Krobo Municipality in the Eastern Region of Ghana

Important note: This is a real application which has been doctored for the purposes of training. Information has been removed from the application and the application has been anonymised. The UREC does not endorse this application as a model.

The application, shown on the following pages, was discussed at the workshop. A summary of the key points raised by the participants, the UREC and the original ethics reviewers follows (this is not an exhaustive list):

- There was a concern raised about the validity of the study (the recruitment criteria and research strategy are not made clear);
- The questionnaire to be used as part of the research has not been provided;
- The application does not recognise the potentially sensitive nature of the research (e.g. the research may raise worries about contracting HIV/AIDS or may bring back memories of relatives who died of the disease); there was a concern that the application appeared to have been reviewed as a 'low-risk' application;
- The application does not recognise the potential safety issues for the researchers in visiting potential participants in their homes; it was noted that a risk assessment should be carried out;
- The information sheet states that any issues ‘emanating from participation will be addressed adequately’ which is a very vague statement;
- The application does not recognise the possibility that neighbours of participants may gain a negative perception of those involved in the research (e.g. suspecting that they have HIV/AIDS);
- There is a lack of clarity and inconsistency concerning who will actually be carrying out the data collection;
- It is not clear whether the community volunteer who will be introducing the research assistant will have any involvement in the research itself – if so, this would raise confidentiality issues;
- Since the researcher will be recruiting people at their door, they will not be given time to think about whether they want to be involved (normally 24 hours would be allowed); it was felt that the recruitment process was too pressurized;
- The application form uses some coercive language, e.g. ‘participants will be made to sign a consent form’;

- There is a concern that the community volunteer may not actually be a ‘volunteer’ since they will be ‘provided’ by the community leader;

- There is a concern that the seeking of permissions from community leaders and the involvement of a community volunteer may mean that some individuals feel coerced into participating (i.e. that there is a community expectation/obligation to participate); however it was also noted that this is an accepted research method in certain cultures;

- It was noted that there was an error in the consent form: under point 3, the words ‘only if true’ had been left in the document when these were intended as guidance text in the template document which the researcher should remove;

- It was agreed that the confidentiality issues presented by the research had not been sufficiently thought through;

- The application forms states, in Q12, that no recorded media will be used, but the information sheet states that ‘responses will be recorded’;

- There is no evidence to show that work has been undertaken to ascertain whether there is a requirement to follow an appropriate route for obtaining ethics approval in Ghana itself.
Research Ethics
Application Form for
UGs and PGTs

This form has been approved by the University Research Ethics Committee (UREC)

Complete this form if you are an undergraduate or a postgraduate-taught student who plans to undertake a research project which requires ethics approval via the University Ethics Review Procedure. If you are a member of staff or a postgraduate research student, this is the wrong form.

Your Supervisor decides if ethics approval is required and, if required, which ethics review procedure (e.g. University, NHS, Alternative) applies.

If the University's procedure applies, your Supervisor decides if your proposed project should be classed as ‘low risk’ or potentially ‘high risk’.

This form should be accompanied, where appropriate, by all Information Sheets/Covering Letters/Written Scripts which you propose to use to inform the prospective participants about the proposed research, and/or by a Consent Form where you need to use one.

Further guidance on how to apply is at:
www.shef.ac.uk/ris/other/gov-ethics/ethicspolicy/approval-procedure/review-procedure

Guidance on the possible routes for obtaining ethics approval (i.e. on the University Ethics Review Procedure, the NHS procedure and the Social Care Research Ethics Committee, and the Alternative procedure) is at:
www.shef.ac.uk/ris/other/gov-ethics/ethicspolicy/approval-procedure/ethics-approval

Once you have completed this research ethics application form in full, and other documents where appropriate, check that your name, the title of your research project and the date is contained in the footer of each page.

If your supervisor has classed the project as ‘low risk’:
• Your supervisor should email this form, together with other documents where applicable, to the department’s Ethics Administrator
• Sign and date Annex 1 of this form and provide a paper copy to your Supervisor.

Important Note for Supervisors:

The Supervisor must work with the student to ensure that the application meets an appropriate academic standard in regard to methodology, grammar and written English. The supervisor provides the Ethics Administrator with a copy of the research ethics application as evidence that they have assessed the application as scientifically, academically, and ethically robust.

If your supervisor has classed the project as potentially ‘high risk’:
• Email this form, together with other documents where applicable, to your department’s Ethics Administrator; and
• Ask your Supervisor to sign and date Annex 2 of this form and provide a paper copy of it to your department’s Ethics Administrator.
I confirm that I have read the current version of the University of Sheffield ‘Ethics Policy Governing Research Involving Human Participants, Personal Data and Human Tissue’, as shown on the University’s research ethics website at: [www.shef.ac.uk/ris/other/gov-ethics/ethicspolicy](http://www.shef.ac.uk/ris/other/gov-ethics/ethicspolicy)

A1. **Title of Research Project:**
Factors influencing the uptake of voluntary counselling and testing services for HIV/AIDS in the Lower Manya Krobo Municipality in the Eastern Region of Ghana.

A2. **Name of Student**

Name: XXXX  
Department: XXXX  
Email: XXXX  
Telephone: XXXX

Name of Supervisor: XXXX

A3. **Proposed Project Duration:**
Start date: XXXX  
End date: XXXX

A4. **Mark ‘X’ in one or more of the following boxes if your research:**

- Involves adults with mental incapacity or mental illness
- Involves prisoners or others in custodial care (e.g. young offenders)
- Involves children or young people aged under 18 years
- Involves using samples of human biological material collected before for another purpose
- Involves taking new samples of human biological material (e.g. blood, tissue) *
- Involves testing a medicinal product *
- Involves taking new samples of human biological material (e.g. blood, tissue) *
- Involves additional radiation above that required for clinical care *
- Involves investigating a medical device *
- **X** Is social care research
- Is ESRC funded
- Is taking place in the health service but does not require NHS ethical approval**
- URMS number if required (please see below)

- If you have marked boxes marked * then you also need to obtain confirmation that appropriate University insurance is in place. The procedure for doing so is entirely by email. Please send an email addressed to insurance@shef.ac.uk and request a copy of the ‘Clinical Trial Insurance Application Form’.
- If you have marked the box** your supervisor, needs to obtain an URMS number

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It is recommended that you familiarise yourself with the University’s Ethics Policy Governing Research Involving Human Participants, Personal Data and Human Tissue before completing the following questions. Please note that if you provide sufficient information about the research (what you intend to do, how it will be carried out and how you intend to minimise any risks), this will help the ethics reviewers to make an informed judgement quickly without having to ask for further details.
A5. Briefly summarise:

i. The project’s aims and objectives:
   (this must be in language comprehensible to a lay person)

   The aims and objectives include:
   - To determine the level of awareness of voluntary counselling and testing (VCT) services for HIV/AIDS in Lower Manya Krobo Municipality.
   - To determine the level of acceptability for VCT services for HIV/AIDS in Lower Manya Krobo Municipality.
   - To determine the barriers to VCT services for HIV/AIDS in Lower Manya Krobo Municipality.
   - To determine the HIV risk perception of VCT services in Lower Manya Krobo Municipality.

ii. The project’s methodology:
   (this must be in language comprehensible to a lay person)

   A descriptive cross-sectional design with a quantitative method approach will be employed in this study (Zhang et al., 2012). A quantitative method will be employed using a structured questionnaire with close-ended questions. Interviews will be conducted using questionnaires which will explore the factors that influence the uptake of VCT services for HIV/AIDS in the Lower Manya Krobo Municipality.

A6. What is the potential for physical and/or psychological harm/distress to participants?

There is no potential physical, psychological or distress to study participants. This is because the study seeks to only interview participants about factors that tend to influence their decision to go for voluntary counselling and testing services for HIV/AIDS. The study will not seek information about participants HIV/AIDS status and will also not seek information about participant’s views or perceptions about people living with HIV/AIDS.

A7. Does your research raise any issues of personal safety for you or other researchers involved in the project? (especially if taking place outside working hours or off University premises)

No. This is because a Research Assistant will visit households throughout only at daytime and will be accompanied by a community volunteer.

If yes, explain how these issues will be managed.

A8. How will the potential participants in the project be:

i. Identified? (please ensure that all practical issues about contacting individuals are covered and that you are not requesting the personal details of individuals be given over without their consent)

   A Research Assistant will be trained on how to identify, approach and recruit participants. The Research Assistant will be taken through the research proposal; questionnaire and consent form via Skype and phone after copies have been emailed to him. The Research Assistant to be trained is a Data manager of XXXX Hospital in the Lower Manya Krobo Municipality. He is also a representative of the Ghana National HIV/AIDS control programme in the Municipality and has expertise in data
collection and has carried out data collection for research work such as ‘Within mental health provision: The reliance upon cognitive behavioural therapy has become too great’, ‘Efficiency versus patient care: The on-going appropriateness of local community-based hospitals’ and ‘The posterity of Health Care Reforms in Ghana’ etc (Unpublished).

The Lower Manya Krobo Municipality has five main communities. The Research Assistant will identify potential study participants using the community entry approach (Hill et al., 2008). Research Assistant will meet community leaders to inform of the purpose of the study. Community leaders will then inform members of the community of the impending exercise and usually will provide a community volunteer who the community members are familiar with to accompany the Research Assistant to meet potential study participants (Hill et al., 2008). The potential participants will be identified by the Research Assistant and the community volunteer using simple random sampling. Simple random sampling will be used to select each household to provide every member of the Municipality an equal chance of taking part in the study (Bowling, 2002). Houses in each community are numbered and these numbers will be obtained from the Lower Manya Municipality Assembly which keeps records of house numbering system of the Municipality (Hagan et al., 2009). These house numbers will be randomly selected using a computerized random generator. Forty (40) households from each of the five communities will be randomly sampled to make up the sample size of 200. Hill et al. (2008) observed that it is very unlikely for community leaders in Ghana to refuse for research to be conducted in their respective communities. However, if for any reason a community leader refuses for his community members to participate in the research work, more households from the other communities will be sampled to represent the Municipality.

### iii. Approached?

The Research Assistant and the community Volunteer will visit each identified household and knock on the door. The community volunteer, who is very likely to be known to the householders already, will introduce the Research Assistant to the potential participants whilst the Research Assistant will explain to potential participants about the purpose of the study and what it involves by taking them through the participant information on the questionnaire.

### iv. Recruited?

The first person to meet the Research assistant in the selected house will be recruited for the study provided he or she is within the age inclusion criteria of 18-55 years and consents to the study with a written consent form. If the person in the selected house is unwilling to take part in the study, does not meet the age inclusion criteria and/or nobody is available at the selected house to meet the Research Assistant, another household is randomly generated for the Research Assistant to move to the next house. This will be repeated until the sample size is reached. A record of the number of selected houses that did not respond to the survey will be recorded. However, the response rate with simple random sampling in Ghana is very high as the hospitable attitude and culture of Ghanaians make them more willing to take part in research at their homes (Buxton and Baguune, 2012). Additionally, Buxton and Baguune (2012) and Opoku (2005) observed that most Ghanaian families after the close of work are often available at their homes and are very willing to take part in research work when their house doors are knocked at.

### A9. Will informed consent be obtained from the participants?

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<tr>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
</table>

If informed consent or consent is NOT to be obtained please explain why. Further guidance is at: [www.shef.ac.uk/ris/other/gov-ethics/ethicspolicy/policy-notes/consent](http://www.shef.ac.uk/ris/other/gov-ethics/ethicspolicy/policy-notes/consent)
A9.1. This question is only applicable if you are planning to obtain informed consent:

**How do you plan to obtain informed consent? (i.e. the proposed process?):**

Informed consent will be obtained from the study participants by taking them through the participant information on the questionnaire which informs them of the purpose of the study and what it involves.

Potential study participants will be given the opportunity to ask questions about the study, so that their concerns can be addressed. Participants will be made to confirm whether they understand the purpose of the research, whether they understand that participation is voluntary and they have the right to withdraw from the study at any time without reason and without any consequences. Finally, participants will be made to provide written informed consent, by completing and signing the participant consent form, to confirm that they agree to take part in the study.

A10. What measures will be put in place to ensure confidentiality of personal data, where appropriate?

(As a minimum please ensure details are included of: how long data will be kept; when and how it will be destroyed; that PCs and other devices are password protected; that personal details are encrypted. This information should also be included on your information sheet).

Individual participant responses to the interview will be recorded on the paper version of the questionnaire. Completed interview forms (and data) collected will be securely stored and protected in a locked cabinet in the house of the Research Assistant. Data collected will be anonymous and confidential as questionnaires will not contain names or house addresses of study participants. However, questionnaires will be assigned study numbers and the numbering will depend on who is recruited first till the sample size of 200 is reached. Completed questionnaires will be posted to the Researcher’s residential address using DHL after data collection is complete. Completed questionnaires received by the Researcher will be stored securely, transferred to a computer database and analysed by the Researcher within an estimated period of one month with a computer which is encrypted and password protected.

A11. Will financial/in kind payments (other than reasonable expenses and compensation for time) be offered to participants? (Indicate how much and on what basis this has been decided)

No

A12. Will the research involve the production of recorded media such as audio and/or video recordings?

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
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<tbody>
<tr>
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<td>X</td>
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A12.1. This question is only applicable if you are planning to produce recorded media:

**How will you ensure that there is a clear agreement with participants as to how these recorded media may be stored, used and (if appropriate) destroyed?**
University Research Ethics Application Form - Annex 1 - Student Declaration

(The student completes Annex 1 if the Supervisor has classed the student’s proposed research project as ‘low risk’)

The Supervisor needs to receive an electronic copy of the form, and other documents where appropriate, plus a signed, dated, paper copy of this Annex 1 ‘the Student Declaration’.

**Full Research Project Title:**

Factors influencing the uptake of voluntary counselling and testing services for HIV/AIDS in the Lower Manya Krobo Municipality in the Eastern Region of Ghana.

**In signing this Student Declaration I am confirming that:**

- The research ethics application form for the above-named project is accurate to the best of my knowledge and belief.
- The above-named project will abide by the University’s ‘Good Research Practice Standards’: [www.sheffield.ac.uk/ris/other/gov-ethics/good](http://www.sheffield.ac.uk/ris/other/gov-ethics/good)
- The above-named project will abide by the University’s ‘Ethics Policy Governing Research Involving Human Participants, Personal Data and Human Tissue’: [www.sheffield.ac.uk/ris/other/gov-ethics/ethicspolicy](http://www.sheffield.ac.uk/ris/other/gov-ethics/ethicspolicy)
- Subject to the above-named project being ethically approved I undertake to adhere to any ethics conditions that may be set.
- I will inform my Supervisor of significant changes to the above-named project that have ethical consequences.
- I will inform my Supervisor if prospective participants make a complaint about the above-named project.
- I understand that personal data about me as a researcher on the research ethics application form will be held by those involved in the ethics review process (e.g. my Supervisor and the Ethics Administrator) and that this will be managed according to Data Protection Act principles.
- I understand that this project cannot be submitted for ethics approval in more than one department, and that if I wish to appeal against the decision made, this must be done through the original department.

**Name of supervisor:**

XXXX

**Name of student:**

XXXX

**Signature of student:**

XXXX  Date:XXXX
University Research Ethics Application Form - Annex 2 - Supervisor Declaration

(The Supervisor completes Annex 2 if s/he has classed the student’s proposed research project as potentially ‘high risk’)  

The Ethics Administrator needs to receive an electronic copy of the form, and other documents where appropriate, plus a signed, dated, paper copies of this Annex 2 ‘the Supervisor Declaration’.

Full Research Project Title:

In signing this Supervisor Declaration I am confirming that:

- The research ethics application form for the above-named project is accurate to the best of my knowledge and belief.
- The above-named project will abide by the University’s ‘Good Research Practice Standards’: [www.sheffield.ac.uk/ris/other/gov-ethics/good](http://www.sheffield.ac.uk/ris/other/gov-ethics/good)
- The above-named project will abide by the University’s ‘Ethics Policy Governing Research Involving Human Participants, Personal Data and Human Tissue’: [www.sheffield.ac.uk/ris/other/gov-ethics/ethicspolicy](http://www.sheffield.ac.uk/ris/other/gov-ethics/ethicspolicy)
- Subject to the above-named project being ethically approved I will undertake to ensure that the student adheres to any ethics conditions that may be set.
- The student or the Supervisor will undertake to inform the Ethics Administrator of significant changes to the above-named project that have ethical consequences.
- The student or the Supervisor will undertake to inform the Ethics Administrator if prospective participants make a complaint about the above-named project.
- I understand that personal data about the student and/or myself on the research ethics application form will be held by those involved in the ethics review process (e.g. the Ethics Administrator and/or reviewers) and that this will be managed according to Data Protection Act principles.
- I understand that this project cannot be submitted for ethics approval in more than one department, and that if I and/or the student wish to appeal against the decision made, this must be done through the original department.

Name of supervisor:

Name of student:

Signature of supervisor:  Date:
THE UNIVERSITY OF SHEFFIELD

QUESTIONNAIRE

Participant Information

1. **Study topic**: Factors influencing the uptake of Voluntary Counselling and Testing (VCT) services for HIV/AIDS in the Lower Manya Krobo Municipality, Ghana.

2. **Invitation and purpose of the study**
   You are kindly invited to take part in a research work by XXXX in partial fulfilment of the XXXX programme of the University of Sheffield, UK. The research will explore what factors in the Municipality influence the decision of individuals to go for VCT services for HIV/AIDS. I will take time to take you through what the research work involves and you can ask questions if you are unclear about any information relating to the study. The study will last for about five months.

3. **Must you take part in the study?**
   No. Participation is voluntary and a written informed consent will be obtained and you are at liberty to withdraw from the study at anytime without reason, and there will be no consequences.

4. **Why you have been chosen?**
   You have been chosen because you are within the age inclusion criteria of 18-55 years and in a house located within the Lower Manya Krobo Municipality.

5. **Is the study confidential?**
   The responses to interviews are strictly confidential and anonymous, as names and addresses will not be required. Data will be entered into a secure database and analysed by the Researcher.

6. **What will happen to you if you take part?**
   The Research assistant will interview participants by reading through a short questionnaire and asking them for their responses which will be recorded. Each interview will last for about 7-12 minutes and will explore the facilitators and barriers to the uptake VCT services in the Municipality.

7. **What are the possible benefits, problem and risk in taking part?**
   There is no intended benefit to the study participant. We do not also anticipate any problems or risk in taking part of the study. However, please be assured that any issues emanating from participation will addressed adequately and will be confidential.

8. **What will happen to the results of the study?**
   Study results will be submitted to the University of Shefield as dissertation work for the Researcher. A copy of the results will be made available to the Lower Manya Krobo Municipal Directorate of Health Services as it may be useful to them. A forum will be organised for stakeholders on HIV/AIDS in the Municipality to present the findings to them as it may be use. Results may be published in research journals to aid doctors, researchers, policy makers and students in Ghana and internationally.
to provide insight into some factors influencing the uptake of VCT services in Ghana.

9. **Who is organising and funding the Research?**
   The Researcher is self-funding the study and Research Assistant will be paid for collecting the data.

10. **Contact information of Researcher**
    XXXX

THANK YOU FOR YOUR TIME AND COOPERATION.
Factors influencing the uptake of Voluntary Counselling and Testing (VCT) services for HIV/AIDS in the Lower Manya Krobo Municipality in the Eastern Region of Ghana.

Name of Researcher: XXXX

Participant Identification Number for this project: Please initial box

1. I confirm that I have read and understand the information sheet/letter (delete as applicable) dated [insert date] explaining the above research project and I have had the opportunity to ask questions about the project.

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason and without there being any negative consequences. In addition, should I not wish to answer any particular question or questions, I am free to decline.

3. I understand that my responses will be kept strictly confidential (only if true). I give permission for members of the research team to have access to my anonymised responses. I understand that my name will not be linked with the research materials, and I will not be identified or identifiable in the report or reports that result from the research.

4. I agree for the data collected from me to be used in future research.

5. I agree to take part in the above research project.

Name of Participant (or legal representative) ____________________________ Date ____________________________ Signature ____________________________

Name of person taking consent (if different from lead researcher) ____________________________ Date ____________________________ Signature ____________________________

To be signed and dated in presence of the participant

Copies:

Once this has been signed by all parties the participant should receive a copy of the signed and dated participant consent form, the letter/pre-written script/information sheet and any other written information provided to the participants. A copy of the signed and dated consent form should be placed in the project’s main record (e.g. a site file), which must be kept in a secure location.