INFORMATION FOR WRITTEN INFORMED CONSENT FROM CONTACT TRACING CO-ORDINATORS

A London School of Hygiene and Tropical Medicine (LSHTM), Innovations for Poverty Action (IPA), and International Medical Corps (IMC) Study

Principal Investigators: Professor Helen Weiss (LSHTM and Professor David Ross (WHO)
Study sponsor: London School of Hygiene and Tropical Medicine
Contact address in Sierra Leone for further information:
Dr Lisa Danquah; DHMT Port Loko: Telephone: 07893 6743

Study Title: Reducing Ebola virus transmission: Improving contact tracing in Sierra Leone

Abbreviated Title: Ebola Contact Tracing Study

Version Number: 3

Date: 29th May 2015

Respondent Identification: _____

This study has been authorized by the Sierra Leone Ethics and Scientific Review Committee (28th November 2014) and the Ethics Committee of the London School of Hygiene and Tropical Medicine (Approval No. 8749)

[Note to Interviewer: Please give this document to the contact tracing co-ordinator and answer any questions they may have.]

Invitation to participate in a research study
You are being asked to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it involves. This information sheet is designed to help you decide whether you would like to participate in this study.

What is the study about?
This study is looking at ways to improve the Ebola response in Port Loko District.

As you know, the Ebola virus is caught from someone with Ebola infection who becomes sick or who has died. It is very important that any person who has had physical contact with someone with Ebola is identified and visited as quickly as possible so that they can be checked for whether they develop Ebola themselves. If they do then it is important that they are isolated, checked, and, if needed, treated as soon as possible after they start feeling unwell.

The current systems that are in place involve using paper forms and time-consuming communication between the team. We are conducting a study to test an alternative system of electronic data collection using smartphones to see whether this can improve the quality and speed of data collection and reduce the workload for staff.

Who has given us permission to conduct this study:
This study has been authorized by the Sierra Leone Ethics and Scientific Review Committee and the Ethics Committee of the London School of Hygiene & Tropical Medicine. It also has the support of the Ministry of Health and Sanitation of Sierra Leone, the District Ebola Response Centre (DERC), the District Health Management Team (DHMT), and other partners working on Contact Tracing in the District, including WHO, GOAL, Marie Stopes and UNFPA.

Why are you being invited to participate in the study?
You have been invited to take part because you are a contact tracing co-ordinator in one of the Chiefdoms in Port Loko District.

If you agree to participate, what will you be asked to do?
For this study we are asking all contact tracing coordinators in Port Loko District to participate in the study.One group of coordinators have already received phones that can send and receive data (a “smartphone”). They have been given training on

- how to use it to receive data from the line-listing form on your smartphone, and to confirm to the DHMT that you have received this.

This study has now been expanded to include your Chiefdom. During this second phase of the study, the contact tracers in your Chiefdom will also have a smartphone, and you will be able to send the line listing to the appropriate contact tracer in your Chiefdom, using your smartphone. The contact tracer’s smartphone will confirm that they have received the information that you sent to them, and they will enter the answers to the Contact Tracing Form directly

on to the smarthpone. The smartphone will be used to send you and the DHMT data on whether the contact is well/sick/not present, each time they visit a contact.

- The smartphone will only be enabled for the app and cannot be used as a normal phone.

Participation is entirely voluntary:
Your participation in this research is entirely voluntary. In other words, it is entirely your choice whether you agree to participate or not. You can discuss whether to participate or not with anyone before making your decision.

You can refuse to participate in the study without giving any reason. Also, if you initially agree to participate in the study and then later change your mind, you can withdraw from the study at any stage. Whether or not you agree to participate in the study will make absolutely no difference to your job or your chances of remaining in it. If you do not agree to participate in the study, you will need to continue following the normal contact tracing procedures using paper forms, and the data you collect will not be included in the study.

Risks and Benefits:
The only potential risk that we foresee that you might face if you agree to participate in the study, beyond the ones associated with your routine job, is that you will need to keep the smartphone safe.

The only benefits that we foresee are thatyou will be given a smartphone to use, you will learn how to use the smartphone, and using the phone may save you time in your work.

You will not receive any payment for your participation in this study, and you will have to return any phone you are given to use to the research team at the end of the study.

Questions:
If you have any questions or if anything is unclear, please ask the person who gave you this information sheet. If later you have any questions, you may contact any of the following people:

Dr Lisa Danquah, Research Coordinator, Ebola Contact Tracing Study, DHMT Port Loko: Telephone: 07893 6743

Miss Fatu Conteh, Innovations for Poverty Action, Freetown ((12 Kosie Williams Drive, off Sir Samuel Lewis Road, Aberdeen, Freetown, 078 526 352)

Also, if you have any questions about your rights as a research study participant, you can contact either of the following people:

- Dr Morgan, Chair, Sierra Leone Ethics and Scientific Review Committee
  Princess Christian Maternity Hospital,
  Fourah Bay Road, Freetown.

Tel: 076-629251

- Professor John Porter, Chair, Ethics Committee, London School of Hygiene & Tropical Medicine, Keppel St, London WC1E 7HT, England.

Summary:
If you agree to participate in this study:

1. You will be asked to collect data on contacts of Ebola cases that are allocated to you. You may or may not be given a mobile phone to record this information. You will not be able to use this phone to make phone calls or to send sms messages, only for data entry and transmission.
2. You can refuse to participate in the study without giving any reason. This will have no consequences for yourself or for your employment.
3. You must return the mobile phone at the end of the study or if you withdraw from the study.
4. You will benefit from participating in a study that we hope will help the Ministry of Health and Sanitation to set up systems to control Ebola infection better.
5. You will not receive any payment for participation in this study.
6. These consent forms and any copies of other forms that are taken for the research study will be kept safely in the locked study offices in Port Loko DHMT. All routine paper contact tracing forms will be kept by the contact tracing team in the normal way.
7. The study will use the contact information that you provide to determine whether the mobile phone system increases the speed at which contacts are visited at home, after a new case is confirmed.
8. The information you collect will be seen by people directly supervising the contact tracing process and researchers at Innovations for Poverty Action, and the London School of Hygiene & Tropical Medicine as agreed by the Ministry of Health & Sanitation, Sierra Leone. Any data leaving the District will not include identifying information about the contacts.

Confirmation

- I confirm that I have read the written information (or have had the information read to me) for this study.
- I have had time to discuss the Informed Consent Form and the study procedures have been explained to me by the study team.
- I confirm that I have had the opportunity to ask questions about this study and I am happy with the answers and explanations that have been provided.
- I have been given enough time and opportunity to decide whether I want to take part in this study.
- I agree that the authorized persons described in the information sheet can have access to the data.
- I understand that I can leave the study at any time and that this will not affect me in any way.
- I agree to participate in this study.

Participant's name	
Participant's signature	Date (DD/MM/YY)
Name of person conducting the consent procedure	
Signature of the person conducting the consent procedure:	Date (DD/MM/YY)

INFORMATION FOR WRITTEN INFORMED CONSENT FROM CONTACT TRACERS

A London School of Hygiene and Tropical Medicine (LSHTM), Innovations for Poverty Action (IPA), and International Medical Corps (IMC) Study

Principal Investigators: Professor Helen Weiss (LSHTM) and Professor David Ross (WHO)
Study sponsor: London School of Hygiene and Tropical Medicine
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Respondent Identification: _____

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[Note to Interviewer: Please give this document to the contact tracer and answer any questions they may have.]

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For this study we are asking all contact tracers in Port Loko District to participate in the study. One group of contact tracers have already received phones that can send and receive data (a “smartphone”). They have been given training on

- how to use it to send and receive data from your contact tracing co-ordinator. This study has now been expanded to include your Chiefdom.
- You will use this smartphone to confirm that your have received the line listing from the contact tracing co-ordinator, and to send data to them on whether the contact is well/sick/not present, each time you visit a contact.

- You will need to send this data back to the contact tracing co-ordinator using your smartphone and if they do not confirm that they have received it, you will need to take action to find out why.
- The smartphone will only be enabled for the app and cannot be used as a normal phone.

Participation is entirely voluntary:
Your participation in this research is entirely voluntary. In other words, it is entirely your choice whether you agree to participate or not. You can discuss whether to participate or not with anyone before making your decision.

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You will not receive any payment for your participation in this study, and you will have to return any phone you are given at the end of the study.

Questions:
If you have any questions or if anything is unclear, please ask the person who gave you this information sheet. If later you have any questions, you may contact any of the following people:

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Summary:
If you agree to participate in this study:

1. You will be asked to collect data on contacts of Ebola cases that are allocated to you. You may or may not be given a mobile phone to record this information. You can use this phone to contact your contact tracing co-ordinator and the DHMT.
2. You can refuse to participate in the study without giving any reason. This will have no consequences for yourself or for your employment.
3. You must return the mobile phone at the end of the study or if you withdraw from the study.
4. You will benefit from participating in a study that we hope will help the Ministry of Health and Sanitation to set up systems to control Ebola infection better.
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Confirmation

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- I have been given enough time and opportunity to decide whether I want to take part in this study.
- I agree that the authorized persons described in the information sheet can have access to the data.
- I understand that I can leave the study at any time and that this will not affect me in any way.
- I agree to participate in this study.

Participant's name	
Participant's signature	Date (DD/MM/YY)
Name of person conducting the consent procedure	
Signature of the person conducting the consent procedure:	Date (DD/MM/YY)

ANNEX 4

The current contact tracing form will contain the following information. The only difference is that the intervention group data will be collected electronically.

Ministry of Health and Sanitation Sierra Leone: *Contact Tracing Form for Ebola Outbreak*

EF02

District: _____ Chiefdom: _____ Town/Village: _____Patient Address:_____

Name of patient: _____Sex: M / F Age: _____ Suspected/Probable/Confirmed Case #: PLK_____

CASE INFO

Patient's Contact Phone Number: _____ Patient relative contact's phone number: _____

Name of contact: _____ Sex: M / F Age: _____ Address of Contact (Community/Village):_____

Name of Town Chief/Village leader: _____ Contact Number: _____

CONTACT INFO

Type of Contact in the last 21 days: 1. Touch body fluids (saliva, urine, faeces) 2. Direct physical contact with body of case 3. Manipulation of clothes or other objects 4. Slept or ate in same household as the case

Circle one type: quarantined contact / non-quarantined contact / Discharged Negative follow-up

Date of last contact (DD/MM/YY): _____/_____/ _____

Instruction: Please write 'Y' for yes and 'N' for no in the correct cell

Contact Tracer's name _____

Contact Tracer's contact phone number _____

Contact Tracing Supervisor's name _____

Contact ID:_____(VHF)

Time of first visit: _____ (to be completed for the first visit only) (M: Monday, Tu: Tuesday, W: Wednesday, Th: Thursday, F: Friday, Sa: Saturday, Su: Sunday)

Date of visit	DAYS AND DATE FOLLOW UP																				
	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/
Day (M, Tu, W, Th, F, Sa or Su)																					
SYMPTOMS/SIGNS	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
Fever																					
Muscles or joints																					
Joint pain																					
Neck rigidity																					
Weakness																					
Nausea and vomiting																					
Diarrhea (non-bloody / bloody)																					
Abdominal pain																					
Headache																					
Back ache																					
Chest pain																					
Sore throat or swallowing																					
Rash																					
Bruising																					
Red eyes																					
Any bleeding																					
Jaundice																					
Other symptoms																					
Sick and not evacuated (filled by supervisor)																					
Sick and evacuated (filled by supervisor)																					