**KEMRI  Wellcome Trust Research Programme: Participant Information Sheet and Consent Form**

**[PROVIDERS & OTHER STAKEHOLDERS; ENGLISH]**

***Improving implementation of fixed-dose combination treatments for cardiovascular disease: the IMPLEMENT-CVD study***

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| Institution  | Investigators  |
| KEMRI- Wellcome Trust    | Dr Peter Mugo, Daniel Mbuthia  |
| London School of Hygiene and Tropical Medicine (LSHTM)  | Dr Adrianna Murphy, Dr Ruth Willis  |
| Ministry of health  | Dr Nasirumbi Magero |
| Kiambu County-Department of Health |  Dr Mary Gichagua |

You are being asked to take part in a study. The box below tells you important things you should think about before deciding to join the study.  We will provide more detailed information below the box. Please ask questions about any of the information before you decide to participate. You may also wish to talk to others (for example, your family, friends, or your doctor) about this study, before agreeing to join.

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| **Key Information for You to Consider**  |
| * **Voluntary Consent**. You are being asked to volunteer for a research study. You can choose whether you would like to participate or not. If you do agree you can change your mind at any time and withdraw from the research. This will not affect your care now or in the future.
* **Purpose**.  The aim of this research is to understand current practices and policies surrounding medical treatment of people with hypertension and cardiovascular disease in Kenya. We also want to understand current use of fixed dose combinations for hypertension and cardiovascular disease treatment, whether there is scope for increasing use, and opportunities for doing so. We are therefore talking to a wide range of people involved in the organisation, planning and delivery of hypertension and cardiovascular disease treatment, including [health workers / pharmacists/policy stakeholders] like yourself, to understand your perspective.
* **Duration.** Your participation in this study will last for up to one hour.
* **Procedures and Activities.** We will discuss your role in and experiences of planning/overseeing/managing/delivering medical treatment for hypertension and cardiovascular disease.
* **Risks or disadvantages.** There are no known risks to you in taking part in this study
* **Benefits**. There are no direct benefits to you in taking part in this study, but we hope that the study will help to support improvements to treatment for people with hypertension and cardiovascular disease in future.
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**Who is carrying out this study and what is this study about?**

* This study is being carried out by KEMRI in collaboration with the London School of Hygiene and Tropical Medicine. KEMRI is a government organization that carries out medical research to find better ways of preventing and treating illness in the future for everybody’s benefit.
* Sometimes research involves only asking questions of patients, community members, health providers or policy makers about what they know, feel or do.
* In this research, we will invite you to discuss your role in and experiences of planning /overseeing/ managing/ delivering medical treatment for hypertension and cardiovascular disease. You do not have to answer any questions that you do not wish to answer.

**Why do you want to talk to me and what does it involve?**

* The study is taking place in up to seven government and private health facilities in Kiambu County. We are aiming to include:
	+ Up to 24 participants involved in planning/ overseeing/ managing/ delivering medical treatment for hypertension and cardiovascular disease from the three health facilities
	+ Up to 6 community pharmacies serving the patient population study health facilities.
	+ Up to 14 stakeholders from the ministry of health headquarters, county headquarters, regulatory authorities, professional associations, and civil society.
* I/my colleague will ask you about topics that are related to your role as a health worker/ pharmacist/ policy stakeholder. This will be done individually or in a group with 7-8 other persons with similar experiences.
* We will only ask for your views from a professional perspective; we will not ask personal questions. If you do not want to answer any of the questions you may say so and the interviewer will move on to the next question.  The discussion will take place in a private room at the health facility/ pharmacy/ place of work or other place that is convenient for you.  No-one else but the interviewer will be present unless you would like someone else there.
* The discussion will be recorded to assist later in fully writing up the information.  No-one will be identified by name in the recording.
* With your permission, we will share your insights, along with those of others in materials that we produce from this study, but we will not associate any direct statements that you may have made with your name or professional role in any of our materials. This means, what you share with us will remain strictly confidential.
* Despite our efforts of keeping your views anonymous, there may be a small risk that your colleagues might recognize that a given statement might have come from you. However, they will not be able to be certain because we will not use your name anywhere in the materials that we will produce from this study. We will request that all participants keep the views discussed here confidential, but we remind participants that this cannot be guaranteed.

**Are there any risks or disadvantages to me of taking part?**

* The discussion should take approximately 45-60 minutes. If the discussion takes place away from your workplace you will be reimbursed actual transport expenses incurred, as per distance travelled based on public transport.  If the discussion takes place remotely (phone or meeting app), you will be reimbursed KES 250 for internet bundle costs incurred.

**Are there any advantages to me of taking part?**

* There are no individual benefits to taking part. In talking to us, you will contribute to knowledge of treatment for blood pressure and heart disease that may help other people in Kenya and elsewhere in the future, for example through developing new health policies to make cheaper and easier treatments more widely available.

**Who will have access to the information I give?**

* All our research records are stored securely in locked cabinets and password protected computers and are accessed only by authorized persons.
* The personally identifiable information you provide will be used to contact you for scheduling of interview/workshop, and verification of consent through signed consent forms.
* We will share anonymized individual and summary information we collect or generate with the London School of Hygiene and Tropical Medicine in ways that do not reveal individual participants’ identities.
* The study site will keep personally identifiable information about you from this study for five years after the study has finished in accordance with applicable Data Protection Requirements both in Kenya and in the UK. You have the right to access the personal data we hold that pertains to you, to object to or make corrections to the processing of all or part of the personal data.
* London School of Hygiene and Tropical Medicine (LSHTM) is responsible for ensuring that LSHTM staff involved in the study in Kenya adhere to the safe and proper use of any personal information you provide. You can contact the research team to facilitate any contacts with the London School of Hygiene and Tropical Medicine Data Protection Officer for any further information about how your data will be managed.
* The knowledge gained from this research will be shared in summary form, without revealing individuals’ identities. This information will be shared with all participating health facilities, the Ministry of Health and the wider scientific community for instance through policy briefs and scientific publications.
* In future, information collected or generated during this study may be used to support new research by other researchers in Kenya and other countries, on hypertension, cardiovascular disease and other health problems. In all cases, we will only share information with other researchers in ways that do not reveal individual participants’ identities. For example, we will remove information that could identify people, such as their names and where they live, and replace this information with number codes. Any future research using information from this study must first be approved by a local or national expert committee to make sure that the interests of participants and their communities are protected.
* All audio recordings will be destroyed at the end of the study.

**Who has allowed this research to take place?**

* All research at KEMRI has to be approved before it begins by a national committee who look carefully at planned work. They must agree that the research is important, relevant to Kenya and follows nationally and internationally agreed research guidelines. This includes ensuring that all participants’ safety and rights are respected.

**What will happen if I refuse to participate?**

* All participation in research is voluntary.  You are free to decide if you want to take part or not.  If you do agree you can change your mind at any time without any consequences.

**What if I have any questions?**

* You are free to ask me any question about this research. If you have any further questions about the study, you are free to contact the research team using the contacts below:

Dr. Peter Mugo, KEMRI Wellcome Trust Research Programme, P.O. Box 43640 – 00100 Nairobi, Kenya.  Telephone: 0722 290087

**If you want to ask someone independent anything about this research please contact:**

Community Liaison Manager, KEMRI Wellcome Trust Research Programme, P.O. Box 230, Kilifi.  Telephone: 041 7522 063, Mobile 0723 342 780 or 0705 154 386

***And***

The Head, KEMRI Scientific and Ethics Review Unit, P. O. Box 54840-00200, Nairobi; Telephone numbers: 0717 719477; 0776 399979 Email address: seru@kemri.org

**KEMRI-Wellcome Trust Research Programme consent form for *IMPLEMENT-CVD Study: Improving implementation of fixed-dose combination treatments for cardiovascular disease***

I have had the study explained to me. I have understood all that has been read/explained and had my questions answered satisfactorily. And I agree to take part in this research

**(*Required for future use*) Please initial the sentences that reflect your choices, and then sign below:**

\_\_\_\_\_ I do wish to be notified by investigators in the event of research findings of possible importance to myself. **Yes ÿ** **No ÿ**

\_\_\_\_\_\_ I agree that the study team use the identifier that I have provided (telephone number, country ID number, etc.) to locate me in the future. **Yes ÿ** **No ÿ**

**I agree for the interview/discussion to be recorded ÿ  Yes  ÿ  No**

I understand that I can change my mind at any stage and it will not affect me in any way.

**Participants Signature:**  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Date:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Participant Name:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Time:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_

(Please print name)

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***Where participant cannot read, a witness****\** ***may observe consent process and sign below if needed:***

I attest that the information concerning this research was accurately explained to and apparently understood by the participant and that informed consent was freely given by the participant.

**Witness’ signature:**  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Date** \_\_\_\_\_\_\_\_\_\_\_\_\_

**Witness’ name**:       \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Time** \_\_\_\_\_\_\_\_\_\_\_\_\_\_

(Please print name)

*\*A witness is a person who is independent from the study or a member of staff who was not involved in gaining the consent.*

Thumbprint of the participant as named above if they cannot write:

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I have followed the study procedure to obtain consent from the participant. S/he apparently understood the nature and the purpose of the study and consents to participation in the study. S/he has been given opportunity to ask questions which have been answered satisfactorily.

**Designee/investigator’s signature:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Date** \_\_\_\_\_\_\_\_\_\_\_\_

**Designee/investigator’s name:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**Time** \_\_\_\_\_\_\_\_\_\_\_\_

                                                                        (Please print name)

**THE PARTICIPANT SHOULD NOW BE GIVEN A SIGNED COPY TO KEEP**

*……………………………………………………………………………………………………………………………………………………………*