Stakeholder Consent form for Formative Study

Title of the Research Study: Caring for Providers to Improve Patient experience (CPIPE) study

NCT05019131

V 4.0 November 24, 2020

Investigators:
Principal Investigator: Dr. Patience Afulani — University of California, San Francisco
Co-Investigators: Dr. Linnet Ongeri — Kenya Medical Research Institute
Ms. Joyceline Kinyua — Kenya Medical Research Institute

Study location: Migori County, Kenya
Emergency Telephone Number: _____

READ each section slowly- you do not need to read section headers, only read the sections in *italics*:
As mentioned earlier, I am asking you to consider taking part in a short interview to inform the research being carried out in Migori County by researchers from KEMRI, in collaboration with the University of California, San Francisco (UCSF) in the United States. I want you to know more about it. If you agree to participate, I will ask you to verbally agree and provide consent.

Participation in Research
Your participation is voluntary and you may stop participating at any time.

Purpose of Interview
We are doing this interview and broader research to identify effective ways to improve quality of care that includes addressing provider concerns such as stress and burnout as well as other factors that affect provider interactions with patients such as unconscious bias.

Remote interview and other participants
If you decide to take part, we shall have a remote in-depth interview, which we will conduct at a mutually agreed upon time convenient for you.

Remote interview Length
The interview will take less than 1 hour. If you need to, we may stop the call and finish at a later time. You will be provided Ksh 300 (via Mpesa) to make up for time lost, after we have completed the interview.

Benefits of interview
Research can benefit society by gaining new knowledge. It may be helpful to you personally as you may feel empowered to have contributed to shaping the intervention.

Risks and discomfort
Most studies have some possible harms that could happen to you if you join. In this study, we expect that you may be uncomfortable answering some questions. If you are uncomfortable about any questions, you have the right to decline to answer or skip questions.

Confidentiality
The information collected will be kept confidential and used only for the purposes of this study. All data collected from you will be coded in order to protect your identity. Only the research study staff will have access to the information. At the end of the study, there will be no way to link your name with your data.

Confirming Remote Consent and Understanding
Since we are doing this consenting process remotely, I want to ensure that you have understood the activities I have described. I will ask you a few questions to confirm please.

Question	**Comprehension assessment**	

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	Adequate	Inadequate	Study staff initials
Can you tell me about what the purpose of our remote discussion today is, in general?	☐	☐	
Can you also confirm to me what the study will provide to thank you for your time?	☐	☐	
If any question is inadequate, please do not consent or proceed- thank the participant for their time and close the consenting process.			

Should you have questions or concerns about the study, I would like you to please write down this number. I will also SMS you the number at the end of our call: ----------.

Participant's Agreement:
Do you agree to take part in the interview and interview now?

	Check only ONE option		RA initials	Date DD/MM/YYYY	Time (use 24hrs) HH:MM
Participation in the interview	_____ **Yes**	_____ **No**			

Signatures:

STUDY STAFF	
Name of Study Staff (printed)	Position
Signature of Study Staff	Date

CPIPE stakeholder consent form for formative research

Title of the Research Study: Caring for Providers to Improve Patient experience (CPIPE) study

NCT05019131

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Version 2.0: 02/10/20

Investigators:

Principal Investigator:	Dr. Patience Afulani	University of California, San Francisco
Co-Investigators:	Dr. Linnet Ongeri	Kenya Medical Research Institute
	Ms. Joyceline Kinyua	Kenya Medical Research Institute

Study location: Migori County, Kenya

You are being asked to take part in a research 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 whether 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.

Key Information for You to Consider(Not more than 500 words)
• **Voluntary Consent**. You are being asked to volunteer for a research study. It is up to you whether you choose to participate or not. There are no penalties and you will not lose anything if you decide not to join or if after you join, you decide to quit. • **Purpose**. We are doing this research to identify effective ways to improve quality of care that includes addressing provider concerns such as stress and burnout as well as other factors that affect provider interactions with patients such as unconscious bias. • **Duration.** Your part of the study will last 30mins to 1 hour • **Procedures and Activities.** We will ask you to provide input on the type of activities that can be feasibly implemented as part of the intervention as well as your thoughts on what is likely to be more acceptable and effective for providers in Migori County. • **Risks.** Most studies have some possible harms that could happen to you if you join. In this study, we expect that you may be uncomfortable answering some questions. If you are uncomfortable about any questions, you have the right to decline to participate in it.   • **Benefits**. You may feel empowered to have contributed to shaping the intervention. For future participants, we expect this research may lead to better understanding of the types of interventions that can be feasibly implemented to improve the experience of health care workers as well as the experience of their clients and lead to overall improvements in quality of health care. • **Alternatives.** Participation is voluntary and the only alternative is to not participate.

Purpose of the Research: The Purpose of this research is to identify effective ways to improve quality of care that includes addressing provider concerns such as stress and burnout as well as other factors that affect provider interactions with patients such as unconscious bias.

1. **Description of the Research:** You are participating in the formative research where want to get stakeholder input on what can be feasibly implemented among health care providers in Migori County and what is potentially going to be acceptable and effective. Should you agree to participate, we will share some of our ideas for the intervention with you and ask you to tell us what you think of those activities and what we can do to increase participation and engagement. We will also ask you to share any other ideas you have with us on what you think are feasible and acceptable activities to help develop positive coping mechanisms among providers, increase, motivation, and reduce bias. Because these interviews are more in-depth, and we don't want to lose any information, we will audio record the interviews to make sure we capture all the information. We will then write out information from the recordings and delete the tapes. We will however not use the recordings directly so do not worry about someone recognizing your voice. These interviews will take about 30mins to 1 hour.

1. **Human genome sequencing:** This study does not involve human genome sequencing

2. **Storage of specimen, exportation of samples and further studies:** This study does not involve collection of specimens

3. **Potential Harm, Injuries, Discomforts or Inconvenience, Risks:** There may be a small risk in that you may be uncomfortable answering some questions. If you are uncomfortable about a particular activity, you have the right to decline to respond.

4. **Potential Benefits:** We think participation in the intervention might benefit you by making you feel empowered to have contributed to shaping the intervention. For future participants, we expect this research may lead to better understanding of the types of interventions that can be feasibly implemented to improve the experience of health care workers as well as the experience of their clients and lead to overall improvements in quality of health care.

5. **Confidentiality:** The information collected will be kept confidential and used only for the purposes of this study. All data collected from you will be coded in order to protect your identity. Only the research study staff will have access to the information. At the end of the study, there will be no way to link your name with your data.

6. **Reimbursement:** You will also be given 300 KES after you complete the interview.

7. **Participation:** Participation is voluntary. You are free to refuse to answer any questions at any time without any consequences.

8. **Sponsorship:** If for any reason the study is terminated, you will be duly informed.

9. **Contact:** If you have any questions or concerns about the study, you may contact the study researchers, Patience Afulani +1-310-498-1015 or Linnet Ongeri at 0722615999 (Address: Kenya Medical Research Institute, Mbagathi Road, Nairobi, Kenya).

- For any questions pertaining to rights as a research participant, the contact person is: The Committee Chairperson, KEMRI Scientific and Ethics Review Unit, P. O. Box 54840-00200, Nairobi; Telephone numbers: 020-2722541, 0717719477; Email address: seru@kemri.org

10. **Consent and signature options:**
    At this time, do you want to ask me anything about the study?
    Should you agree to participate in the study, please sign your name below, indicating that you have read and understood the nature of the study, your responsibilities as a study participant, the inconveniences associated with voluntary participation in the study and that all your questions and concerns concerning the study have been answered satisfactorily. You will receive a copy of this signed consent form to take away with you.

- I agree to interview: · Yes · No
- I agree to audio recording: · Yes · No · N/A

SIGNATURE OF PARTICIPANT

_____
Printed Name of Participant

_____ _____
Signature of Participant Date

_____
Permanent Address of Participant

(*Use the following signature blocks for representative, parents, and guardians, only if applicable****)***

Your signature below indicates you are legally authorized to act on behalf of the participant, and have read this document. You will receive a copy of this document. *(The Principal Investigator is responsible for confirming that an individual is a Legally Authorized Representative based on local and state laws.*

SIGNATURE OF LEGALLY AUTHORIZED REPRESENTATIVE

_____
Printed Name of Legally Authorized Representative

_____
Relationship to the Participant

_____ _____
Signature of Legally Authorized Representative Date

(Remove the witness signature if this study is conducted under ICH GCP. Determine if your institution requires witness to the entire consent process or only witness to the final signature.)

SIGNATURE OF WITNESS TO CONSENT/CONSENT PROCESS
(This individual can be a relative of the participant, but cannot be an individual involved with the research study.)

_____
Printed Name of Witness

_____ _____
Signature of Witness Date

SIGNATURE OF INDIVIDUAL ADMINISTERING CONSENT
(Can only be signed by an investigator or staff approved to administer consent)

_____
Printed Name of Administering Individual

_____ _____
Signature of Administering Individual Date

Provider Consent Form

Title of the Research Study: Caring for Providers to Improve Patient experience (CPIPE) study

NCT05019131

Version 3.0: 02/10/20

Investigators:

Principal Investigator:	Dr. Patience Afulani	University of California, San Francisco
Co-Investigators:	Dr. Linnet Ongeri	Kenya Medical Research Institute
	Ms. Joyceline Kinyua	Kenya Medical Research Institute

Study location: Migori County, Kenya

You are being asked to take part in a research 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 whether 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.

Key Information for You to Consider(Not more than 500 words)

- **Voluntary Consent**. You are being asked to volunteer for a research study. It is up to you whether you choose to participate or not. There are no penalties and you will not lose anything if you decide not to join or if after you join, you decide to quit.
- **Purpose**. We are doing this research to identify effective ways to improve quality of care that includes addressing provider concerns such as stress and burnout as well as other factors that affect provider interactions with patients such as unconscious bias.
- **Duration.** Your part of the study will last 6 months
- **Procedures and Activities.** We will ask you to participate in intervention activities that include participating in trainings and activities to provide peer support and mentorship. In addition, we will ask you to participate in interviews to enable us to assess what you think of the intervention and how it has affected you. We will also measure your heart rate variability and ask you provide as with a small sample of your hair to measure your hair cortisol levels to be able to estimate your level of stress.
- **Risks.** Most studies have some possible harms that could happen to you if you join. In this study, we expect that you may be uncomfortable participating in some activities or answering some questions in the survey or you may feel anxious when your heart rate and hair sample is being taken. However, these procedures are not harmful. If you are uncomfortable about a particular activity, you have the right to decline to participate in it.
- **Benefits**. We expect some benefits from this study, as well. For you, we expect the intervention might benefit you through helping you to better manage your stress and help improve your work experience. For future participants, we expect this research lead to better understanding of the types of interventions that can be implemented to improve the experience of health care workers as well as the experience of their clients and lead to overall improvements in quality of health care.
- **Alternatives.** You may be assigned to participate in the intervention immediately after the first interview or in six months after you have completed the second interview.

Purpose of the Research: The Purpose of this research is to identify effective ways to improve quality of care that includes addressing provider concerns such as stress and burnout as well as other factors that affect provider interactions with patients such as unconscious bias.

1. **Description of the Research:** Should you agree to participate, you will be invited you to participate in intervention activities that include participating in trainings and activities to provide you with peer support and mentorship. These activities will be spread over a 6 month period and will mostly happen at your health facility at times that are convenient to you. In addition, we will ask you to participate interviews before and after the intervention to enable us to assess what you think of the intervention and how it has affected you. We will also

measure your heart rate variability and ask you provide as with a small sample of your hair to measure your hair cortisol levels to be able to estimate your level of stress. The data collection will take place in a private space at a time and place that is convenient to you. You may choose to not to participate in any of the activities. Here are some more details of the different data collection procedures.

- ***Surveys:*** The first interviews will be in the form of a survey, where we would ask you questions in private about your job, the things that make you satisfied or dissatisfied with your job, how you treat pregnant and childbearing women, what causes you to sometimes treat people differently, what stresses you and how you deal with it and what you think can be done to improve your work experience. We will also ask you some questions about yourself and the facility you work in and what can be done to improve your work experience. We may also ask you about experiences related to work including suicidal thoughts or substance abuse to cope with stress. After the intervention, we will also ask you what you think about the intervention and how you can improve it. This interview will take between 30mins and 1 hour and your responses will be entered on a tablet.

- ***Implicit association test:*** As part of the surveys, we will ask you to do a short and simple exercise on the computer which involves categorizing groups of words. This test is to help us understand how your brain makes certain connections unconsciously (like someone's age and their perceived behavior) that could affect how you interact with patients. This will take only about 5 mins.

- ***Heart rate variability measurement***: With your permission we will also like to measure your heart rate variability using this simple device (show them device). We will ask put this device on your finger and ask you to sit still for 5mins while the device is measuring your heart rate, to enable us get a one-time 5-minute reading of your heart rate variability. The data from the device will be transmitted to this phone and uploaded later to a computer.

- ***Hair cortisol measurement:*** Finally, we will like to take a small sample of your hair: about 30 strands which is about this quantity (show picture), to measure the level of cortisol, which is a stress hormone, in your hair. The hair sample will be labelled with a unique ID (not your name) and stored safely until transported to a lab in the University States for analysis. The sample will be discarded after the analysis.

- ***In-depth interviews*****:** We may follow up to invite you to a second type of interviews at a later date, where we will ask you more detailed follow up questions. Because these interviews are more in-depth, we will audio record those interviews to make sure we capture all the information. We will then write out information from the recordings and delete the tapes. We will however not use the recordings directly so do not worry about someone recognizing your voice. These interviews will take about 30mins to 1 hour. **In the event necessary due to COVID-19 related restrictions, we may conduct these interviews using remote based alternatives such as phone.**

- ***You will be assigned to one of two groups*****.** If you are assigned to the first group, you will participate in the intervention activities after the first set of interviews, and then participate in a second set of interviews after the intervention activities. If you are assigned to the second group, you will first participate in two sets of interviews and then be invited to participate in the intervention activities at a later date.

2. **Human genome sequencing:** This study does not involve human genome sequencing

3. **Storage of specimen, exportation of samples and further studies:** Your hair sample will be labelled with a unique ID (not your name) and stored safely until transported to a lab in the United States for analysis the cortisol levels in your hair. The sample will be discarded after the analysis is completed and the results are recorded. The data may be shared with other researchers for future studies without additional consent from you. Such data will not contain your name or other information that can be used to identify you. You can **decline** to have your information used or shared with other researchers for future research. If you agree to let researchers collect and store your specimens for future research, the following will happen:
    - After the tests required for the study are finished, we will discard your leftover specimens.

- We may share the hair sample results and information about you (for example, diagnosis, blood pressure, age) with other researchers, but we will not give them your name, address, phone number, or any other information that would identify you.

4. **Potential Harm, Injuries, Discomforts or Inconvenience, Risks:** There may be a small risk in that you may be uncomfortable participating in some activities or answering some questions in the survey. These may include questions that may include experiences of suicidal thoughts or substance abuse. We will refer you to locally available resources and help, as needed. You may feel anxious when your heart rate and hair sample is being taken. However, these procedures are not harmful. If you are uncomfortable about a particular activity, you have the right to decline to participate in it.

5. **Potential Benefits:** We think participation in the intervention may benefit you through helping you to better manage your stress and help improve your work experience. There will be no direct benefit to you from allowing your specimens results to be used or future research. However, we hope we will learn something that will contribute to the advancement of science and understanding of health and disease. There may be no direct benefit to you from participating in this study. But the information that you provide will help us to better understand the types of interventions that can be implemented to improve your experience as well as the experience of your clients towards improving quality of health care.

6. **Confidentiality:** The information collected will be kept confidential and used only for the purposes of this study. All data collected from you will be coded in order to protect your identity. Only the research study staff will have access to the information. At the end of the study, there will be no way to link your name with your data. Donating specimens may involve a loss of privacy, but information about you will be handled as confidentially as possible. Study data will be physically and electronically secured

7. **Reimbursement:** We will provide meals and/or snacks during intervention activities depending on the length of the activity. If an activity requires travel, we will cover the cost of your transportation to the site. You will also be given 300 KES for each interview you complete.

8. **Participation:** Participation is voluntary. You are free to withdraw or refuse to answer any questions at any time without any consequences.

9. **Sponsorship:** if for any reason the study is terminated, you will be duly informed.

10. **Contact:** If you have any questions or concerns about the study, you may contact the study researchers, Patience Afulani +1-310-498-1015 or Linnet Ongeri at 0722615999 (Address: Kenya Medical Research Institute, Mbagathi Road, Nairobi, Kenya).

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11. **Consent and signature options:**
    At this time, do you want to ask me anything about the study?
    Should you agree to participate in the study, please sign your name below, indicating that you have read and understood the nature of the study, your responsibilities as a study participant, the inconveniences associated with voluntary participation in the study and that all your questions and concerns concerning the study have been answered satisfactorily. You will receive a copy of this signed consent form to take away with you.

- I agree to intervention activities: · Yes · No
- I agree to survey: · Yes · No
- I agree to in-depth interview, including remote options: · Yes · No
- I agree to audio recording: · Yes · No · N/A

- I agree to implicit association test: · Yes · No
- I agree to heart rate variability measurement: · Yes · No
- I agree to hair cortisol measurement: · Yes · No
- I agree for my specimen/information to be used for future research and shared with other researchers without my additional consent as long as identifiers have been removed · Yes · No

SIGNATURE OF PARTICIPANT

_____
Printed Name of Participant

_____ _____
Signature of Participant Date

_____
Permanent Address of Participant

(*Use the following signature blocks for representative, parents, and guardians, only if applicable****)***

Your signature below indicates you are legally authorized to act on behalf of the participant, and have read this document. You will receive a copy of this document. *(The Principal Investigator is responsible for confirming that an individual is a Legally Authorized Representative based on local and state laws.*

SIGNATURE OF LEGALLY AUTHORIZED REPRESENTATIVE

_____
Printed Name of Legally Authorized Representative

_____
Relationship to the Participant

_____ _____
Signature of Legally Authorized Representative Date

(Remove the witness signature if this study is conducted under ICH GCP. Determine if your institution requires witness to the entire consent process or only witness to the final signature.)

SIGNATURE OF WITNESS TO CONSENT/CONSENT PROCESS
(This individual can be a relative of the participant, but cannot be an individual involved with the research study.)

_____
Printed Name of Witness

_____ _____
Signature of Witness Date

SIGNATURE OF INDIVIDUAL ADMINISTERING CONSENT
(Can only be signed by an investigator or staff approved to administer consent)

_____
Printed Name of Administering Individual

_____ _____
Signature of Administering Individual Date