# Informed Consent

# Randomized Controlled Trial to Address Unintended Pregnancy Rates in Low Resource Settings

**NCT number** NCT05328648
**Document Date** 10/22/2021

**University of North Carolina-Chapel Hill**
**Consent to participate in a research study**
**Adult Consent** [Service Providers In-Depth Interview]

| | |
|---|---|
| **Consent Form Version:** | 10/22/2021 |
| **IRB Study #:** | 21-2217 |
| **Title of study:** | Randomized Controlled Trial to Address Unintended Pregnancy Rates in Low Resource Settings |
| **Principal Investigator:** | Kat Tumlinson, PhD |
| **Department:** | Maternal and Child Health, Gillings School of Global Public Health |
| **Phone Number**: | +1-919-824-4722 |
| **Email address:** | ktumlin@email.unc.edu |
| **Co-Investigators:** | Sian Curtis, PhD; Kavita Singh, PhD; Sean Silvia, PhD |
| **Source of funding:** | NIH National Institute of Child Health and Human Development |
| **Study contact:** | Eric Ochieng, Innovation for Poverty Action Kenya |
| **Phone number:** | +254-742984643 |
| **Email address:** | eochieng@poverty-action.org |

**Concise Summary**

The purpose of this study is to find out if communities can monitor services provided at government healthcare facilities.

You may live in a community – or be employed at a healthcare facility – that is selected to participate in a community-based intervention to improve healthcare services. Before and after the intervention, we will interview women in the community about their health seeking behaviors. We will also interview healthcare providers about the care they provide. We will also conduct focus groups before the study to seek local input on the intervention, and we will conduct focus groups and in-depth interviews after the intervention to seek local input on the acceptability of the interventions. Interviews will range from 30 minutes to 1.5 hours.

There are no known risks associated with participating in this study other than a possible breach of confidentiality.

If you are interested in learning more about this study, please continue to read below.

1. **What are some general things you should know about research studies?**

You are being asked to take part in a research study. To join the study is voluntary. You may choose not to participate, or you may withdraw your consent to be in the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study.

You will be given a copy of this consent form. You should ask the investigators mentioned on this form, or anyone who is assisting them, any questions you have about this study at any time.

2. **What is the purpose of this study?**

The purpose of this study is to evaluate social accountability interventions designed to improve delivery of healthcare services.

3. **How many people will take part in this study?**

If you decide to participate in this study, you will be one of approximately 30 people taking part in an in-depth interview for this study.

4. **How long will your part in this study last?**

If you decide to participate in this study, your participation would last approximately 1.5 hours. We will not need to contact you again after today.

5. **What will happen if you take part in the study?**

If you agree to participate in this study, you will be invited to participate in an in-depth interview about feedback mechanisms available to patients and the impact of feedback on professional fulfillment.

6. **What are the possible benefits from being in this study?**

Research is designed to benefit society by gaining new knowledge. You may will not benefit personally from being in this research study.

7. **What are the possible risks or discomforts from being in this study?**

There are no known risks associated with participating in this study, other than a possible breach of confidentiality. However, as stated below, we have mechanisms in place to uphold your confidentiality. There may be uncommon or previously unknown risks. You should report any problems to the researcher.

**8. How will information about you be protected?**

We value your privacy and will take several steps to protect the confidentiality of the information that you provide us. All of the data that we collect today will be stored on a password protected computer and any identifying information will be removed from the data and stored separately.

Participants will not be identified in any report or publication about this study. We may use de-identified data and/or specimens from this study in future research without additional consent.

Although every effort will be made to keep research records private, there may be times when USA federal or NC state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies (for example, the FDA) for purposes such as quality control or safety.

IPA may transfer your data inside or outside Kenya including:

- All the data points listed above will be shared with the study researchers from the University of North Carolina at Chapel Hill. These parties will be responsible for data analysis seeking to understand the impact of the project's interventions on health in Kenya.
- Innovations for Poverty Action-United States (IPA-US): IPA-US will access the data points as they will be responsible for ensuring the data is stored in a secure storage and ensuring all data recipients have data security standards similar to those of IPA before the data is transferred.

When collecting, storing, processing, and transferring data, IPA uses Boxcryptor software and limits access to your personal data on a need-to-know basis. When IPA transfers your data to the above third parties, IPA will ensure the recipients will have similar security standards to IPA.

**9. What if you want to stop before your part in the study is complete?**

You can withdraw from this study at any time, without penalty. The decision not to participate in this study, or to leave the study before it ends, will not affect your relationship with the investigator, with the focus group moderators, with Innovations for Poverty Action, or with the University of North Carolina-Chapel Hill.

If you withdraw from this study, all data collected up until the point of withdrawal will be retained, unless otherwise requested, however no additional information will be collected unless you provide additional written permission for future data collection at the time of your withdrawal. Your data will be anonymized or de-identified (removed personal identifiers from), in a manner to ensure you are no longer identifiable. Afterwards, your information will be retained for at least three years.

**10. Will you receive anything for being in this study?**

You will not receive anything for participating in this study.

**11. Will it cost you anything to be in this study?**

It will not cost you anything to be in this study.

**12. Who is sponsoring this study?**

This research is funded by the National Institutes of Health in the United States. This means that the research team is being paid by the sponsor for doing the study. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study.

**13. What if you have questions about this study?**

You have the right to ask, and have answered, any questions you may have about this research. If you have questions about the study (including payments), complaints, concerns, or if a research-related injury occurs, you should contact the researchers listed on this form.

**14. What if you have questions about your rights as a research participant?**

All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may contact the UNC Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu. You may also contact the Maseno University Ethics Review Committee (MUERC), via phone (+254-57-351-622 EXT. 3050), email (muerc-secretariate@maseno.ac.ke) or mail to the following address: Maseno University Ethics Review Committee, Directorate of Research, Publications and Innovations (DRPI), Maseno University Main Campus Along Kisumu-Busia Road, P. O. Box, Private Bag, Maseno, Kenya.

Please also feel free to reach out to study staff- contacts on the first page of this document.

**Participant's Agreement:**

By consenting you are freely providing consent for Innovations for Poverty Action (IPA) to collect, process and transfer your sensitive personal data and personal data ("data"). In doing so, IPA commits to comply with the principles of data protection set forth in the Kenya Data Protection Act, 2019. IPA has informed you that you have the right: 1) to be informed on IPA's use of your data, 2) access your data that IPA holds, 3) request IPA update, correct, or delete your data, or opt-out at any time. By signing this consent, you also acknowledge that you are least 18 years of age or older.

You hereby confirm to have read the information provided above. You have asked all the questions you have at this time and you voluntarily agree to participate in this research study.

_____ _____

Signature of Research Participant Date

_____

Printed Name of Research Participant

_____ _____

Signature of Research Team Member Obtaining Consent Date

_____

Printed Name of Research Team Member Obtaining Consent