**Exploring the understanding and motivation to participate in randomized clinical trials of Emergency Obstetric and Newborn care in Uganda**

**In-depth research Interview guide for potential research participants (survivors of severe obstetric complications in the postnatal clinic)**

**Interview characteristics**

Date of the interview: ……………………… Start time of the interview: ……………..

End time of the interview: ………………… Hours: …………………………………..

Interview number: …………………….

**Participant information**

Thank you for accepting to be interviewed. We would like to assess how much you know about research and how people make the decision to participate or not participate in research involving emergency obstetric and newborn care. The discussion shall take about 30-45 minutes. We request your permission to audio record the discussion we shall have with you. This information recorded will not mention your personal details such as names or telephone numbers. All the information that we collect will be kept confidentially and will not mention your personal details. Be free to say whatever you want to say as there is no right or wrong answer.

Please feel free to ask any questions.

**Interview questions**

1. What is your opinion about research on emergency obstetric and newborn care?

Probe for:

* 1. Is it necessary to conduct such research?
  2. How should researchers deliver information inviting participants?
  3. How should researchers try to check whether participants have understood the information?
  4. What could be the potential benefits of this research?
  5. What could be the potential risks of this research?
  6. Should there be *compensation* for adverse events or any harms that may arise during the research? Probe for: What kind of adverse events or harms could potentially occur and what form of compensation could be availed to participants

1. What factors may affect how participants understand the given information?

Probe for:

* 1. Nature of disease
  2. Severity of disease?
  3. Language?
  4. The way information is presented?
  5. Timing of the information?
  6. Ongoing medication?
  7. Complexity of consent document?
  8. The contextual factors such as research environment, privacy, confidentiality?

1. In your view, what do you think are some of the reasons or factors that influence decisions to participate in research in emergency contexts?

Probe for:

* 1. What could be incentives?
  2. Is it financial?
  3. Is there a need to promote scientific advancement?
  4. Contextual factors?
  5. Medical benefit?
  6. Family and friends?
  7. Healthcare providers and relationship with them?

**Thank you very much for your participation**

**The Johns Hopkins University**

**Bloomberg School of Public Health**

**Institutional Review Board**

**Draft consent form for the in-depth interviews for former research participants of randomized clinical trials in emergency obstetric and newborn care**

**Exploring the understanding and motivation to participate in randomized clinical trials of Emergency Obstetric and Newborn care in Uganda.**

PI Version Date: **September 19,2018**

**What you should know about this study**

* You are being asked to join a research study.
* This consent form explains the research study and your part in the study.
* Please read it carefully and take as much time as you need.
* You are a volunteer. You may choose not to take part at all, and if you join, you may quit at any time. There will be no penalty if you decide to quit the study.
* During the study, we will tell you if we learn any new information that might affect whether you wish to continue to be in the study.

My Name is Dan K. Kaye, a lecturer from Makerere University and a researcher who has an interest in assessing whether and what research participants understand about research in emergency care. This research has been approved by The Ethics Committee of the School of Medicine of Makerere University College of Health Sciences, as well as the ethics committee of Johns Hopkins University Bloomberg School of Public Health, and Uganda National Council of Science and Technology. This work is in partial fulfillment of requirements for completion of a postdoctoral fellowship in bioethics from Johns Hopkins University School of Public Health.

**Purpose of the project:**

This is a research project to be conducted among former research participants in randomized clinical trials (RCTs) of emergency obstetric and newborn care in Uganda. The purpose of this project is to assess what former research participants for RCTs in emergency obstetric and newborn care understand about the research in which they participated, specifically whether they understand the purpose of the studies, the benefits/risks involved and what motivated them to participate. You are invited because you or your child was a participant in such studies in the last few months.

**Procedures:**

lf you agree to be in this study, you will be requested to have a one-to-one discussion with a member of our research team. The discussion will focus on what you know about that research where you participated, as well as what motivated you to participate. This interview shall take place in a private room where the discussions are not likely to be interrupted. We shall request permission from you to audio record the discussion. The discussions shall last 30-45 minutes.

**Risks:**

There are minimal anticipated related to participation in this study. It is possible that the discussion may remind you of the discomfort you went through during that time when the investigation you participated in took place.

**Benefits:**

There are no direct benefits to you from being involved in this study. You may like knowing that the information you share with us will be used to help improve the process of recruiting individuals in studies that are conducted in a similar situation to the one that you participated in. We shall provide you with some money (about shillings 50,000/=) for refund of your transport costs as a token of appreciation of your willingness to participate in the discussions.

**Confidentiality:**

We will ask you for some personal information such as your name. We would also like to audio record the discussion that we conduct with you. All the information that we collect from you will be kept private. The only people who have access to the information will be the research team members. All the information you give us including the audio recording of your interview will be kept confidential, and shall be kept safe in a locked filing cabinet. We will not use your name or other identity in all the information that we get from you. We will also erase any private information that may identify you from the interviews. We will destroy the audio recording of your interview when we have completed the study.

**Voluntariness:**

You have every right to decide whether or not you take part in this study. The care that you receive at this clinic will not be affected by whether you agree or decline. You are free to stop the interview at any time. You also decline to answer any of the questions in the discussions. You are free to ask the person whose names are listed below any questions related to this research study..

**Who to Contact**:

If you want to talk to anyone about this research study you should call Dan Kaye on tel +256772587952 or Prof Ponsiano Ocama at Makerere University Uganda or the Institutional Review Board (ethics committee)at the Johns Hopkins University in the USA at 410-614-1856.If you agree to be in the study, the counselor will sign the form below. Her signature tells us that she had read this form to you and you have agreed to be in this study.

NOT VALID WITHOUT THE

COMMITTEE OR IRB STAMP OF

CERTIFICATION

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of the participant

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Investigator

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date

Note. Signed copies of this consent form must be a) retained on file by the Principal

Investigator) given to the participants, c) put in the patient's medical records(when applicable).