**INFORMED CONSENT FORM**

**IMPLEMENTATION AND EVALUATION OF KMC DELIVERY MODEL**

 Interview with mothers/caregiver

**Consent form 3AB: Interview with mothers of <2.0 kg babies**

This informed consent form is for interview with mothers/caregivers for the study titled “*Implementation Research Initiative for Accelerating Scale-up of Kangaroo Mother Care"*

*Name of the Principal Investigator*:

*Name of Organization*:

This Informed Consent Form has two parts:

* Information Sheet (to share information about the research with you)
* Certificate of Consent (for signatures if you agree to take part)

You will be given a copy of the full Informed Consent Form.

**PART I: Information Sheet**

**Introduction and Purpose of Research**

I [name of worker] am working for the [name of the organization]. We are doing a research project on care of low birth weight babies. We would like to discuss with you and learn about how you have been caring for your baby. We would also like to observe you and the other family members as to how the care of newborn baby is being done. We would also like to talk about your experience with KMC.

We are doing this to learn how to provide better care for low birth weight and preterm babies in the health facility and in the community. This information will be used to find improved ways to promote the health of such babies.

**Participant Selection**

We are inviting mothers who have recently delivered LBW babies who are eligible to receive KMC, in the [study area] or the caregivers in the family to take part in this interview.

**Voluntary Participation**

Your participation is entirely voluntarily. If you choose not to participate, you and your family will still receive the same care and attention from the health centres in the area as before.

**Procedures and duration**

If you agree for you and your baby’s participation in this research project, then:

* We will contact you twice, at the time of discharge from the facility and at 7 days after discharge
* During these visits we will talk to you to understand your experiences and what you felt during your current delivery and immediate period after it, your feelings about KMC, the feelings of your neighbors and relatives about KMC, your determination to practice KMC and willingness to encourage other mothers with a low birth weight baby to practice KMC. We will also like to collect information on the barriers and difficulties you faced while practicing KMC.

The interview may take 30 minutes to 1 hour. You will not receive any compensation for participating in the interview. The interview will take place in [location], and no one, except me, will be present. The interview will be recorded so that we do not miss any information.

If you have any concerns about the interview or the project, please talk to me or other researchers, whose contact numbers are given in this information sheet.

**Risks and Benefits**

There are no physical or psychological risks to participate in this interview. If you are not comfortable, you may choose not to answer a particular question.

There are no direct benefits as such. As it has probably been explained to you after the baby was born, there are no particular risks associated with KMC. The benefit that you and your child would receive is that by practicing KMC you would give warmth, help maintain your baby’s temperature and be able to give breastfeeding more often. It will also promote the growth of your child. However, when we visit, you will have an opportunity to ask questions about the health of your baby. Your participation will help us to know if KMC is being practised as desired, to identify the problems you are facing if any, in doing KMC and any facilitating factors. The information that you will share will help us to improve the way KMC is promoted in our hospitals.

**Confidentiality**

The information that we collect for this research project will be kept private and confidential. No participant will be identified by name on any record. You will be given a number and only the researchers will know what your number is. We will store that information under lock and key. The recordings will be kept for 1 year.

**Sharing the Results**

The knowledge that we get from this interview will be shared through reports given to the government and through publications.

**Right to Refuse or Withdraw**

You do not have to take part in this project if you do not wish to do so, and you may also stop participating at any time during the trial without giving any justification.

**Who to Contact**

If you have any questions you may ask them now or later; you may contact any of the following:

[Name of the person and contact details]

This proposal has been reviewed and approved by the Ethics Committee of [name of the local ethics committee], whose task is to make sure that research participants are protected from harm. If you wish to find out more about the ethics committee you can contact them on \_\_\_\_\_\_\_\_\_\_\_\_. The research proposal has also been reviewed by the Ethics Committee of World Health Organization (WHO) which is supporting the study.

Part II: Certificate of Consent

**I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any question I have asked has been answered to my satisfaction. I consent voluntarily to:**

**□** Participate in the project and be interviewed

**□** The interview being recorded

**□** Be visited by the study team according to the timeline mentioned above

Name of Participant\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Day/month/year

Signature of Participant \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

***If illiterate or less than 18 years of age***

**I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely to:**

**□** Participate in the project and be interviewed

**□** The interview being recorded

**□** Be visited by the study team according to the timeline mentioned above

**Name of witness\_\_\_\_\_\_\_\_\_\_\_\_ AND Thumb impression of participant**

**Signature of witness \_\_\_\_\_\_\_\_\_\_\_\_\_**

**Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

 **Day/month/year**

***Statement by the researcher/person taking consent***

**I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understood the research project. I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.** **A copy of this informed consent form has been provided to the participant.**

Name of researcher/person taking the consent\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of researcher /person taking the consent\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Day/month/year