Written Informed Consent Form for Mothers

This Informed Consent Form (ICF) is for mothers attending participating hospitals in Uttar Pradesh and who are invited to participate in the research to improve overall health of babies who are born too soon or small, or both, by providing KMC immediately after birth and support government to scale up iKMC at state and national levels.

Study Title: Implementation research to develop & evaluate a health system model to integrate immediate Kangaroo Mother Care into the routine care of preterm or low birth weight infants in Uttar Pradesh
Overall Principal Investigator (UP): Dr. Vishwajeet Kumar, Ms. Aarti Kumar
Organization: Community Empowerment Lab (CEL)
Name of Sponsor: World Health Organization (WHO)
Version Date: 10 March 2023

Part I: Invitation for Participation

Namaskar! My name is _____ ,and under this study, I represent

- ☐ SN Medical College, Agra
- ☐ Jawaharlal Nehru Medical College, Aligarh
- ☐ GSVM Medical College, Kanpur
- ☐ Institute of Medical Sciences, Varanasi
- ☐ Dr Ram Manohar Lohia Medical Institute of Medical Sciences Lucknow)
- ☐ Others (please specify)_____

and Community Empowerment Lab (CEL), Lucknow. We are supporting the government and the medical & scientific communities in developing solutions to improve the health of children. We are conducting a research study in collaboration with the World Health Organization (WHO) and National Health Mission, Uttar Pradesh (NHM-UP) in this district, for how to implement Kangaroo Mother Care (KMC) initiated immediately after birth on babies born too soon or small, or both. Kangaroo Mother Care means provision of skin-to-skin contact and support for exclusive breastmilk/breastfeeding for newborn. I am working as a study team member associated with this research study.

Now, I am going to give you some more information about the study and invite you to be part of this research. Before you decide to participate, it is important for you to understand why the study is being done and what it will involve. This information sheet will explain what we are doing. Please take time to **read** the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information on. Take time to decide whether you wish to take part.

Who are we?
We are a team of doctors, nurses and public health specialists from this hospital and Community Empowerment Lab.

What is KMC?
KMC means continuous skin-to-skin contact between the mother and the baby and feeding the baby with only mother's breastmilk. Keeping the mother and baby together right from birth with zero separation in a respectful manner, while the baby receives required medical care, this improves your baby's survival, as well as help regulate baby's heart rate and temperature, lowers stress, improves breastfeeding, reduce infection and helps bonding between the mother and the baby. Kangaroo mother care is already known to be a promising and cost-effective intervention, reducing mortality by 40% among hospitalized infants with a birth weight less than 2.0 kg when started once they are clinically stable. However, an important study coordinated by WHO showed a further 25% reduction when it is initiated immediately after birth, either with the mother or a surrogate.

What is the purpose of the study?
Babies born with birth weight lower than 1800 grams are at a high risk of illness and are routinely separated from their mothers and treated in a special newborn care unit. In the current research, we want to provide continuous KMC starting immediately after birth to babies born too soon or small, or both while giving them all the current care in the special newborn care unit and study its effect on health and survival of these babies. Thus, the purpose of this study is to find out the best way to provide KMC immediately after birth as a standard of care.

Why have I been chosen?
We are inviting all mothers of babies requiring care at special newborn care unit to participate in this research. Your baby is going to be admitted to special newborn care unit therefore we are approaching you to be part of this study.

Do I have to take part?
Your participation in this research is completely voluntary. You have the right to choose whether or not to participate. You can also withdraw your participation at any time even after you have agreed for it. A copy of this informed consent form will be provided to you. You will not have to make any payment or penalty if you don't wish to participate in this study. If you choose not to participate in this study, you will receive the standard treatment from hospital and your medical care or rights will not be affected in any way.

What will I have to do?
If you agree, you will be invited to participate in an interview or a group discussion along with other mothers like you. The interviews are expected to last approximately 45-60 minutes, while the group discussions may take approximately 60-75 minutes. I and/or one of my team members will conduct the interview or group discussion, making sure that you are comfortable. We will also answer any questions about the research that you might have.

During the interview/ discussions, we will ask you to share your experiences and care practices at the facility and the SNCU, and in providing KMC. We would also like to know about any challenges that you may have faced.

I will share a copy of this consent form with you. You can withdraw at any time without giving a reason and that will not adversely affect you in any way. You do not have to share any knowledge that you are not comfortable sharing. With your permission, we would like to audio record the discussion. The audio recordings will be transcribed, to help make sure the write-up is accurate and complete. Only members of the research team shall have access to the recordings. The recording will be erased from the recorder as soon as it is transferred onto the computer. The computer files of the audio-recordings will be password protected during the study and destroyed at the end of the study. Refusing the recording does not mean you cannot participate in the study. After we remove all the identification, the information you provide will be securely stored for 10 years.

We will also collect information from your clinical records including skin-to-skin contact and breastfeeding and some details related to newborn outcomes.

What will happen to the results of the study?
The findings from this research will help us to find ways to support mothers and health providers of vulnerable babies in initiating Kangaroo Mother Care immediately after birth. A report about the study and related articles will be published in academic journals or presented at academic conferences, so that others can use the information. You will not be identified in any way in any report or publication.

Confidentiality
The information that we collect from this research study will be kept confidential. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and we will lock that information up with a lock and key. Identifiable information will not be shared with or given to anyone outside the research team. A report about the study and related articles will be published in academic journals or presented at national and international academic conferences, so that others can use the information. You will not be identified in any way in any of these.

What will you get out of this study?
The implementation of this study might help to identify the best way of providing Kangaroo Mother Care for babies born too soon or too small, or both, which will not only improve survival of babies but also mother's confidence to take care of her baby. This study will strengthen quality of routine care in facility while improving care at level 2 special newborn care unit. Apart from the direct benefits, your contribution may also help researchers, health providers and policy makers to understand the impact the Kangaroo Mother Care initiated immediately after birth when implemented in routine care setting.

What is the "risk" to you?
There is no physical risk involved with the study. It is possible that some of the questions you will be asked could make you feel uncomfortable. You may decline to answer any questions asked, and you may ask any question about this study at any time. Please, tell the researcher if you feel uncomfortable or upset during your participation. Every effort will be made by the researcher or other field investigators who visit you at the hospital or home, to make you feel at ease and comfortable when you are completing the questionnaire or when we are collecting any information in relation to the study.

Whom do I call if I have questions or problems?
This study has been reviewed and approved by the members of an ethical committee. The task of this committee is to make sure that research participants are protected from harm. If you have any questions about the study, please contact:

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A-6-14, H-1489, Vineet Khand 6, Gomti Nagar
Lucknow-226010, Uttar Pradesh
Phone: +91-88107-25123
Email: vinaypratap.singh@celworld.org

If you have any questions or concerns about the conduct of the study, you may also contact the Ethics Committee of the study:

Ethics Committee CEL
Institutional Ethics Committee, Community Empowerment Lab
A-6-14, H-1489, Vineet Khand 6, Gomti Nagar
Lucknow-226010, Uttar Pradesh
Phone: 0522-4070395

Thank you for taking the time to read this information.

PART II: Certificate of Consent

I confirm that I have read/heard this consent form and understood the purpose, procedures, possible benefits and risks of the process for this research. I have had the opportunity to ask the questions and got satisfactory answers to all my queries.

I understand that:

- My participation in this study is completely voluntary.
- I am free to withdraw my participation at any time without giving any reason and without my or my child medical care or rights being affected.
- I can ask more questions/ information about the study at any point of time.
- I will be given a copy of this consent form for my own records.
- My and my child's participation in this study will be kept strictly confidential.
- I don't need to pay or will receive any payment or incentive for my participation in this study.

I voluntarily agree to participate in this study.

Yes ☐ No ☐

_____ _____

Name and Signature/Thumb impression of Parent Date (dd/mm/yyyy)

Witness to the Consent (if parent is illiterate):
[If the parent is illiterate and is not able to sign her/his name, a literate witness other than the member of the study team needs to sign that they confirm that the participant has agreed to allow her/his child to participate.]

I have witnessed the accurate reading of the consent form to the parent of the child, who has had the opportunity to ask questions. I confirm that the parent has given his/her consent freely.

_____ _____ _____

Name of Witness to the Consent Signature Date (dd/mmm/yyyy)

Study Team Member Obtaining Consent

I have accurately read the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm the consent was given freely. The participant has been given a copy of this consent form for his/her own records.

_____ _____ _____

Name of Research Team Member Signature Date (dd/mmm/yyyy)