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 term born healthy babies of normal birth weight (≥2500 grams).

Study Title: Can Kangaroo Mother Care (KMC) during the first 72 hours lead to improved breastfeeding and growth among normal birth weight newborns? - A randomized controlled trial
Overall Principal Investigator (UP): Ms**.** Aarti Kumar
Organisation: Community Empowerment Lab (CEL)
Name of Sponsor: Indian Council of Medical Research (ICMR)
Version Date: 18 December 2024

Part I: Invitation for Participation

Namaskar!

My name is _____, and under this study, I'm from (Hospital Name_____),

☐ GSVM Medical College, Kanpur

☐ Institute of Medical Sciences, Varanasi

☐ King George's Medical University, Lucknow

☐ Other Medical college/Hospital

and Community Empowerment Lab (CEL), Lucknow. We are collaborating with the government and medical and scientific communities to develop solutions that enhance the health of newborns. As part of this effort, we are conducting a research study in partnership with the ICMR and the National Health Mission, Uttar Pradesh (NHM-UP) in this district. The research aims to assess the impact of KMC on newborns with a normal birth weight i.e. 2500 grams or more. We will measure changes in the average weight loss during the first few days of life, the average weight gains in newborns during the first month of life, and improvements in infant feeding practices. 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 take part in 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 that. Please take your 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 it. 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 selected hospitals and Community Empowerment Lab.

What does this study include?

In this study we aim to generate evidence of whether KMC, when provided in the first few days of birth is beneficial even for normal birth weight infants. If found to be beneficial, this could go a further step in normalizing this life-saving practice for all newborn as standard of care within facilities and improving nutritional and growth outcomes in settings with poor early infant feeding practices.

What is the purpose of the study?

Kangaroo Mother Care started immediately after birth is already a strong recommendation for low birth weight infants, including those that are unstable, and contributes towards improved survival. However, high mortality

states like Uttar Pradesh also have poor nutritional outcomes amongst children. Even infants born with normal birth weight are at risk of growth faltering due to poor and sub optimal feeding practices. Based on our early work, we hypothesize that KMC (Kangaroo Mother Care) can play an important role in helping newborns adjust to the transition from the womb to the outside world and in supporting mothers to initiate breastfeeding. However, KMC is currently not recommended for normal birth weight infants.

We would like to study this topic because the development of babies born healthy with a normal birth weight may be significantly influenced by early nutrition, care, and Kangaroo Mother Care (skin-to-skin contact) during the first 48 to 72 hours. We hope to learn if this early days KMC practice facilitates the feeding & lactation support to mothers, improves their experience in terms of common mother-child micro-biome, baby's health, thermoregulatory activities of baby and the care hygiene that is given.

What is the procedure of the study?
In this study, 516 newborns with normal birth weight (2500 grams or more) will be enrolled. They will be randomly assigned to either an intervention group or a control group immediately after birth. Mothers and infants in the intervention group will receive education and counselling on prolonged skin-to-skin contact in the KMC (Kangaroo Mother Care) position, with a minimum of 8 hours per day during their stay at the facility and on-demand breastfeeding. Skin-to-skin contact can continue as long as the baby is comfortable, and both the baby and mother will be bare-chested in the KMC position. In the control group, mother-infant pairs will receive standard care, including general counselling on early and exclusive breastfeeding after birth. Each pair will have a unique identification number.

Why have I been chosen (Participation Criteria)?
We are inviting all mothers/surrogates of babies who delivered their babies in one of the selected facilities. We have invited you and your baby to take part in this research study because your baby was healthy and born with normal birth weight i.e. 2500 grams or more.

Do I have to take part (Voluntary Participation)?
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 the hospital and your medical care or rights will not be affected in any way. However, we may still use the information you already gave us. If you decide to leave the research, please contact the research staff. It is possible that the investigator may ask you to stop the study before it is finished. If this happens, we will tell you why and arrange for other care for baby if needed.

Confidentiality
The information that we collect from this research study will be kept confidential. Any information about you and your baby will have a number on it instead of your and your child's 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 learn from it. You will not be identified in any way in any of these.

Benefits for the participation or what will you get out of this study?
We cannot promise any benefits to you or others who are in this study. The implementation of this study might help to identify the best way of providing feeding support via implementing Kangaroo Mother Care practices for newborn, which will not only improve survival of these babies but also helps in thermoregulatory activities, weight gain, and empowering mother's confidence to take care of her baby. This study will strengthen the quality of routine care in the facility. Apart from the direct benefits, your contribution may also help researchers, health providers and policy makers to understand the impact of this new early KMC care and feeding practice initiated after birth when implemented in a routine care setting.

What is the "risk or discomfort" 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. There is a small chance of a breach of confidentiality - that your name and what you say could be shared with someone outside of the study. Only study investigators will know your and your baby's health information. We will provide appropriate referrals for conditions when you and/or your child may be at risk for physical or mental harm. This may include referral to health services to support your and/or your child's mental health.

It will not cost you anything to participate in this research. 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, 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:

Dr. Vishwajeet Kumar Founder, Community Empowerment Lab F-09, 9th floor, Tower-B, Shalimar Grand, 10, Jopling Road, Lucknow 226 001 Uttar Pradesh, Phone: +91-7217863617 Email: vkumar@celworld.org	**Ms. Aarti Kumar** CEO & Co-Founder Community Empowerment Lab F-09, 9th floor, Tower-B, Shalimar Grand, 10, Jopling Road, Lucknow 226 001 Uttar Pradesh, Phone: +91-8810723107 Email: aarti.kumar@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, 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

a) 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:

- Me and my child's participation in this study is completely voluntary.
- I am free to withdraw me and my child's participation at any time without giving any reason and without me 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/mmm/yyyy)

b) Witness to the Consent (if mother is illiterate):

[If the mother 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 mother of the child, who has had the opportunity to ask questions. I confirm that the mother has given his/her consent freely.

_____ _____ _____

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

c) 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)