Consent form for Mother/ Caregiver (Verbal Autopsy)

Part I: Participant Information Sheet

This informed consent form is for mothers/ caregivers of infants who died when they were less than 60 days old.

Study Title: Implementation research to develop and evaluate a mother-infant centred, pandemic-resilient, scalable model for improving the identification and management of possible serious bacterial infections in young infants in Uttar Pradesh, India
Principal Investigator: Ms. Aarti Kumar Dr. Vishwajeet Kumar
Organization: Community Empowerment Lab
Name of Sponsor: World Health Organization (WHO)
Version Date: August 08, 2022

Introduction
Namaskar! My name is_____, and I am from the Community Empowerment Lab (CEL). For the last 20 years, our team has been working with communities and the health system to improve the health and survival of mothers and babies.

I am extremely sorry that you have lost your precious baby. I understand how difficult it may be to cope with this tremendous loss, and that you may be in a state of shock and mourning at this time. My organization is committed to working with the government, health providers and the community to change this tragic outcome for infants in our state.

We are co-developing and implementing various innovations to improve the timely and appropriate care of infants and improve their survival. We are trying to study gaps in healthcare services that can inform the design of these innovations. We would also like to assess how these interventions are working and what we can do to further refine and improve them to benefit more infants.

We would like to invite you to participate in this study as it will help us understand the cause of your baby's death, and learn more about the gaps in services based on your experience of care. Your contribution may help us in understanding and developing innovations to prevent such deaths in the future.

This consent form may contain unfamiliar words or language. Please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can ask them of me or my team. You may also wish to talk to anyone who you feel comfortable with to share about this study and take your time to decide whether you want to participate in it or not.

Purpose of the study
The objective of the study is to identify the gaps, barriers in early identification of illnesses, care seeking practices and its management services at community and health facilities level and furthermore, to identify challenges posed due to the pandemic. We will develop and evaluate a model to improve early identification and management of illnesses and in particular, infections, in infants under 2 months of age. This model will be developed, implemented, and refined in one block of Kanpur Nagar district, with participation from mothers/ caregivers, health workers, health providers and other stakeholders.

Voluntary Participation
Your participation in this research is completely voluntary. It is your choice whether to participate or not. You have the right to withdraw your participation from this study at any time. Even if you do not agree to

participate or if you withdraw from the study you will still receive the same quality of medical care and services as you do now.

What if I agree to participate?
We have approached you as we have learnt about the unfortunate demise of your infant. This must be a most difficult time for you and your family, and we do not wish to disturb you in your time of grief. However, your participation in this study will help us to document the sequence of events, signs and symptoms, care-seeking and treatment that preceded this tragic event. The responses to these questions will be assessed by trained doctors to interpret the most likely cause of your child's death.

If you agree to participate, we will request you to sign this consent form to acknowledge that you have understood the purpose of this study and what it will involve, and agree to voluntarily participate in this study. I will share a copy of this consent form with you. If you feel uncomfortable or upset during the interview, you have right to withdraw participation at any time without giving a reason and that will not adversely affect you in any way.

I or one of my team members will administer a questionnaire to you called a verbal autopsy. During our interaction, we will sit with you in a comfortable place either at your home. We will ask you questions related to your child's illness, care-seeking and treatment, and any other details such as birth history that may help our team assign the most likely cause of death of your child. We might also abstract information from any medical records of your baby that you may have. We will also ask you some questions related to your experience of care and the challenges that you faced in getting timely care for your baby.

This interview will take around 90-120 minutes. You can also take as much time as you want and take breaks, if needed, to respond. If you do not wish to answer any of the questions during the interview, you may say so and the interviewer will move on to the next question. No one else but the interviewer will be present from our team. You may choose to be accompanied by any person or persons that you are comfortable with, during this interview.

Confidentiality
All the information shared by you will be kept strictly confidential and information only be used for study purposes. Your and your baby's personal information will never be made public. All the information gathered will be stored securely and anonymously on a digital platform. The doctors who review this information to assign a cause of death will be presented this information without your or your child's identifying information. Once a cause of death has been assigned, we can share this information with you if you wish. The causes of death of children in your community will be analyzed and shared openly. The results of the study will be shared with your community, and a wider audience through various means, including scientific articles, meetings and other forms of public communication.

Risks & discomforts
This is a very difficult time for you and your family, and the questions that I will ask may cause you pain and grief. We are very sensitive to your condition and I will do my best to make you and your family comfortable. You do not have to answer any questions that make you uncomfortable.

I also wish to inform you that my team and I will follow all essential COVID-19related protocols during our interactions. My team and I are also fully vaccinated, and all measures are being taken to protect you, your infant and family from any harm. You have every opportunity to withdraw from the study if you feel uncomfortable at any point**.**

Benefits/Incentives for my participation
There will be no incentives or any direct benefit to you from participation in this research. Your participation will help us assess and improve the system that has been put in place to prevent and treat infections in young infants, and will be used to help society in general.

Who to Contact:- This study has been reviewed by members of an ethical committee and approved by it. The task of this committee is to make sure that research participants are protected from harm. If you wish to find out more about any aspects of this or the study ethics, you can contact the following persons:

Ms. Aarti Kumar
CEO & Co-Founder
Community Empowerment Lab
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Shalimar Grand, 10, Jopling Road,
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Uttar Pradesh
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Mr. Vinay Pratap Singh
Director, Research Management
Community Empowerment Lab
Flat No. 202, Sai Samriddhi Apartment
Near Namak Factory Chauraha
Sector-M, Kakadev
Kanpur City 208025, Uttar Pradesh
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Email: vinaypratap.singh@celworld.org

This study has been reviewed and approved by the WHO Ethics Review Committee and Institutional Ethics Committees of the Community Empowerment Lab and GSVM Medical College, Kanpur Nagar. Being a participant in this study if you have any queries or concerns about your rights, you may contact CEL's ethics committee at the following address:

Institutional Ethics Committee
Community Empowerment Lab
F-09, 9th floor, F-Block, Tower-B, Shalimar Grand, 10, Jopling Road,
Lucknow-226001 Uttar Pradesh
Phone: 0522-4070395

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Part II: Certificate of Consent

A: Participant

I confirm that I have read/heard this consent form and understood the purpose, procedures, possible benefits and risks of this study. I was given an opportunity to ask questions and have received a satisfactory response to my questions, if any.

I understand that:

- My participation in this study is completely voluntary.
- I am free to withdraw my participation from this study at any time without giving any reason and without my rights being affected.
- I will be given a copy of this consent form for my own records.
- My participation in this study will be kept strictly confidential and anonymized data will be stored in a secure database.
- There is no financial incentive for participating in this study.

I voluntarily agree to participate in this study.

Yes ☐ **No** ☐

_____ _____

Name and Signature/Thumbprint of participant Date (dd/mmm/yyyy)

B: Witness to the Consent (if mother/caregiver is illiterate and is not able to sign her/his name): I have witnessed the accurate reading of the consent form to the participant, who has had the opportunity to ask questions and has received satisfactory responses. I confirm that the participant has voluntarily and freely given his/her consent or refused to participate, as indicated above.

_____ _____ _____

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

C: Research team member obtaining consent:

I have explained the purpose, procedures, possible benefits and risks of this study to the potential participant and given them the opportunity to ask questions. I confirm that the consent was given freely.

_____ _____ _____

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