

Consent form for healthcare workers/ providers (Observations)

Part I: Participant Information Sheet

This informed consent form is for observations of healthcare workers / providers.

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 of mothers and babies. In our state of Uttar Pradesh, children under 2 months of age often get very sick because of infections. The government has already put some programs, systems and processes in place to facilitate early identification, care-seeking and management of infections in these young infants. However, it does not always work as intended, and many infants are deprived of timely care. Together with mothers, health workers, nurses, doctors and government functionaries, we are trying to improve the current system to better support mothers and families in identifying illnesses in their young infants, and helping them get access to early and effective treatment to cure infections. We are doing this study to develop innovations to refine this system, assess how it is working, and continue to improve and refine it so that a high proportion of sick infants are able to receive timely, appropriate and complete care. We would like to invite you to participate in this study as you are caring for your baby and may be in a position to contribute to this study with your experiences.

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, that shall not adversely affect you in any way.

What if I agree to participate?

If you agree to participate, I 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. You can withdraw at any time without giving a reason and that will not adversely affect you in any way.

I would like to observe how you work and provide care, support, and/ or treatment to young infants or their mothers/ caregivers. During the observation, I will not disturb you or intervene in any situation or process, for e.g., identification of sickness, care seeking, management, referral, etc., unless you ask for any help or support. While observing, I will take detailed notes. If you specifically consent, I may also take some pictures or videos that are aligned to the goals of this study during the process of observation.

If you do not wish to have me observe any process, you may say so and I will stop immediately. It is also possible that you are ok with the observation, but do not wish to be photographed or videotaped. If this is the case, please let me know and I will not take any photographs or videos, and also permanently delete any photos or videos that I may have already taken. No one else will be present during this process, unless you would like someone else to be there.

This observation will take 3-4 hours or sometimes extended a day in different shifts if the process takes time. You will be given a copy of this consent form. You can withdraw your participation at any time without giving a reason, and it will not adversely affect you in any way.

Confidentiality

All the information shared by you and observed during the study will be kept strictly confidential, I and information only be used for the purpose of this study and improving care of young infants. My observation notes will not contain your name, but will record the observation in an anonymized way. Whatever I may have observed will never be shared to pinpoint or implicate you or impact your performance or employment in any way.

If you consent to have photographs or videos taken, then they will be stored securely on a computer with an anonymous identifier, and will only be accessed by members of the analysis team, who will review them to draw insights based on them related to aspects of infant care. Only if you give specific consent for your photographs or videos to be published as part of reports, scientific articles or educational material, will they be made more widely accessible to the larger public through these media. We will not use these photographs or videos for any purpose that you have not provided consent for.

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

It is possible that you may not be comfortable while being observed doing certain activities. We do not wish to put you in any discomfort. While I will try my best to be silent and not hinder or disturb you in any way in the normal course of your work, if you feel uncomfortable with my presence at any point in time, please do not hesitate to let me know, and I will stop the observation and leave the room immediately. If you have given your overall consent to be photographed or videotaped, but there is any photo(s) or video(s) that you would like me to delete, please let me know, and I will delete them permanently.

We will follow all essential COVID-19 related 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 direct benefit to you from participation in this research. If you would like, our team would be happy to help with care-seeking for your baby. Your participation will help us assess and improve the system that has been put in place to identify 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
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Community Empowerment Lab
F-09, 9th floor, F-Block, Tower-B,
Shalimar Grand, 10, Jopling Road,
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Mr. Vinay Pratap Singh
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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

☐

I voluntarily agree for the photographs and/or videos of me and my baby to be captured and used in the following ways:

For analysis purposes by the study team.

Yes

☐

No

☐

For publication in related scientific reports, articles or educational material that is in alignment with the purpose of this study.

Yes

☐

No

☐

Name and Signature of participant

Date (dd/mmm/yyyy)

B: 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/mm/yyyy)