Written Informed Consent Form for Screening of Sick Young Infants

This consent form will be administered to the parent/ accompanying guardian of a young infant (i.e. aged 0-59 days) presenting with signs of possible serious bacterial infection at the time of postnatal discharge/ OPD consultation or SNCU/ emergency admission. If the child is critically ill, the consent will be administered after providing immediate care.

Study Title: Optimizing place of treatment and antibiotic regimens for young infants presenting with signs of possible serious bacterial infection
Overall Principal Investigator (UP): Dr. Vishwajeet Kumar, Community Empowerment Lab (CEL) **Site Principal Investigator:** Prof (Dr) Yashwant Kumar Rao, Head of the Pediatrics Department, GSVM Medical College, Kanpur
Organization: GSVM Medical College, Kanpur
Version Date: 06 APRIL 2020

Part I: Invitation for Participation

Namaskar! My name is _____, and I represent the GSVM Medical College, Kanpur and Community Empowerment Lab (CEL), Lucknow. We are supporting the government and the medical and 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 Kanpur for young infants presenting with signs of possible serious bacterial infection (PSBI). I am working as a study team member associated with this research study.

Purpose of the Screening

We are currently doing research to find out if hospital-based care or outpatient treatment in the home is better for infants aged 0-59 days showing signs of infection. Infants will need to be screened to identify based on their present condition and certain criteria, they are eligible to participate in this research study.

Procedure

If you agree for your child to be screened, then we will ask you some questions about your child like their date of birth or current age, presenting complaints, and assess your child to see if they would be eligible to participate in this research. We will record this information and the assessment findings. While doing the assessment, we will also make a short video or a video call on a smart phone with our supervising clinicians to verify the assessment findings. Only my supervisor or study staff directly involved will see this video. If you do not want your child to participate in video call, please let us know.

If your child is eligible to participate in this research, then we will provide you complete information regarding the study, answer any questions you might have, and seek your consent. Based on our assessment, it is possible that your child may need immediate hospitalization. In this case, we will reassess your child after 2 days through observation and a routine blood test taking venous sample, to identify if they are still eligible to participate in this research.

In case your child is found to be not eligible to participate in any of the studies, treatment will be provided using the hospital standard of procedures and a different study staff will visit your child (either at home or in hospital) and confirm with you how the child is doing after 14 days.

Before you decide to participate in this screening, you can talk to anyone you feel comfortable with. Please ask us to stop as we go through the information and we will take time to explain. If you have questions later, you can ask them of the treating physician/nurse, the staff or me.

Voluntary Participation

Your participation in this screening and research is completely voluntary. You have the right to choose whether or not to allow your child to be screened. You can also withdraw your child from the screening and follow-up 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 pay any payment or penalty for not participating 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.

Confidentiality

Any information collected from this study will be used solely for this research study. Only authorized research staff members will have access to documents and data related to the research. If you consent for the video/ video call, it will be stored securely for quality purposes, and will never be shared with anyone other than the supervising clinician and the principal investigator/ co-principal investigator. We may publish a summary of findings from this research study but we will not publish any information that may identify you. All the information shared by you during this study will be kept strictly confidential and will be stored securely and anonymously on a digital platform.

Risks and Discomforts

There are no risks or discomfort involved in this screening – except for your time to answer some basic questions. We will ensure that if your child needs immediate care, it will be provided in a timely manner. As mentioned, all information, videos, etc., will be kept strictly confidential. However, if you face any problems or inconvenience due to the screening, please share them with us, and we will try our best to address them.

Benefits/ incentive for the participation

The screening may reveal an existing medical condition, which may benefit your child. You will not receive any payment or incentive for consenting to the screening.

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

Ethics Committee GSVM medical College,
Opp. CRS Complex, GSVM Medical College, Kanpur – 208002, Uttar Pradesh
Phone – +91-9454581649
Email id: ec.gsvmmedicalcollege@gmail.com

Part II: Certificate of Consent

A. Parent/ guardian of child:

I confirm that I have read/heard this consent form and understood the purpose, procedures, possible benefits and risks of the screening 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 child's participation in this study is completely voluntary.
- I am free to withdraw my child from being screened or followed-up at any time without giving any reason and without their medical care or rights being affected.
- I am aware that I will be given a copy of this consent form for my own records.
- 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 child's participation in this study

I voluntarily give permission to screen my child.

Yes ☐ No ☐

I also allow my child to be part of a video call for screening.

Yes ☐ No ☐

_____ _____

Name and Signature/Thumb impression of Parent of the Child Date (dd/mmm/yyyy)

B. Witness to the Consent (if parent is illiterate):

[If the mother/father 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 be screened.]

I have witnessed the accurate reading of the consent form to the mother/father 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)

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)