Breastfeeding Education Support Tool for Baby (BEST4Baby)

Consent for Peer Counselors

ClinicalTrials.gov Identifier: NCT03533725

Date: July 1, 2017

CONSENT FOR PEER COUNSELORS

Breastfeeding Education Support Tool for Baby Study

(BEST4Baby)

INVESTIGATORS: Dr. N S Mahantshetti, Principal Investigator

Dr. Shivaprasad S Goudar, Co-Investigator

Dr Roopa M Bellad,Co-Investigator

KLE University's Jawaharlal Nehru Medical College, Belgaum, Karnataka, India

Purpose of the Study

We (KLE University's J N Medical College Belgaum in collaboration with Thomas Jefferson University, USA) are conducting **"BEST4Baby"** a study to promote optimal infant feeding practices in Karnataka, India. In the Study, you are requested to participate in the breastfeeding training Programme, which will include multimedia content and use of mobile health (m-Health) technology which will aid you in educating and supporting mothers to increase their commitment to exclusively breastfeed their infants to six months and adopt other recommended breastfeeding practices.

Type of Study

This study will involve your participation in a training that will take about 1-2 days. You are requested to participate in the training in order to provide information and share your knowledge about local feeding practices; experiences and problems that women face during breast feeding.

Voluntary Participation

Your participation in this training Programme is entirely voluntary. It is your choice whether to participate or not. There will be no penalty or loss of benefits to which you are otherwise entitled and will not affect your position in anyway. You may change your mind later and stop participating anytime even if you agreed earlier or during the course of study. You can withdraw from study any time.

Potential Risks of Discomfort

There are no possible risks involved in the study. You may be trained with multimedia contents like paper forms and m-Health technology which may pose some discomfort. Photographs may be taken during this training; these will be used for scientific purposes only and will not contain any other personal information.

Benefits

There may be no direct benefit to you, but your participation is likely to help us find out more about how to improve the Infant feeding practices in your community.

Reimbursements

You will not receive any monetary reimbursements for participating in the study; your participation will be voluntary.

Confidentiality

Your confidentiality will be respected. No information that discloses your identity will be released. All the information taken through interviews with you will be kept safely and no person other than authorized local key investigators will be able to trace the information to your name or your address. The de-identified data will be shared to Women's and Children's Health Research Unit, KLE University's JNMC, BEST4Baby working group in Belagavi and Thomas Jefferson University's BEST4Baby working group in USA for further analysis and interpretation. However, data will not contain any personal identifiers.

Whom to contact with questions about the study

We have given you information about the study called "BEST4Baby Study" We have discussed the risks and benefits of the study and you understand that you do not have to agree to be in the study or may decide later not to be part of the study. This will not affect your or your baby's care in any way.

If you have any questions, please call:

Dr. N S Mahantshetti,

Dr. Shivaprasad S Goudar.

Dr. Roopa M Bellad

If you have questions about your rights as a study participant, please contact Dr Subarna Roy, Chairman, JNMC Institutional Ethics Committee on Human Subjects Research at +91 94490 33133.

I have read this consent form or it has been read to me in presence of a witness in my vernacular. I was given opportunity to ask questions and they were answered to my satisfaction. By signing this document I declare that I have consented to participate in this study.

_____

Signature or Thumbprint of Person Providing Consent Date

_____

Signature or Thumbprint of Witness Date

_____

Signature of Person Obtaining Consent Date

Person requesting consent, please check applicable boxes:

- ☐ Consent obtained (for adult respondent)
- ☐ Assent (for minor respondents)
- ☐ Consent from authorized person of minor respondent