Protocol Title: LIFE: Low-birthweight Infant Feeding Exploration
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Description of Study Population: Low birthweight infants and their mothers who live within the catchment area of the study health facility.
Version Date: June 26, 2019

Key Information

The following is a short summary of this study to help you decide whether or not to participate. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?

We have invited you to take part in a research study because your baby is low-birthweight and you live within the catchment area of this health facility.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You may discuss your decision with your family, your friends and/or your doctor.
- You can ask all the questions you want before you decide.

Why is this research being done?

We are doing this research to understand how healthcare workers provide care to low-birthweight babies in this health facility and to understand how moms feed their babies over time. We want to study this topic because babies who are born low-birthweight are at higher risk of illnesses, death and poor growth than normal-weight babies. There is not a lot of information about how to improve feeding for these babies, so we hope to learn more by doing this study.

How long will I take part in this research?

We will follow up with you and your baby over a six-month period. We will start by completing a baseline visit. During the first six weeks, we will ask you to make four study visits. Over the remaining 18 weeks we will ask that you make four additional visits. The first study visit could take up to 3 hours and all other study visits could take up to 2 hours. If your baby becomes sick and is

brought to the health facility during the six-month study period, we may ask you additional questions and take additional measurements of your baby during your baby's sick visit.

You will be asked to answer a series of questions about your baby's diet as well as about you and your baby's health. We will also measure your baby by taking his/her weight, height, length, head circumference and middle upper arm circumference at each study visit and we will measure you by taking your weight and height at the first visit, at six-weeks and at the last visit. We will ask you to write down any time your baby gets sick on an illness diary.

If you feed your baby during our study visit we will observe how your baby eats. If you miss a study visit, the study team may come to your home for the study visit, and while there, we may observe where food is prepared for the baby.

More detailed information about the study procedures can be found under the *"What can I expect if I take part in this research*?" section.

Is there any way being in this study could be bad for me?

The frequent study visits may be burdensome for you. There may be times when the questions, feeding observations or measurements make you or your baby feel uncomfortable. There is also a small risk that your name and what you say could be shared with someone outside of the study. More detailed information about the risks of this study can be found under the *"What are the risks and possible discomforts?"* section.

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits to others may include better care for low-birthweight babies because of this study.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You can decide to participate or not to participate. Your alternative to participating in this research study is to not participate.

Detailed Information

To follow, please find more detailed information about this study than already provided above.

About this consent form

Please read this form carefully. It provides important information about participating in research. You have the right to take your time in making decisions about participating in this research. If you have any questions about the research or any portion of this form, you can ask us at any time. If you decide to participate in this research you will be asked to sign this form. A copy of the signed form will be provided to you for your record.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at *[Site-specific contact information for the research team will be inserted here]*.

This research has been reviewed by the Harvard Longwood Medical Area Institutional Review Board (IRB). If you wish to speak with someone from the IRB, you may contact the Office of Human Research Administration (OHRA) at +1-617-432-2157 (or toll-free at +1-866-606-0573) or at irb@hsph.harvard.edu for any of the following:

- If your questions, concerns, or complaints are not being answered by the research team,
- If you cannot reach the research team,
- If you want to talk to someone besides the research team,
- If you have questions about your rights as a research participant, or
- If you want to get information or provide input about this research.

Participation is voluntary

You are invited to take part in this research because your baby is low-birthweight and you live within the catchment area of this health facility. It is your choice whether or not to participate. If you choose to participate, you may change your mind and leave the study at any time. Refusal to participate or stopping your participation will involve no penalty or loss of benefits to which you are otherwise entitled.

How many people will take part in this research?

About 850 mothers and babies per sites, and a total of about 3400 mother and babies across all study sites, will take part in this research.

What can I expect if I take part in this research?

As a participant, you will be expected to complete the following:

We will follow up with you and your baby over a six-month period. We will start by completing a baseline visit. During the next six weeks, we will ask you to make four study visits. Over the remaining 18 weeks we will ask that you make four additional visits. You will be asked to return to the clinic with your baby for each follow up visit. Efforts will be made to schedule the clinic visits to coincide with your regularly scheduled standard of care visits. When this is not possible, you can choose either home visits or to come in for a clinic study visit. If you miss a facility visit, then study staff will make a home visit.

If your baby becomes sick and is brought to the health facility during the six-month study period, we will ask you questions about your baby's illness during your baby's sick visit at the health facility. We will check to see if you are comfortable before proceeding to collect study data during your baby's sick visit.

The first study visit could take up to three hours. All other study visits could take up to two hours.

During the study visits, you will be asked to answer a series of questions about your baby's diet as well as about you and your baby's health. We will also measure your baby by taking his/her weight, height, length, head circumference and middle upper arm circumference at each study visit. We will measure you by taking your weight and height at the first visit, and your weight again at six-weeks and at the last visit.

Starting at the week 6 follow-up visit, we will ask you to write down any time your baby gets sick on an illness diary at home. If your baby does not have an illness you do not need to fill anything out. The diaries will be given out at the week 6 follow-up visit. The purpose of the diaries is for you to record daily details on specific illnesses experienced by your baby (diarrhea, vomiting, fever and respiratory infections) in between monthly study visits. You will be asked to tick the corresponding box when your baby has the corresponding symptoms. At subsequent monthly follow-up visits, you will bring the completed diaries to the study team and will be given a fresh set of blank illness diaries for the next month.

If you feed your baby during our study visit we may observe how your baby eats. If you miss a study visit, the study team may come to your home for the study visit, and while there, we may observe where food is prepared for the baby.

In addition to speaking with you and observing the baby's feeding, we will record information from the mother's medical chart about her health, including her HIV status if known, that is relevant for the care and feeding of the baby

What are the risks and possible discomforts?

The frequent study visits may be burdensome for you and clinic attendance may be costly from both a monetary and time perspective. There may be times when the questions, feeding observations or measurements make you or your baby feel uncomfortable. There is also a small risk that your name and what you say could be shared with someone outside of the study. If you do not feel comfortable being observed while feeding your baby, please tell a member of the study team. You can stop your participation at any time. If you choose to not participate, your clinical care will not be affected.

Are there any benefits from being in this research study?

There are no direct benefits to you from your taking part in this research.

What happens if I say yes, but I change my mind later?

You can leave the research at any time it will not be held against you. If you stop being in the research, already collected data may not be removed from the study database.

Can I still get medical care at [local facility name] if I choose not to participate in this research*?*
Yes, you may still get medical care at *[local facility name(s)]* if you choose not to participate in this study. Your decision will not change the care you receive now or in the future. Taking part in this research is your choice. If you decide to take part in this study, you may leave/stop the study at any time. There will be no penalty to you and your medical care will not be affected. If you would like to stop participating in this research you should let us know. We will make sure that you stop the study safely.

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 you if needed.

Will I be compensated for participating in this research?

Study Site	Incentive
Karnataka and Odisha	We will give you loss of wages, travel allowance and dearness allowance (DA) at the end of each completed study visit up to US $4.00, if you come to the study hospital for a follow up visit
Lilongwe	We will give you the Malawi Kwacha equivalent to $10 at the end of each completed study visit. This amount is to cover the costs of your transport expenses to and from the research clinic.
Dar es Salaam	We will give you travel allowances at the end of each completed study visit up to 10,000 TZS.

What will I have to pay for if I participate in this research?
It will not cost you anything to participate in this research.

If I take part in this research, how will my privacy be protected? What happens to the information you collect?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of these organizations involved in this research, such as Jawaharlal Nehru Medical College (India), Muhimbili University of Health and Allied Sciences (Tanzania), UNCH Project Malawi (Malawi), University of North Carolina (USA), Harvard University (USA), Emory University (USA), Brigham and Women's Hospital (USA), Boston Children's Hospital (USA), PATH (USA), Bill and Melinda Gates Foundation (USA).

If identifiers are removed from your identifiable private information that are collected during this research, that information could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

A description of this study will be available on http://www.ClinicalTrials.gov. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

What else do I need to know?

This research is being funded by the Bill and Melinda Gates Foundation.

Statement of Consent
I have read the information in this consent form including risks and possible benefits. All my questions about the research have been answered to my satisfaction. I understand that I am free to withdraw at any time without penalty or loss of benefits to which I am otherwise entitled.

I consent to participate in the study.

SIGNATURE

Part I: Your signature below indicates your permission for you and your baby(ies) to take part in this research

Name of participant

Signature / thumb impression of participant | Date

Part II: Signature of Person Obtaining Consent

Signature of person obtaining consent | Date

Printed name of person obtaining consent

If the participant is unable to read or write:

Name of impartial witness	Date
Signature of impartial witness	Date