Lactoferrin and lysozyme supplementation for long-term diarrhea sequelae

The Lactolyze Trial

NCT05519254

A collaboration between the:
Kenya Medical Research Institute (KEMRI) &
University of Washington (UW)

Informed Consent Forms
Approved date: July 21, 2022

Kenya Medical Research Institute (KEMRI) & University of Washington (UW)

Lactoferrin and lysozyme supplementation for long-term diarrhea sequelae

Child and Caregiver Screening Consent

Emergency telephone number staffed 24 hours a day: Dr. Benson Singa 0725234844

Researcher's statement: We are conducting a research study called "Lactoferrin and lysozyme supplementation for long-term diarrhea sequelae". We would like to tell you about this study to see if you might be interested in having your child screened to see if she/he is eligible to participate.

Purpose of the study: Diarrhea is a leading cause of death among children under the age of five in sub-Saharan Africa. The purpose of this study is to determine whether the addition of specific products called Lactoferrin and Lysozyme, to the standard of care for diarrhea treatment (a process called "supplementation") will help reduce the number of new cases of diarrhea and improve the nutritional recovery of children aged 6-24 months returning home from the hospital after seeking care for diarrhea.

Eligibility: For us to know if your child can be included in this study, we will need to undergo a process called "screening" where we will collect information about your child and you by checking your child's hospital records and asking you questions about the child's medical history, measuring your child's arm to determine their nutritional status, and by asking you about your relationship to the child. The screening is only to help us determine the children who are eligible and is not giving permission for them to participate in the study. If your child is found to be eligible, we will give you more information about the study for you to decide if you want your child to participate or not.

Voluntary participation: Your participation in this screening process is voluntary. You may choose not to participate, without any penalty. By signing this consent form, you are permitting us to collect this information. Signing this consent form does not commit your child to participate in the study, neither does it guarantee that your child will participate.

Subject's statement:

I, being the guardian/parent of _____ (Name of child) have understood all that has been read and my questions have been answered satisfactorily. I therefore, give my permission to the researchers to review my child's medical records and ask me any questions to screen for eligibility of my child for the study.

SIGNATURE OF LEGALLY AUTHROIZED REPRESENTATIVE (PARENT/GUARDIAN)	
_____ Parent/Guardian Printed Name:	_____ Date (DD-MMM-YYYY)
_____ Parent/Guardian Signature	_____ Time (24:00)
OR THUMBPRINT IF PARENT/GUARDIAN CANNOT WRITE	

KEMRI / SERU APPROVED 18 AUG 2021 P.O. Box 54840-00200, NAIROBI.

SIGNATURE OF WITNESS: (if Parent/Guardian cannot read or write)
This individual can be a relative of the participant but should be independent from study staff.

I attest the information in this form was accurately explained to, and apparently understood by, the Parent/Guardian, and that informed consent was freely given by the Parent/Guardian

Witness Printed Name:	Date (DD-MMM-YYYY)
Witness Signature	Time (24:00)

SIGNATURE OF STUDY STAFF (*can only be signed by an investigator or staff approved to administer consent)*

I have followed the study protocol to obtain consent from the parent/guardian. He/she apparently understood the nature and the purpose of the study and consents to her child's participation in the study. He/she has been given opportunity to ask questions which have been answered satisfactorily.

Study Staff Printed Name	Study Staff Signature	Date (DD-MM-YYYY)

Please provide a copy to the Participant's accompanying caregiver, and place a copy of the consent form in the Participant's folder.

Lactoferrin and Lysozyme Supplementation for Long-term Diarrhea Sequelae

Child and Caregiver Consent (English)

Investigator	Title	Institution	Telephone Contact
Benson Singa	MBChB, MPH	Kenya Medical Research Institute/ University of Washington	07 25 234 844
Patricia Pavlinac	PhD, MPH	Kenya Medical Research Institute/ University of Washington	+1-619-992-6059

Emergency telephone number staffed 24 hours a day: Dr. Benson Singa 0725234844
Study location: Homa Bay, Kisii and Migori Counties

You are being asked to take part in a research study. The box below tells you important things you should think about before deciding to join the study. We will provide more detailed information below the box. Please ask questions about any of the information before you decide whether to participate. You may also wish to talk to others (for example, your family, friends, or your doctor) about this study, before agreeing to join.

Key Information for You to Consider

- **Voluntary Consent.** You are being asked to volunteer for a research study. It is up to you whether you choose to participate or not. There are no penalties, and you will not lose anything if you decide not to join or if after you join, you decide to quit.
- **Purpose.** We are doing this study to see whether addition of nutritional supplements called Lactoferrin and Lysozyme to the treatment plan for children with diarrhea will help reduce the number of new cases of diarrhea and to improve nutritional recovery of children aged 6-24 months returning home from the hospital after seeking care for diarrhea.
- **Duration.** Your part of the study will last for 6 months.
- **Procedures and Activities.** We will ask that you and your child return to this hospital at 4, 10,16, and 24 weeks after today to examine your child and record his/her size of the upper arm, weight and height and ask about any changes in the child's health since we saw you last.
- Study community health workers (CHWs) will also visit your home for the next 2 days (following enrollment), as well as week 2, 6, 8, 12, 14, 18, 20, and 22 to collect health information including any episodes of diarrhea.
- We will collect stool sample, a sample from inside your child's anus and blood sample today and during the 4 study clinic follow-up visits. Urine will be collected from a small number of children during the 4 study follow-up visits to test for amount of sugar that is passed in urine. A very small amount of blood will also be collected today as well as week 4,10, 16, 24.
- **Risks.** We may collect sensitive information to talk about and the sample collection procedure on the child may cause discomfort/pain or very rarely an infection at the blood draw site. One of the investigational products is made from cow milk, which some children are allergic to. If your child is allergic to dairy, they may show signs of allergy.
- **Benefits.** By participating in this study, your child may benefit from the examination and treatment he/she obtains, free of charge, as part of the study.
- **Alternatives.** Participation is voluntary. Alternatives to study participation include continuing your usual care and treatment available through this or other health facilities.

Purpose of the Research:
More than half a million children die each year from diarrhea. Current diarrhea treatment strategies include giving drugs known as oral rehydration solution [ORS] and zinc. New treatments for young children recovering from diarrhea are needed. Nutritional products called Lactoferrin and Lysozyme have been shown to improve children's intestinal health, a key determinant of diarrhea outcomes. These products are sometimes used in baby formula. The purpose of this study is to determine whether the addition of nutritional products (Lactoferrin and Lysozyme) to the standard of care for diarrhea treatment (a process called "supplementation") will help reduce the number of new cases of diarrhea and improve the recovery of children aged 6-24 months returning home from the hospital after seeking care for diarrhea.

1. Description of the Research:
Should you agree to participate, we will ask you to remain here in the hospital for approximately 1 - 2 hours. During this time, we will review your child's medical records to better understand your child's medical history, as well as previous inclusion in any nutrition program. We plan to enroll 600 children in this study.

We will also briefly examine your child to assess their general health and obtain height, weight, and size of the upper arm from you and your child to assess your health status. We will ask you questions about your child's medical history as well as questions related to you and your household. Some of the questions may be personal. For example, we will

ask you where you and your child live, what kind of toilets are used in your household, how much money the household makes. You have the right to refuse any question that you feel uncomfortable answering.

Your child will be assigned to one of the four study groups: 1) Lactoferrin Arm [Lactoferrin + pure rice powder], 2) Lysozyme Arm [Lysozyme + pure rice powder], 3) Combination Arm [Lactoferrin + Lysozyme + pure rice powder], 4) Placebo arm [pure rice powder]. A "placebo" is inactive product (does not contain the two milk products) that will consist of pure rice powder used to compare the effect of the two milk products. Your child will be placed into one of these groups randomly, like the flip of a coin. Neither you nor the study staff can choose which group to be in.

We will help you administer the study product to your child today and ask you to continue administering it daily to this child for the next 16 weeks. We will ask you to mix the study product with half a small cup (125 ml) of your child's morning porridge. We will also provide porridge flour to prepare the porridge which you will mix with the IP for the next 16 weeks. It is very important your child receives the entire product for the full 16 weeks and you do not give it to other members of your household, including other children. At your follow up visits, we will ask you to bring the study product's sachets with you so we can measure how much of the supplement your child received.

We will collect whole stool from your child and swab the inside of your child's anus to obtain stool specimens. If your child is unable to produce whole stool within 1 hour of the study visit, we will provide you with a stool sample container and you will be asked to obtain a stool sample from your child upon your return home. The study staff will then visit your home to collect the sample. The stool samples will be tested for infections and for signs of swelling in the intestines. A very small amount of blood (approximately ½ to 1 teaspoon [3-5mL]) will be collected from your child today and at the four follow-up visits. The amount of blood we collect will be determined by the international standards for safe blood collection. The blood will be used to measure the amount of iron in your child's body to help us better understand their health status.

Your child may also be selected to be in a small study to help assess the amount of sugar that passes through urine. We will randomly select, like a flip of a coin, 1 out of 3 children in each of the four study groups to participate in this smaller study at each of the four follow-up visits. To perform the sugar test, the child will be required not to take food, drink or breast milk for 1 hour after which he/she will be given a sugar-water solution. Using a small plastic bag attached to your child's nappy area, we will collect the child's urine at the beginning of the fasting period and then over the next 2 hours after the child is fed sugar-water solution. Participation in this small study (if selected) will take approximately 2-3 hours.

Follow up procedures:
Clinic visits: It is important to us to determine how your child is doing in months after enrolment in the study. To do so, we will ask that you and your child return to this hospital at 4, 10, 16, and 24 weeks after today. Our study staff will schedule these visits with you. During the 4 study visits, you may be required to stay in the facility for 1 - 3 hours. The study staff will perform a brief physical examination, take measurements for growth assessment and ask about your child's health. We will also obtain a stool/swab taken from inside your child's anus, and small blood sample as was done at the enrolment visit. The cost of transportation to these visits will be covered by the study.

Home visits: In addition to the clinic visits, study community health workers (CHWs) will visit your home for the next 2 days (following enrolment), as well as week 2, 6, 8, 12, 14, 18, 20, and 22 to collect basic health information and your reflections on administering the study product.

Sick visits: If your child falls sick during the study period, we ask that you bring him/her back to the study hospital. Study clinician will examine the child and treat any illness as per standard of care. The cost of treatment will not be covered by the study

2. Human genome sequencing
We will extract genetic material from the stool samples to help describe in detail the characteristics of germs causing disease. However, no human genome sequencing will be done in this study.

3. Storage of specimen, specimen data, exportation of samples and further studies:
The specimens and data from those specimens that obtained from your child for this study might be stored and used for future studies. We may remove anything that might identify your child from the specimens. If we do so, the specimens may be used for future research studies without getting additional permission from you. After the follow up period for this study has ended, we may be interested in contacting you to ask whether you would like to participate in other studies we conduct in the future. We will only do this if you give us permission and you will be able to choose whether or not you would like to participate at that time.

4. Return of Results
Blood sample test may yield clinically relevant results for some children in the study and may identify children who require urgent blood transfusion, or those who need iron supplementation. If children are identified to have abnormal

concentration of blood cells, their results will be discussed with the study clinician and management will be determined accordingly. Any children found to have moderate or severe anemia (as a result of the study's testing procedures) will be contacted and informed of their result and caregivers will be informed to return to the clinic for standard of care treatment. However, we will make the results available to your clinical provider and this health facility. Stool pathogen results will not be shared because they will not be available until the end of the study, which will no longer have relevant implications for your child's clinical management.

5. Potential Harm, Injuries, Discomforts or Inconvenience, and Risks:
The study may collect personal information that may be sensitive to discuss. The swabbing of the inside of the anus can be uncomfortable to your child. Your child might feel pain and/or get a bruise where the needle enters the vein and there is also a small chance of infection occurring at the site where we collect your child's blood. The study staff will take every precaution to prevent any infections and discomfort to your child.

Your child may experience a possible allergic reaction to the investigational product, which may include diarrhea, vomiting, skin rash, lip swelling, difficulty breathing/wheeze, seizure, or need for future hospitalization. It is possible that you and your child may not receive any direct benefit from participating in this study, either because the intervention does not have a beneficial effect or because your child was assigned to the placebo group. The study product is a well-tolerated supplement and safe to be consumed by children. One of the investigational products is made from cows milk. If your child is allergic to dairy, they may show signs of allergy.

6. Potential Benefits:
Your child may benefit from the examination and treatment he/she obtains, free of charge, as part of the study. All participants will benefit from free clinical and laboratory monitoring, both of which can improve the medical providers' ability to make important decisions about your child's care.

7. Alternative Procedures or Treatments:
Participation is voluntary. Alternatives to study participation include continuing your usual care and treatment available through this or other health facilities.

8. Confidentiality:
All information about you and your child is confidential and will be stored in a locked office accessible only to authorized research team. Documents containing you and your child's name and contact information will be destroyed three years after completion of the study. Information about your child's health status and participation in the research will be available to you, the study team, and safety monitors from the UW, KEMRI, and the Kenya Ministry of Health. Data and samples collected in this study will be labeled with a special number code, and not you or your child's name. Only the study staff involved in management and follow-up of your child will have access to your child's name. Although we will make every effort to keep your and your child's information confidential, no system for protecting confidentiality and privacy can be completely secure and it is possible unauthorized persons might discover that you and your child are participating in this study or might obtain information about you and your child. University and government offices sometimes review studies like this one to make sure they are being done safely and legally. If a review of this study takes place, you and your child's records may be examined. The reviewers will protect your privacy and the study records will not be used to put you or your child at legal risk of harm. A description of this clinical trial will be available on http://www.clinicaltrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

9. Reimbursement:
If you agree to your child's participation, the study will reimburse you Ksh. 250.00 for your transport from the facility. For each scheduled follow-up visit you attend, you will be reimbursed Ksh. 500.00 for your transportation cost to and from the facility. Additionally, you will be provided with Ksh. 100.00 upon returning the study product satchets during each scheduled visit. If you are selected to participate in the sub-study, you will receive additional Ksh. 300.00 for your time and effort. If you bring the child back to the study hospital for an unscheduled sick visit, you will be reimbursed Ksh. 300.00.

10. Participation:
Participation in this study is voluntary, therefore, you can decide to join, not to join or after joining, you can withdraw your child's participation at any time. You will be given a copy of the signed and dated consent form to keep for your records. You do not give up any legal rights by signing this consent form. If any changes are made to the study or new information becomes available, you will be informed by the study team appropriately.

Research-Related Injury: If you think you or your child have an injury related to this study, contact Dr Benson Singa at 0725234844. If your child is injured as a result of being in the study, we will offer care at the study hospital or refer them to a different hospital if the child requires medical care the study hospital cannot provide.

Early Termination and Withdrawal. You are free to withdraw from this study at any time without penalty or loss of benefits to which you are otherwise entitled. Your child may also be withdrawn from the study if you are unable to administer the study product; you and your child are unable to return to the study hospital for follow up visits and cannot be traced at your residence with the locator information you provided at enrolment; and for other reasons beyond our control.

11. Sponsorship:
The principal investigator and sponsor retain the right to terminate the study in the event of loss of approval from overseeing agencies, funding being withdrawn, when adequate sample size is reached, or if there are clear benefits or adverse effects associated with the study. In the event of early termination of the study, you will be informed appropriately and all pending follow-ups will be completed for safety reasons.

12. Source of funding:
This study is funded by the National Institutes of Health in the United States.

13. Contact:
If you have any question or concern about the study, or if you think your child has a problem arising from participating in the study, please inform the Study Coordinator or contact any of the numbers provided on your study appointment card. If you have questions pertaining to your rights as a research participant, please contact the Committee Chairperson, KEMRI Scientific and Ethics Review Unit, P.O. BOX 54840-00200, Nairobi; Telephone numbers: 020-2722541, 0717719477; Email address: seru@kemri.org

14. Consent and signature options:
This study has been explained to me in detail and I have had a chance to ask questions and I have received satisfactory answers. I therefore volunteer to take part in this study with my child if we are deemed eligible to participate. I understand that if I have any other questions later about the research, I can ask one of the researchers listed above or if I have questions about our rights as a research subject, I can call the Ethical Review Committee at **Kenya Medical Research Institute**, at 020-2722541 or 0722205901 or 0733400003, P. O. Box 54840-00200, Nairobi. I give permission to the researchers in this study to use my child's medical records and laboratory specimens as described in this consent form. I also understand that I will receive a copy of this consent form for my records.

I, being the guardian/parent of_____ (Name of child) have understood all that has been read and my questions have been answered satisfactorily.

Please initial next to the statement you are agreeing to:

I agree for my child to participate in this research study.....	___ Yes	___ No
I agree for my child to be followed up by home visits	___ Yes	___ No
I agree for my child to participate in the Dual Sugar Permeability Test sub-study if selected	___ Yes	___ No
I agree to have my child's coded information and samples stored for future use in research	___ Yes	___ No
I agree to have my child's coded samples sent to the United States or any other offshore country for further testing	___ Yes	___ No
I agree to be contacted again in the future to request my child's participation in potential future research	___ Yes	___ No
I wish to be notified by investigators in the event of research findings of possible importance to my family members or myself.....	___ Yes	___ No

SIGNATURE OF LEGALLY AUTHROIZED REPRESENTATIVE (PARENT/GUARDIAN)

_____ Parent/Guardian Printed Name:

_____ Date (DD-MMM-YYYY)

_____ Parent/Guardian Signature

_____ Time (24:00)

OR. **THUMBPRINT IF PARENT/GUARDIAN CANNOT WRITE**	

SIGNATURE OF WITNESS: (if Parent/Guardian cannot read or write)
This individual can be a relative of the participant but should be independent from study staff.

I attest the information in this form was accurately explained to, and apparently understood by, the Parent/Guardian, and that informed consent was freely given by the Parent/Guardian

Witness Printed Name:	Date (DD-MMM-YYYY)
Witness Signature	Time (24:00)

SIGNATURE OF STUDY STAFF
Can only be signed by an investigator or staff approved to administer consent.

I have followed the study protocol to obtain consent from the parent/guardian. He/she apparently understood the nature and the purpose of the study and consents to her child's participation in the study. He/she has been given opportunity to ask questions which have been answered satisfactorily.

Study Staff Printed Name	Study Staff Signature	Date (DD-MMM-YYYY)

Please provide copies to the Participant's accompanying caregiver, and place a copy of the consent form in the Participant's study folder.

Lactoferrin and Lysozyme Supplementation for Long-term Diarrhea Sequelae

Focus Group Discussion Consent Form – Healthcare Workers (English)

Local and International Investigators

Investigator	Title	Institution	Telephone Contact
Benson Singa	MBChB, MPH	Kenya Medical Research Institute	0725234844
Patricia Pavlinac	PhD, MPH	University of Washington	+1-619-992-6059

Study Location: The Kenya Medical Research Institute and the University of Washington have partnered to carry out this study in Homa Bay, Kisii and Migori Counties.

You are being asked to take part in a research study. The box below tells you important things you should think about before deciding to join the study. We will provide more detailed information below the box. Please ask questions about any of the information before you decide whether to participate. You may also wish to talk to others (for example, your family, friends, or your doctor) about this study before agreeing to join.

Key Information for You to Consider

- **Voluntary Consent:** You are being asked to volunteer for a research study. It is up to you whether you choose to participate or not. There are no penalties and you will not lose anything if you decide not to joint or if after you join, you decide to quit.
- **Purpose:** We are doing this study to see whether addition of nutritional supplements called Lactoferrin and Lysozyme to the treatment plan for children with diarrhea will help reduce the number of new cases of diarrhea and to improve nutritional recovery of children aged 6 - 24 months returning home from the hospital after seeking care for diarrhea. Additionally, we are conducting focus group discussions (FGDs) with health care workers to determine the acceptability of the Lactoferrin and Lysozyme supplements and administration methods.
- **Duration:** We are inviting you to participate in a focus group discussion (FGD) lasting approximately 2 hours.
- **Procedures and Activities:** You will be asked to join a focus group discussion (FGD) consisting of 6 - 8 health care workers and answer questions asked by a researcher about methods of delivering the study products and factors that facilitate or complicate the administration of the study products. We will not ask you about any personal information regarding your health or your family's health.
- **Risks:** We do not anticipate any significant level of risk/stress or discomfort for participation in this study; however, there may be some personal discomfort associated with responding to the questions. While we ask participants to respect the privacy of the focus group and all discussion, there is the possible loss of confidentiality during your participation.
- **Benefits:** Your feedback will help us understand how to improve the delivery of treatment for better childhood diarrhea outcomes in Kenya and other countries where diarrhea associated death is high.
- **Alternatives.** Participation is voluntary. Alternatives to study participation include continuing your usual work in this hospital.

1. Purpose of the Research:

The purpose of this study is to determine whether the addition of Lactoferrin and Lysozyme to the standard of care for diarrhea management will help reduce the number of new cases of diarrhea and improve the health recovery of children aged 6-24 months returning home from the hospital after seeking care for diarrhea. Additionally, we are conducting focus group discussions (FGD) with health care workers to determine the acceptability of the study products and administration methods.

2. Description of the Research:

We are inviting you to participate in focus group discussions (FGD) consisting of 6-8 people per group, lasting approximately 2 hours. We will ask you questions about methods of delivering the study products and factors that facilitate or complicate the administration of the study products. We will not ask you about

any personal information regarding your health or your family's health. The discussion will be audio recorded and the words will be transcribed by study staff. The audio recording will not be shared, and your name will not be associated with the transcription.

3. Potential Harm, Injuries, Discomforts or Inconvenience, Risks:
We do not anticipate any significant level of risk/stress or discomfort for participation in this study, however, sometimes you may feel uncomfortable discussing some personal things. All interviews will be confidential and all names or identifying information will be removed from transcripts to protect the identity of the participants. While we ask participants to respect the privacy of the focus group discussion, there is the possibility for breach of confidentiality during your participation.

4. Potential Benefits:
You will not directly benefit from participating in the focus group discussion. However, your feedback will help us understand how to improve the delivery of treatment for better childhood diarrhea outcomes in Kenya and other countries where diarrhea associated death is high.

5. Alternative Procedures or Treatments:
Participation is voluntary. Alternatives to study participation include continuing your usual work in this hospital.

6. Confidentiality:
The following protections against risk will protect the privacy of participants and maintain confidentiality of research data: (1) All study staff will be well trained and will receive ongoing supervision in confidentiality and data security procedures, specifically in ethical conduct, confidentiality protection, mandated reporting, and other topics of human participant protection. (2) As part of the informed consent procedure, focus group discussions (FGD) participants will be informed of the limits of confidentiality (harm to self or others) and mandated reporting requirements. (3) Privacy will be maintained by conducting all focus group discussions (FGD) in closed and private rooms in each facility, or in research team offices. (4) Data (including audio-recordings, and qualitative transcripts from focus group discussions (FGD)) will be securely stored in separate locked file cabinets in locked offices and in password-protected documents on password-protected computers and secure servers. Access to data storage areas and computers will be restricted. (5) The study link log will be stored on a secure server, accessible only through password-protected computers with encryption, in a password protected electronic file. (6) Analysis will occur only on de-identified data. (7) Audio recordings and qualitative transcripts from focus group discussions (FGD) will be destroyed three years after study completion. (8) The information gathered will be used only for scientific, educational, or instructional purposes. A description of this clinical trial will be available on http://www.clinicaltrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

7. Reimbursement:
The study will compensate you Ksh. 600.00 for your time and effort.

8. Participation:
Participation in this study is voluntary therefore, you can decide to join, not to join or after joining, you can withdraw your participation at any time.

Research-related Injury: It is unlikely that you will be injured as a result of participating in the focus group discussion (FGD).

You will be given a copy of the signed and dated consent form to keep for your records. You do not give up any legal rights by signing this consent form.

9. Future Data Use:
The information that we collect from you for this study might be used for future studies. We may remove anything that might identify you from the information. If we do so, that information may then be used for future research studies or shared with another investigator without getting additional permission from you.

10. Sponsorship:
Early termination of this study by the sponsor will not affect you given that your participation in the focus group discussion only takes place once.

11. Sources of Funding:
The study is funded by the National Institutes of Health (NIH) in the United States.

12. Contact Information
If you ever have any questions or feel you have been harmed by the study, you should contact Dr. Benson Singa at 0725234844. For any questions pertaining to your rights as a research participant, the contact person is: The Committee Chairperson, KEMRI Scientific and Ethics Review Unit, P. O. Box 54840-00200, Nairobi; Telephone numbers: 020-2722541, 0717719477; Email address: seru@kemri.org

13. Consent and Signature Options:
This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have questions later about the research, I can ask one of the researchers listed above. If I have questions about my rights as a research participant, I can call the Ethics and Research Committee at Kenya Medical Research Institute (KEMRI) 020-2722541, 0717719477. I will receive a copy of this consent form.

Please initial the sentences that reflect your choices, and then sign below:

_____ I agree for my de-identified information to be used for future research or shared with other researchers without my additional consent.

_____ I do not agree for my information to be used for future research or shared with other researchers.

_____ I authorize the storage of data collected as a part of this study for use in future research studies.

_____ I do not authorize the storage of data collected as a part of this study for use in future research studies.

_____ I authorize the audio recording of the discussion.

_____ I do not authorize the audio recording of the discussion. *(ineligible, stop consenting process)*

SIGNATURE OF PARTICIPANT

Participant Printed Name:	Date (DD-MMM-YYYY)
Participant Signature	Time (24:00)

SIGNATURE OF STUDY STAFF (*can only be signed by an investigator or staff approved to administer consent)*

I have followed the study protocol to obtain consent from the Participant. He/she apparently understood the nature and the purpose of the study and consents to participation. He/she has been given opportunity to ask questions which have been answered satisfactorily.

Study Staff Printed Name	Study Staff Signature	Date (DD-MMM-YYYY)

Please retain a copy of this form for the study's records and provide a copy to the Participant.

Lactoferrin and Lysozyme Supplementation for Long-term Diarrhea Sequelae

Focus Group Discussion Consent Form – Caregivers (English)

Local and International Investigators

Investigator	Title	Institution	Telephone Contact
Benson Singa	MBChB, MPH	Kenya Medical Research Institute	0725234844
Patricia Pavlinac	PhD, MPH	University of Washington	+1-619-992-6059

Study Location: The Kenya Medical Research Institute and the University of Washington have partnered to carry out this study in Homa Bay, Kisii and Migori Counties.

You are being asked to take part in a research study. The box below tells you important things you should think about before deciding to join the study. We will provide more detailed information below the box. Please ask questions about any of the information before you decide whether to participate. You may also wish to talk to others (for example, your family, friends, or your doctor) about this study before agreeing to join.

Key Information for You to Consider

- **Voluntary Consent:** You are being asked to volunteer for a research study. It is up to you whether you choose to participate or not. There are no penalties and you will not lose anything if you decide not to joint or if after you join, you decide to quit.
- **Purpose:** We are doing this study to see whether addition of milk products called Lactoferrin and Lysozyme to the treatment plan for children with diarrhea will help reduce the number of new cases of diarrhea and to improve nutritional recovery of children aged 6 - 24 months returning home from the hospital after seeking care for diarrhea. Additionally, we are conducting focus group discussions (FGDs) with caregivers to determine the acceptability of the Lactoferrin and Lysozyme supplements and administration methods.
- **Duration:** We are inviting you to participate in a focus group discussions (FGD) lasting approximately 2 hours.
- **Procedures and Activities:** You will be asked to join a focus group discussions (FGD) consisting of 6 - 8 caregivers of participants in the parent trial and answer questions asked by a researcher about methods of delivering the study products and factors that facilitate or complicate the administration of the study products. We will not ask you about any personal information regarding your health or your family's health.
- **Risks:** We do not anticipate any significant level of risk/stress or discomfort for participation in this study; however, there may be some personal discomfort associated with responding to the questions.
- **Benefits:** Your feedback will help us understand how to improve the delivery of treatment for better childhood diarrhea outcomes in Kenya and other countries where diarrhea associated death is high.
- **Alternatives.** Participation is voluntary. Alternatives to study participation include continuing your usual care and treatment available through this or other health facilities.

1. Purpose of the Research:

The purpose of this study is to determine whether the addition of milk products called Lactoferrin and Lysozyme to the standard of care for diarrhea treatment (a process called "supplementation") will help reduce the number of new cases of diarrhea and improve the recovery of children aged 6-24 months returning home from the hospital after seeking care for diarrhea. Additionally, we are conducting focus group discussions (FGD) with caregivers to determine the acceptability of the study products and administration methods.

2. Description of the Research:

We are inviting you to participate in focus group discussions (FGD) consisting of 6-8 people per group, lasting approximately 2 hours. We will ask you questions about methods of delivering the study products and factors that help or hinder the use of the study products. We will not ask you about any personal information regarding your health or your family's health. The interview will be audio recorded and the

words will be transcribed (put in written form) by study staff. The audio recording will not be shared, and your name will not be associated with the transcription.

3. Potential Harm, Injuries, Discomforts or Inconvenience, Risks:
We do not anticipate any significant level of risk/stress or discomfort for participation in this study, however, sometimes you may feel uncomfortable discussing some personal things. All interviews will be confidential and all names or identifying information will be removed from transcripts to protect the identity of the participants.

4. Potential Benefits:
You will not directly benefit from participating in the focus group discussions (FGD). However, your feedback will help us understand how to improve the delivery of treatment for better childhood diarrhea outcomes in Kenya and other countries where diarrhea associated death is high.

5. Alternative Procedures or Treatments:
Participation is voluntary. Alternatives to study participation include continuing your usual care and treatment available through this or other health facilities.

6. Confidentiality:
The following protections against risk will protect the privacy of participants and maintain confidentiality of research data: (1) All study staff will be well trained and will receive ongoing supervision in confidentiality and data security procedures, specifically in ethical conduct, confidentiality protection, mandated reporting, and other topics of human participant protection. (2) As part of the informed consent procedure, focus group discussions (FGD) participants will be informed of the limits of confidentiality (harm to self or others) and mandated reporting requirements. (3) Privacy will be maintained by conducting all focus group discussions (FGD) in closed and private rooms in each facility, or in research team offices. (4) Data (including audio-recordings, and qualitative transcripts from focus group discussions (FGD)) will be securely stored in separate locked file cabinets in locked offices and in password-protected documents on password-protected computers and secure servers. Access to data storage areas and computers will be restricted. (5) The study link log will be stored on a secure server, accessible only through password-protected computers with encryption, in a password protected electronic file. (6) Analysis will occur only on de-identified data. (7) Audio recordings and qualitative transcripts from focus group discussions (FGD) will be destroyed three years after study completion. (8) The information gathered will be used only for scientific, educational, or instructional purposes. A description of this clinical trial will be available on http://www.clinicaltrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

7. Reimbursement:
The study will compensate you Ksh. 600.00 for your time and effort.

8. Participation:
Participation in this study is voluntary therefore, you can decide to join, not to join or after joining, you can withdraw your child's participation at any time. If you decide not to join the focus group discussion, you can still continue your child's participation in the main study.

Research-related Injury: It is unlikely that you will be injured as a result of participating in the focus group discussion (FGD).

You will be given a copy of the signed and dated consent form to keep for your records. You do not give up any legal rights by signing this consent form.

9. Future Data Use:
The information that we collect from you for this study might be used for future studies. We may remove anything that might identify you from the information. If we do so, that information may then be used for future research studies or shared with another investigator without getting additional permission from you.

10. Sponsorship:

Early termination of this study by the sponsor will not affect you given that your participation in the focus group discussion only takes place once.

11. Sources of Funding:
The study is funded by the National Institutes of Health (NIH) in the United States.

12. Contact Information
If you ever have any questions or feel you have been harmed by the study, you should contact Dr. Benson Singa at 0725234844. For any questions pertaining to your rights as a research participant, the contact person is: The Committee Chairperson, KEMRI Scientific and Ethics Review Unit, P. O. Box 54840-00200, Nairobi; Telephone numbers: 020-2722541, 0717719477; Email address: seru@kemri.org

13. Consent and Signature Options:
This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have questions later about the research, I can ask one of the researchers listed above. If I have questions about my rights as a research participant, I can call the Ethics and Research Committee at Kenya Medical Research Institute (KEMRI) 020-2722541, 0717719477. I will receive a copy of this consent form.

Please initial the sentences that reflect your choices, and then sign below:

_____ I agree for my de-identified information to be used for future research or shared with other researchers without my additional consent.

_____ I do not agree for my information to be used for future research or shared with other researchers.

_____ I authorize the storage of data collected as a part of this study for use in future research studies.

_____ I do not authorize the storage of data collected as a part of this study for use in future research studies.

_____ I authorize the audio recording of the discussion.

_____ I do not authorize the audio recording of the discussion. *(ineligible, stop consenting process)*

SIGNATURE OF PARTICIPANT

Participant Printed Name: _____ Date (DD-MMM-YYYY) _____

Participant Signature _____ Time (24:00) _____

OR
THUMBPRINT IF PARTICIPANT CANNOT WRITE

SIGNATURE OF WITNESS: (if Participant cannot read or write)
This individual can be a relative of the participant but should be independent from study staff.

I attest the information in this form was accurately explained to, and apparently understood by, the Participant, and that informed consent was freely given by the Participant.

Witness Printed Name: _____ Date (DD-MMM-YYYY) _____

Witness Signature _____ Time (24:00) _____

SIGNATURE OF STUDY STAFF (*can only be signed by an investigator or staff approved to administer consent)*

I have followed the study protocol to obtain consent from the Participant. He/she apparently understood the nature and the purpose of the study and consents to participation. He/she has been given opportunity to ask questions which have been answered satisfactorily.

Study Staff Printed Name _____ Study Staff Signature _____ Date (DD-MMM-YYYY) _____

Please retain a copy of this form for the study's records and provide a copy to the Participant.