Consent Form for Participation in a Research Study

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Study Title: Impact of an agricultural intervention on child health, nutrition and development

Sponsor: National Institute for Mental Health

Introduction

You and your child or children are invited to participate in a research study being done to learn whether an agricultural intervention can lead to improvements in the health, nutrition and development of young children. You are being asked to participate because your child is 6- to 36-months old and you are either participating in the *Shamba Maisha* adult study yourself, or because you live in the same household or compound as a person who is participating in the *Shamba Maisha* adult study.

Why is this study being done?

The purpose of this research study is to learn whether an agricultural intervention can lead to improvements in the health, nutrition and development of young children who live in the household or compound of an adult who is participating in an agricultural intervention study called *Shamba Maisha*.

Who is carrying out this research study, and where is it being done?

The study being conducted by researchers from the University of Connecticut, Boston Children's Hospital (BCH) and the Kenya Medical Research Institute (KEMRI) in collaboration with researchers from the University of California San Francisco (UCSF), the University of South Carolina (USC), and Massachusetts General Hospital (MGH). The study is paid for by US National Institutes of Health (NIH). The study is being done in Nyanza Region, Kenya.

What are the study procedures? What will I be asked to do?

If you agree to take part in this study, the following activities will be carried out with you and your child over a 24 month period.

1. **Interviews at your home:**
    a. You will be visited at your home and interviewed by a staff member 5 times over the next 2 years - at baseline and 6, 12, 18, and 24 months later. Interview topics at baseline will include questions about yourself, your child, and your household, as well as your child's diet and behaviors. The first interview will take about 1 hour. Interviews at 6, 12, 18 and 24 months will each take up to 30 minutes.
    b. You will be visited at your home by another staff member with training in child development 5 times over the next 2 years - at baseline and 6, 12, 18, and 24 months later. The staff member will ask you questions about your child's motor, language and social development skills and observe your child's activities in the home. Each visit will take up to 2 hours. You may be asked your permission for a study staff member to video tape the child development assessment.
2. **Interviews and child health assessments at the clinic:** You will also be asked to visit the clinic with your child 5 times over the next 2 years - at baseline and 6, 12, 18, and 24 months later. If your child is 6 to 9 months old at baseline, additional child health assessments will be made every 3 months until the child is 12 months old, after which time measurements will be made every 6 months. At each clinic visit, the following will happen:
    a. **Interview.** You will be interviewed by a staff member from our study about your child's recent health as well as your health. The interview will take about 30 minutes.
    b. **Child Growth Examination.** Your child will be examined by a nurse to measure your child's length, weight and arm and head circumference. If your child is 6 to 9 months old at baseline, additional growth measurements will be made every 3 months until the child is 12 months old, after which time measurements will be made every 6 months. Each exam will take about 10 minutes.
    c. **Adult Nutritional Status**. You will be examined by a nurse to measure your height, weight and arm circumference. Each exam will take about 5 minutes.
    d. **Child Physical Health**. Your child will be examined by a nurse to measure your child's temperature, breathing, and evaluate for dehydration. If your child is 6 to 9 months old at baseline, additional physical examinations will be made every 3 months until the child is 12 months old, after which time measurements will be made every 6 months. Each exam will take about 15 minutes.
    e. **Hemoglobin** is a marker in the blood that indicates levels of iron that is related to diet. At each clinic study visit, a finger prick will be done to collect a small amount of blood – 0.01 millitres (total of 0.05 millitres over 2 years) - from your child and tested in a machine which will tell us if the child's iron level is low or not. Each test will take about 5 minutes.

3. **Collecting information from research records**: In addition to talking to you, if you are a participant in the main *Shamba Maisha* study, we will collect data on your health, nutrition and household economics from study records.
4. **HIV testing for child.** If your child has not been documented as HIV-positive, an HIV test for your child will be offered by the nurse. If the child is 18 months old or older, a rapid HIV test will be done where the results are given on the spot. However if the child is younger than 18 months old, a heel prick will be performed and a filter papers blood blot prepared for a special test which will be done in the study laboratory.
5. **Exit interviews.** If a member of your household is participating in the *Shamba Maisha* intervention, we may interview you at the end of the study to explore what your experiences were in relation to the *Shamba Maisha* intervention. The interview will take up to 45 minutes.
6. **Contact to remind you about a study visit.** A study staff member will contact you by phone within a week before upcoming study visits to remind you of your and your child's study visit. The study staff member will identify themselves by name and as an employee of the *Shamba Maisha* study.

What other options are there?

You are free to decide whether or not to participate in this study with your child. If you choose for you and your child to not to participate but are a participant in the main *Shamba Maisha* study, you can still participate in the main *Shamba Maisha* study.

What are the risks or inconveniences of the study?

There are a few risks that may be associated with participating in the study; however we will try as much as possible to minimize the risks as follows:

- Potential loss of privacy or confidentiality. One possible risk of study involvement is loss of privacy if information you reveal during the interview were to be disclosed outside of the research team. Your information will be handled with as much privacy as possible. In order to protect your name, only your participant number will be used. Information identifying you will be kept in a secure location. All identifying information will be omitted from any data distributed to others, or any publications to result from this study.
- Stress. One potential risk of study participation is increased stress for you that may result from learning about previously unknown HIV infection in your child and/or developmental delay. If your child is found to be HIV positive and/or shows signs of a delay in development, study staff will make a referral for appropriate medical and/or mental health care.
- Risk of momentary discomfort or soreness and/or minimal bruising with blood collection (phlebotomy). A qualified nurse will perform the finger stick to collect a small amount of blood from your child. They will collect blood using standard sterile procedures.

- Risk of personal discomfort or embarrassment. You will be asked some questions that you may feel are sensitive and may make you feel uncomfortable or embarrassed. TO reduce this risk, interviewers will always inform you about the kinds of questions to be asked, will keep all information shared confidential, and will be available after the interview to answer any concerns that may arise. You also always have the right to refuse to answer any question.

What are the benefits of the study?

Children will directly benefit from regular physical health and developmental assessments. Children who are found to be ill, who are not growing well, and/or test HIV-positive will be referred for a full clinical assessment at the nearest FACES-supported Ministry of Health clinic that provides HIV care and treatment and general child health services. Also, caregivers found to need medical or mental health support will also be referred to appropriate medical or mental health care. This study will help doctors learn more about how a farming intervention affects the children in your home, and it is hoped that this information will help in designing programs to benefit children and their families in your community and other communities like yours.

Will I receive payment for participation? Are there costs to participate?

There are no costs and you will not be paid for taking part in the study.

You will be reimbursed for your time and travel expenses related to your participation in each interview for this study. For clinic-based study visits, you will receive up to 800 Kenyan Shillings, depending on the distance from your home to the clinic. For the baseline home visit, you will receive 300 Kenyan Shillings. For the 6, 12, 18 and 24 month follow-up home visits, you will receive 250 Kenyan Shillings. You will be paid in cash immediately after you complete the interview.

How will my personal information be protected?

The following procedures will be used to protect the confidentiality of your data. We will do our best to protect the confidentiality of the information we gather from you but we cannot guarantee 100% confidentiality. The researchers will keep all study records, including any codes to your data, locked in a secure location.

Research records will be labeled with a code. The code will be derived from a number indicating study site (F01 to F16) and a sequential 3 digit code for your child (C01-Cxx) that reflects how many people have enrolled in the study. A master key that links names and codes will be maintained in a separate and secure location. The master key and audiotapes will be destroyed after 3 years.

All electronic files (e.g., database, spreadsheet, etc.) containing identifiable information will be password protected. Any computer hosting such files will also have password protection to prevent access by unauthorized users. Only study investigators and study management staff will have access to the passwords. Data that will be shared with others will be coded as described above to help protect your identity. At the conclusion of this study, the researchers may publish their findings. Information will be presented in summary format and you will not be identified in any publications or presentations.

Your personal information may be given out if required by law.

If you decide to withdraw from the study, all data collected up to the point of withdrawal will be kept.

You should also know that the UConn Institutional Review Board (IRB) and Research Compliance Services and KEMRI Institutional Review Board (IRB) may inspect study records as part of its auditing program, but these reviews will only focus on the researchers and not on your responses or involvement. The IRB is a group of people who review research studies to protect the rights and welfare of research participants.

What happens if I am injured or sick because I took part in the study?

In the event you or your child(ren) become sick or injured during the course of the research study, immediately notify a member of the research team, the study coordinator or site-Principal Investigator. If you require medical care for such sickness or injury, you will pay for your care in the same manner as your other medical needs are addressed.

Can I stop being in the study and what are my rights?

You do not have to be in this study if you do not want to. If you agree to be in the study, but later change your mind, you may drop out at any time. There are no penalties or consequences of any kind if you decide that you do not want to participate.

You will be notified of all significant new findings during the course of the study that may affect your willingness to continue.

During interviews, you do not have to answer any question that you do not want to answer.

Participants may be removed from the study under the following conditions:

1. Participant requests withdrawal from study for any reason
2. Participant moves out of study area
3. Participant noncompliance with study rules
4. Study termination

Whom do I contact if I have questions about the study?

Take as long as you like before you make a decision. We will be happy to answer any question you have about this study. If you have further questions about this study or if you have a research-related problem, you may contact the site principal investigator, Dr. Phelgona Otieno (0721973971), or the principal investigator, Dr. Lisa Butler (Lisa.Butler@uconn.edu). If you have any questions concerning your rights as a research participant, you may contact the Secretary, KEMRI Ethics Review Committee (ERC) at 020-272-2541 or University of Connecticut Institutional Review Board (IRB) at irb@uconn.edu. These committees are concerned with the protection of volunteers in research projects. Study staff members can also help you contact the right person to answer any questions you may have.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You can decide not to participate or to withdraw from the study at any point in time without penalty or loss of benefits to which you are entitled.If you decide not to take part in this study, there will be no penalty to you and you will not lose your regular medical care.

Questions? : DO YOU HAVE ANY FURTHER QUESTIONS NOW?

Documentation of Consent:

I have read this form and decided that I will participate in the project described above. Its general purposes, the particulars of involvement and possible risks and inconveniences have been explained to my satisfaction. I understand that I can withdraw at any time. My signature also indicates that I have received a copy of this consent form.

Consent to Take Part in the Research Study

Do you provide consent to participate in the study? Yes No

_____ DATE

GIVEN BY:

NAME OF PARTICIPANT	SIGNATURE or THUMBPRINT OF PARTICIPANT

BY:

NAME OF STAFF MEMBER	SIGNATURE OF STAFF MEMBER

WITNESSED BY:

NAME OF WITNESS	SIGNATURE OF WITNESS

Consent to Take Part in Video and Audio Recording

GIVEN BY:

NAME OF PARTICIPANT	SIGNATURE or THUMBPRINT OF PARTICIPANT

Research Staff Member's Statement & Signature

- I have fully explained the research study described above, including the possible risks and benefits, to all involved parties (subject/parents/legal guardian as applicable).
- I have answered and will answer all questions to the best of my ability.
- I will inform all involved parties of any changes (if applicable) to the research procedures or the risks and benefits during or after the course of the study.
- I have provided a copy of the consent form sign by the subject/ parent / guardian

_____ _____

Date (DD/MM/YEAR) Signature of **Study Staff Member**

WE WILL GIVE YOU A COPY OF THIS CONSENT FORM.