Study Title: The Impact and Implementation of a Mobile Messaging Intervention to Improve Infant and Young Child Nutrition in Senegal

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Department of Urban-Global Public Health
School of Public Health
Rutgers, The State University of New Jersey
One Riverfront plaza
1037 Raymond Blvd, 10th fl
Newark, NJ 07102

RUTGERS
School of Public Health

CONSENT TO TAKE PART IN A RESEARCH STUDY: cRCT and Process Evaluation

Title of Study: The Impact and implementation of a **M**obile **M**essaging intervention to **I**mprove **N**utrition among **I**nfant and young child in Senegal (MMINIS Study)

Principal Investigator: Shauna Downs, PhD

The information in this consent form will provide more details about the research study and what will be asked of you if you choose to take part in it. If you have any questions now or during the study, if you choose to take part, you should feel free to ask them and should expect to be given answers you completely understand. After your questions have been answered and you wish to take part in the research study, you will be asked to sign this consent form. You are not giving up any of your legal rights by agreeing to take part in this research or by signing this consent form.

Who is conducting this study?
Dr. Shauna Downs and Professor Souleymanne Mboup are Principal Investigators of this research study. Principal Investigators have the overall responsibility for the conduct of the research. However, there are often other individuals who are part of the research team. The Project Coordinator of this study is Mr. Daouda Gueye.

Daouda Gueye may be reached at +221 77 376 99 09 or daouda.gueye@iressef.org.

The Principal investigators or another member of the study team will also be asked to sign this informed consent. You will be given a copy of the signed consent form to keep.

Sponsor of the Study: Eunice Kennedy Shriver National Institute of Child Health & Human Development in the United States.

Why is this study being done?
This study is being done to examine the effectiveness of sending mobile messages to parents that describe how to feed their young children well. The research will help us to understand if mobile interventions lead to improvements in child feeding practices and nutrition.

Who may take part in this study and who may not?
We are asking mother and fathers (or guardians) of young children (6-19 months) to participate in this research. In order to be included in this research you must have access to a mobile telephone.

Why have I been asked to take part in this study?
You are being asked to participate in this study because you are a parent or guardian of a young child living in a farming village in Thies, Diourbel or Fatick.

How long will the study take and how many subjects will take part?
In total, we will include 510 mother, father and children triads in this study. The study will take place over about six months and will involve about 3 hours of your time during that period.

What will I be asked to do if I take part in this study?
If you take part in the research, you will be asked to participate in a mobile messaging intervention about how to best feed your baby.

We will also ask you to answer survey questions related to how you feed your child at two time points. The survey will take approximately 45 minutes each time. In addition, we would like to measure the iron in the blood of your baby to measure anemia. We will ask to do this by pricking their finger and testing a drop of blood. We will ask you these questions in your house or in a location of your choice within the village.

This study is a randomized control trial. This means that half of the households participating will receive the intervention after the first study visit and the other half of households will receive it after completing the second study visit. If your household is randomly selected to receive the messages after the first visit, we will send you one message per week for a sixteen-week period. We will ask you to listen to these messages which will take approximately a total of 30 minutes of your time. At the end of each message, you will be asked whether you understood the message, if you found it helpful and if you intend to adopt the behavior. We will also record the amount of time that you listened to the message. If you are randomly selected to receive the messages after the second visit, you will receive two messages per week for a period of eight weeks.

We may also ask you to participate in an interview about the messages. In the interview, we would ask you questions about your understanding of the voice messages and which parts you liked and disliked. You may choose to not be involved in this part of the project, even if you participate in the intervention. If you do participate, you may choose not to answer any question that we ask. You may leave the discussion at any time.

With your permission, the interview will be audio-recorded. The information on the recordings is confidential and only the study team members will listen to them. The recordings will be used for data analysis by the research team. The recordings will be destroyed after they have been recorded in writing. If you do not wish to be audio-recorded, a member of the study team will take notes instead.

What are the risks of harm or discomforts I might experience if I take part in this study?
Possible harms or burdens of taking part in the study may be some discomfort when we measure your child's iron in their blood. The study will also require your time and this may be inconvenient for you. You may feel worried about answering the nutrition questions in the surveys but there is no penalty for incorrect answers. It is also possible that your personal information is mistakenly shared with someone who is not on the research team and was not supposed to see or know your information. We will do our best to protect your identity and the information you share with us.

Are there any benefits to me if I choose to take part in this study?
The benefits of taking part in this study may be increasing your knowledge about how to feed your child better. However, it is possible that you may not receive any direct benefit from taking part in this study.

What are my alternatives if I do not want to take part in this study?
There are no alternative treatments available. Your alternative is not to take part in this study.

How will I know if new information is learned that may affect whether I am willing to stay in the study?
During the study, you will be updated about any new information that may affect whether you are willing to continue taking part in the study. If new information is learned that may affect you after the study or your follow-up is completed, you will be contacted.

Will I receive the results of the research?
As soon as we measure your child's hemoglobin, we will share the results with you. We will notify you if your child is found to have severe anemia and refer them to a community health worker or health post. We will also provide you with a summary of the results of this study.

Will there be any cost to me to take Part in this study?
There will be no cost to participating in this study.

Will I be paid to take part in this study?
You will not be paid to take part in this study.

How will information about me be kept private or confidential?
All efforts will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed. We will not be sharing information about you to anyone outside of the research team. The information that we collect from this research project will be kept private. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and we will protect that information using password protected files. It will not be shared with or given to anyone outside of our project. All interview recordings will be destroyed as soon as we transcribe the recordings.

The research team may use or share your information collected or created for this study with the following people and institutions:
- The Rutgers University Institutional Review Board and Compliance Boards
- The Office for Human Research Protections in the U.S. Dept. of Health and Human Services
- Institut de Recherche en Santé de Surveillance Epidemiologique et de Formation in Senegal.
- National Institutes of Health

A description of this clinical trial will be available on ClinicalTrials.gov, as required by U.S. law. 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 will happen to my information—data, recordings and/or images—collected for this research after the study is over?

- The information collected about you and your child for this research will not be used by or distributed to investigators for other research.
- After information that could identify you has been removed, de-identified information collected for this research may be used for other research we conduct without obtaining additional informed consent from you.

What will happen if I do not wish to take part in the study or if I later decide not to stay in the study?
It is your choice whether to take part in the research. You may choose to take part, not to take part or you may change your mind and withdraw from the study at any time. If you do not want to enter the study or decide to stop taking part, your relationship with the study staff will not change, and you may do so without penalty and without loss of benefits to which you are otherwise entitled.

You may also withdraw your consent for the use of data already collected about you, but you must do this in writing to Mr. Daouda Gueye, the Project Coordinator: daouda.gueye@iressef.org.

Who can I contact if I have questions?

If you have questions, concerns or complaints about the research, wish more information or if you feel you may have suffered a research related injury, you can contact the Project Coordinator: Daouda Gueye +221 77 376 99 09 or daouda.gueye@iressef.org

If you have questions, concerns, problems, information or input about the research or would like to know your rights as a research subject, you can contact the Rutgers IRB Director at: Brunswick/Piscataway Health Sciences IRB 335 George St., Liberty Plaza Ste. 3100, New Brunswick, NJ 08901 or the Rutgers Human Subjects Protection Program at (973) 972-3608 or (732)235-9806), email us at human-subjects@research.rutgers.edu., or write us at 335 George Street, Liberty Plaza Suite 3200, New Brunswick, NJ 08901.

AGREEMENT TO TAKE PART IN RESEARCH

Subject Consent:

I have read this entire consent form, or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form and this study have been answered. I agree to take part in this study.

Subject Name (Print):_____

Subject Signature:_____ Date:_____

Signature of Investigator/Individual Obtaining Consent:

To the best of my ability, I have explained and discussed all the important details about the study including all of the information contained in this consent form.

Investigator/Person Obtaining Consent (Print):_____

Signature:_____ Date: _____