Moi University College of Health Sciences / Moi Teaching and Referral Hospital
Institutional Research and Ethics Committee (IREC)
Informed Consent Form

Study Title: Measuring Adverse Pregnancy and Newborn Congenital Outcomes (MANGO)

Name of Principal Investigator: Edwin Were[1], John Humphrey[2], Rena Patel[3]

Name of Organization: Moi University School of Medicine[1], Indiana University School of Medicine[2], Washington University[3]

Name of Sponsor: National Institutes of Health, USA

PART I: INFORMATION SHEET

Introduction:
We are asking you to participate in a research study. This form provides you with information about the study. The information below will be read aloud to you. Please ask questions about anything you do not understand before deciding whether you want to participate in the study. If you decide to participate the study, you will be given a copy of this consent form.

Why is this study being done?
This study plans to learn more about the pregnancy and birth outcomes of women and why some babies are born with birth defects. This research is being done by investigators at Moi University, Indiana University, University of Washington, and the Kenya Ministry of Health. You are being asked to be in this study because you are pregnant and attended the antenatal clinic at Moi Teaching and Referral Hospital (MTRH).

How many people will participate in the study?
Approximately 800 women will participate in the study along with their infants.

What happens if you agree to participate?
These are the things we will ask you to do if you agree to participate in the study:

1. We will review your mother-baby booklet today and ask you questions about your pregnancy and medical history including any medications, alcohol or other substances you took while you were pregnant;
2. We will contact you once per week by phone starting a few weeks prior to and after your estimated delivery date to ask you whether you are still pregnant, and if so, where you plan to deliver, and again whether you have started taking any new medications or other substances during pregnancy;
3. If you deliver at MTRH, we will encounter you and your baby on the postpartum ward prior to your discharge from the hospital. We will ask you questions about your pregnancy, and a researcher will examine your baby to see whether he/she has any visible birth defects.
4. If you do not deliver at MTRH, we will contact you once per week for up to two weeks after your estimated delivery date to ask you whether you are still pregnant or already delivered. After your delivery, we will ask you questions by phone about the outcome of the delivery and how your baby is doing. We will also arrange for a future time and place, such as at the facility or your home according to your preference, for a researcher to examine your baby to see whether he/she has any visible birth defects. If it is acceptable to you, the researcher may also attempt to visit you in person at your home during daytime hours if you cannot be reached by phone after you deliver. To do this, we will ask for your home address, which may require you to draw a map that shows how we can physically reach your home.
5. If your baby has a possible birth defect, we will take a standardized set of 15 digital photos and

three, 10-second videos of the baby's entire body to document any birth defect that is present. These images will be reviewed by a panel of experts who will determine whether the abnormality pictured is a birth defect and the type of birth defect it is.

6. Rarely, a baby will be born with a major birth defect that has medical or surgical significance. In that case, we will also contact you at 1, 6 and 12 months after delivery to understand how your baby is doing and whether he/she is accessing healthcare.

How long will the study last?
If you enroll in the study during pregnancy, your participation will last until at most a few weeks after delivery. If your baby has a possible birth defect, you and your baby's participation will last 12 months after delivery.

What are the possible discomforts or risks?
Discussing some of the aspects of your pregnancy and delivery may be uncomfortable for you. We will make every effort to protect your and your baby's confidentiality. A breach of confidentiality is possible but the risk for that happening is very small.

What are the possible benefits of the study?
There are no direct benefits to you for participating in the study. However, your baby will be examined by a trained researcher who will be able to detect whether your baby may have a birth defect. If any possible defects are detected, the researcher will refer you to MTRH for further management. Additionally, the researchers hope that the knowledge gained from this study will help pregnant women and their babies in the future.

Who is paying for this study?
The United States National Institutes of Health (NIH).

Will I be paid for being in the study?
No, you will not be paid for being in the study.

Will I have to pay for anything?
No, taking part in the study will not cost you anything.

Is my participation voluntary?
Yes, taking part in this study is voluntary. You have the right to choose not to participate. If you choose to participate, you have the right to stop at any time. If you refuse or decide to withdraw later, you will not lose any benefits or rights to which you are entitled. If you leave this study, you will still receive your usual medical care.

Can I be removed from this study?
The study team may decide to remove you from the study without your permission if the study team thinks that being in the study may cause you harm or for any other reason. A study team member will inform you in such a case.

Who will see my research information?
We will do everything we can to keep your records confidential, but we may share them with others if required by law. The results from the research may be shared at a meeting or published in articles. Your information will be kept private when any information is presented. The experts who review the photos/videos of babies with possible birth defects will not have access to any identifying information for your or your baby.

Certificate of Confidentiality
We have a Certificate of Confidentiality from the United States NIH. These protections only apply to

data held in the United States.

This helps us protect your privacy. The Certificate means that we do not have to give out identifying information about you even if we are asked to by a court of law in the United States. We will use the Certificate to resist any demands for identifying information.

We can't use the Certificate to withhold your research information if you give your written consent to give it to an insurer, employer, or other person. Also, you or a member of your family can share information about yourself or your part in this research if you wish.

There are some limits to this protection. We will voluntarily provide the information to:

- A member of the United States government who needs it to audit or evaluate the research;
- Individuals at the universities, the funding agency, and other groups involved in the research, if they need the information to make sure the research is being done correctly; and
- To relevant authorities as required by other Federal, State, or local laws.

Will my information be used for research in the future?

Information collected from you/your baby during this study may be used for future research or shared with other researchers for future research if you provide consent. If this happens, information which could identify you will be removed before any information is shared. Since identifying information will be removed, we will not ask for your additional consent.

Who do I contact if I have questions?

You may ask any questions you have now. If you have questions, concerns, or complaints later, you may call the study coordinator Ms. Marsha Alera at 0721 433 175.

If you have questions about your rights as a research participant or if you wish to voice your concerns about the study, please contact the IREC office in Eldoret, Kenya at +254 787 723 677 or write to P.O Box 3-30100, Eldoret, Kenya.

PART II: CERTIFICATE OF CONSENT

Agreement to be in the study

I have read this paper about the study or it was read to me. I understand the possible risks and benefits of this study. I know that my participation in this study is voluntary. I choose to take part in this study. The study staff will give me a copy of this consent form if I want a copy.

Participant Name:_____ Date:_____

Participant Signature:_____

Consenting Staff Name:_____ Date:_____

Staff Signature:_____

If consented orally

Name of witness: _____ Thumbprint of participant

Signature of witness: _____

Date:_____

I give permission to be contacted by phone or text messaging

Yes, Participant Signature:_____

No

I give permission to be visited at my home after delivery

Yes, Participant Signature:_____

No

I give permission to examine my baby and take photos/videos of any possible birth defects

Yes, Participant Signature:_____

No

I give permission for my data/my baby's data (de-identified) to be used in future research

Yes, Participant Signature:_____

No