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

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

Researcher's statement: Today, we are asking if you would like to be interviewed for a research study. This study is being conducted by researchers at Moi University, Indiana University, Washington University and the Kenya Ministry of Health. The purpose of this consent process is to give you the information you will need to help you decide whether to be in the study or not. You may ask any questions at any point. When we have answered all your questions, you can decide if you want to be in the study or not.

Why is this study being done? We are doing this study to learn more about the pregnancy and birth outcomes of women and why some babies are born with birth defects. As part of the study, we record routine care information from the medical records of all postpartum women and their infants delivered at the Moi Teaching and Referral Hospital (MTRH) with the permission of the hospital. Sometimes, the care providers do not enter all the routine information into the patient files, perhaps due to pressure of work or just forgetfulness. If we find missing or incomplete information in the medical record while the mother is still in the hospital after her delivery, we plan to ask the mother to help us fill in this information. We are requesting your permission to ask you about certain information that may have been missing or incomplete in your medical records.

What happens if you agree to participate? We will ask you questions to clarify missing or incomplete information in your medical record. For example, we may ask you to verify a medication or test result you may have received during pregnancy. Your responses will be entered into a study form, one copy will be kept with the research team and another copy will be filed in your chart.

How many people will participate in this study activity? We plan to review the medical records of all women delivering at MTRH Mother and Baby Hospital, approximately 12,300 women and infants each year. Women with missing or incomplete information will be requested by the researchers to provide this information about themselves, their pregnancy and delivery, and/or their baby.

How long will the study activities last? We will only ask you questions once, and after that your participation is finished. We estimate that it will take less than 5 minutes depending on how many questions we ask you.

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, complete recording of your care notes may assist the providers in making decisions that affect the quality of your care in the future. 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, your participation is voluntary. You may decline to be asked any questions by the research. Refusal to be asked any questions by the researchers will not change the kind of care you receive from the hospital in any way.

Who will see my research information? The information you tell us will be shared with your care providers, which may help them determine the care that you need. We will do everything we can to keep your information private and not share it with anyone who is not part of the study team, but we may share it with others if required by law. The results of the research may be shared at a meeting or published in articles. Your information will be kept private when any information is presented.

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 0721433175. 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.

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.

Would you like to participate in the study? Please indicate yes or no to the study staff.