Informed Consent (for women participating in focus groups)

Title: Group Antenatal Care to Promote a Healthy Pregnancy and Optimize Maternal and Newborn Outcomes: A Cluster Randomized Controlled Trial

Principal Investigators: Jody Lori, PhD, University of Michigan and Dr John Williams, Dodowa Health Research Centre
Co-investigators: Cheryl Moyer, PhD, University of Michigan

Study Sponsor: National Institutes of Health; Eunice Kennedy Shriver National Institute of Child Health & Human Development. Grant#: RO1HD096277

Invitation to be Part of a Research Study
The Dodowa Health Research Centre and University of Michigan in the United States are leading a research study on group antenatal care. We want to find out how to help women in Ghana have safer births and healthier babies. You are being asked to be in this focus group study because you were a participant in the study group antenatal care. You can choose to be in the focus group or not, it is up to you. If you choose not to be in the focus group, there will be no problem for you now or in the future. You can leave at any time without any problem to you now or in the future.

Important Information about the Research Study
The purpose of the focus group is to get your opinion about group antenatal care (ANC) compared to individual antenatal care. We will ask for ideas about how ANC can be improved.

What will happen if you take part in this study?
If you take part in this study, you will be asked to complete one focus group discussion. We will make voice tapes of the focus group to make sure we have a recording of everyone's ideas. We will not use names on the tape or during the focus group discussion. The recording will only be used for research purposes. Once the audiotape has been transcribed, the recording will be destroyed. This process will take about one month. The group discussion will take approximately 1 hour.

How could you benefit from this study?
You will not get special treatment or rewards for being in the focus group, but we do hope that being in the group and sharing your ideas might help other women and their babies in the future. Sometimes people tell us they feel good about helping make things better for others. Your participation will also benefit the health system of Ghana with program implementation and improved quality of care for pregnant women and their unborn babies.

What risks might result from being in this study?
Being in the focus group is not likely to cause you any harm, however there is a small risk of breach of confidentiality. We will ask everyone in the group not to talk outside of the group about anything that we discuss in the group. This way whatever you say will be confidential. We don't think anything we talk about will upset you, but if it does you can leave at any time with no problem to you. If this does

happen, you can privately talk to the midwife or other health facility staff who can help you get over being upset.

How will we protect your information?
The information you give us will be kept strictly confidential. We will ask everyone in the group not to talk outside of the group about anything that we discuss in the group. This way whatever you say will be confidential. Researchers will not discuss what happens in the group outside the research team. We will not talk about you being in the group outside the research team. We will store and use your information for future research. We may share it with other researchers but we will not share any information that could identify you. If you do not want your data to be stored and shared you may choose to not be in the study. You will be identified in research records only by a code number that will be stored on a computer that is password protected. Information that identifies you personally will be kept in a separate locked file cabinet. No one will be able to see it except the research team. You will not be named in any reports and there is no link between you and the answers you give in the focus group. Because names are not used during the group discussion, if you leave before the discussion is finished your responses will be analyzed with the group data. Once the focus group discussion has been transcribed, the recordings will be destroyed. This process will take approximately one month.

This trial will be registered and may report results on www.ClinicalTrials.gov, a publicly available registry of clinical trials.

You will not be named in any reports (including www.clinicaltrials.gov) and at no time will a link between you and the answers you give be released.

How will we compensate you for being part of the study?
You will not be paid to be in the study but you will receive a small token of appreciation such as a baby hat, baby blanket, baby socks.

Your Participation in this Study is Voluntary
It is totally up to you to decide to be in this focus group study. Participating in this study is voluntary. Even if you decide to be part of the study now, you may change your mind and stop at any time. You do not have to answer any questions you do not want to answer. If you decide to withdraw before this group discussion is completed, we will not use your details in our analysis but you will only be captured as a number of who withdrew from the study.

Contact Information for Study Team and Question about the Research
If you any questions concerning this study, you can ask me now or contact the study coordinator Ms Vida Kukula on 0208451202 at the Dodowa Health Research Centre or call her on 0208451202/0244167999.

If you have questions or concerns about the research, please contact the Principal Investigators, **Dr John Williams at Dodowa Health Research Centre on telephone number 0244755358 or Prof. Jody Lori. For international calls from Ghana to the US, +1734-763-0097 or email: jrlori@umich.edu.** Please note the time in Michigan is 5 hours earlier than in Ghana.

Contact Information for Questions about Your Rights as a Research Participant

This research has been reviewed and approved by the Ghana Health Service Ethics Review Committee, the Institutional Review Boards of Dodowa Research Health Centre, and the University of Michigan Health Sciences and Behavioral Sciences Institutional Review Board.
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Ann Arbor, MI USA 48109-2800
For international calls from Ghana to the US, +1734-936-0933 or email: irbhsbs@umich.edu. Please note the time in Michigan is 5 hours earlier than in Ghana.
If you have any questions about your rights as a research participant, or wish to obtain information, ask questions, or discuss concerns about this study with someone other than the researchers, please contact the following:
Administrator of Ghana Health Service Ethical Review Committee, Ms. Hannah Frimpong on 0302681109/0507041223.

If you wish to find out more about the Dodowa Institutional Review Board, you may contact Ms. Irene Honam Tsey on 0208420640.

Part 2: Informed Consent Form

I have been adequately been informed of (or I have read and understood) the purpose, benefits, risks and procedures for the research title *Group Antenatal Care to Promote a Healthy Pregnancy and Optimize Maternal and Newborn Outcomes: A Cluster Randomized Controlled Trial* . I have been given an opportunity to ask any questions about the research and any questions that I have asked have been answered to my satisfaction. I know that I can refuse to participate in this study and understand that if I agree to participate I can withdraw my consent at any time without any problem. I also understand that any information collected will be treated confidentially. I hereby freely agree to participate in this study.

_____ _____

Date Name and signature or mark of participant

If participants cannot read the form themselves, a witness must sign here:

I was present while the benefits, risks and procedures were read to the participant. All questions were answered and the participant has agreed to take part in the research.

_____ _____

Date Name and signature of witness

I certify that the nature and purpose, the potential benefits, and possible risks associated with participating in this research have been explained to the above individual.

_____ _____

Date Name and signature of person who obtained consent