Approval Date: February 9, 2015

Approved Consent Version No.: 2

PI Name: Cherrie Evans

IRB No. 00005383

Consent 1: Birth Attendants/Providers

PI Name: Dr. Cherrie Evans
Study Title: *Saving Lives on the Day of Birth: Building and Sustaining Capacity of Frontline Health Workers in Uganda*
JHSPH IRB No.: 5383
Makerere University IRB No.:11353
PI Version/Date: Version 3/February 4, 2015

[**DATA COLLECTORS:** ***Before the data collection, the supervisor will have checked the appropriate boxes for today. Ask your supervisor if it needs to be done.]***

[Greeting]. My name is _____. I am from Jhpiego and would like to talk to you about your work. Jhpiego is an organization in Uganda and affiliated with Johns Hopkins University in USA working to improve maternal and newborn health care. We would like to see if a new training package using simulators improves prevention and treatment of postpartum hemorrhage and neonatal asphyxia. We ask you to help us in our research study because you attend births regularly at this health facility. All birth attendants at this facility are being asked to participate in this study. You do not have to help us in this study; it is your choice.

If you say yes, during the next year we **will**:

- Invite you to participate in two separate trainings, each lasting one day. One training is about preventing and treating postpartum hemorrhage. The other is about neonatal resuscitation.
- Ask you to take brief written knowledge tests and ask you to demonstrate how to treat delivering women and newborns using simulators.
- Ask you to participate in short practice sessions at your facility with one of your colleagues every week in the 2 to 3-month period after each training.
- Ask you to record information about the deliveries you conduct in the facility delivery register and a short supplemental register, and this data will be reviewed by the study team.

If you say yes, during the next year we (our study research team) **may or may not**:

- Observe you as you attend births at your facility over the course of several days. This may occur at the beginning, middle and end of our study. The observer will take notes on what happens during the birth.

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- Ask you to be a Peer Practice Coordinator and lead the weekly practice sessions with your co-workers using the simulator. We will orient you on doing this role. We will collect information about the timing and frequency of these practice sessions and we may telephone you or send you SMS reminders asking you to hold practice sessions. We will ask you to collect data from the maternity registers to give to the study team.
- Give you the option of receiving text messages on your phone to remind you about information that was taught during the one-day trainings.
- Interview you about your experiences practicing with the simulators.

[*Data Collector: Check only the checked box for today's activities.]*

If you say yes, **TODAY** we will:

☐ Ask you to participate in a 1-day training about postpartum hemorrhage.

☐ Ask you to participate in a 1-day training about neonatal resuscitation.

☐ Invite you to be oriented to be a Peer Practice Coordinator.

☐ Ask you to take brief written knowledge tests and to demonstrate how to prevent and manage PPH and newborn asphyxia using simulators.

☐ Observe you as you attend births at your facility.

☐ Give you the option of receiving text messages on your phone to remind you about information that was taught during the one-day trainings.

☐ Interview you or have you participate in a group discussion with your co-workers about your experiences practicing with the simulator.

[*Data Collector: Check and read the statement about time required in the appropriate box(es) for today's activities.]*

☐ *For the training in postpartum hemorrhage or neonatal resuscitation:* The training will last up to 8 hours.

☐ *For orientation to the Peer Practice Coordinator role:* This will take up to 4 hours on the day after each of the two trainings.

☐ *For knowledge tests and OSCEs:* The tests will take no more than 90 minutes.

☐ *For observations:* The observation will last the duration of the birth, but you will not be required to do anything in addition to your normal job responsibilities.

☐ *For text messages:* You may spend a few minutes each month reading the text messages.

☐ *For an interview about your experience with practicing on the simulators:* The interview will take no more than 30 minutes.

We do not expect this project to cause you any risks or discomforts. The information collected during this study is not an evaluation of your job performance, but of the training program. Your level of participation in this study will have no effect on future job evaluations. If you are a supervisor, we ask that you to refrain from using information about health workers' degree of participation in practice sessions or other aspects this study to evaluate their job performance.

There is a risk that someone outside the study will see your information. We will do our best to keep your information safe by using a special code instead of your name on data collection tools and by keeping your name in a locked file.

You will receive no monetary benefits for participating in the training or the data collection. We think that the training you receive will improve your ability to provide care for pregnant women and newborns. This study will also work to improve the availability of necessary supplies and medicines at your health facility. Therefore, we think that your participation in this study could improve your job satisfaction.

Do you have any questions? You may contact the Principal Investigator, Cherrie Evans, at 410-537-1986 or Innocent Atukunda for Jhpiego in Uganda at 256.712.210802 about your questions or problems with this work. You may contact Dr. Suzanne Kiwanuka, the Chairperson, School of Public Health Institutional Review Board (MakSHS-IRB) Tel: (+256) 0772 886 377.

May I begin?

Approval Date: February 9, 2015

Approved Consent Version No.: 2

PI Name: Cherrie Evans

IRB No. 00005383

Oral Consent 2: Laboring or Postpartum Woman/ or Family Member

PI Name: Dr. Cherrie Evans
Study Title: Saving Lives on the Day of Birth: Building and Sustaining Capacity of Frontline Health Workers in Uganda
JHSPH IRB No.: 5383
Makerere University IRB No.:11353
PI Version/Date: 3/February 4, 2015

Hello. My name is ……. I am a midwife/doctor from Jhpiego/PREFA. Jhpiego is an organization in Uganda and affiliated with Johns Hopkins University in USA working to improve maternal health. PREFA is an organization in Uganda working in heath.

STUDY PURPOSE

We are conducting a study of the effect of a training program for providers who care for mothers and newborns. The training is designed to improve maternity health services in Uganda.

STUDY PROCEDURES

I would like to be present to observe your care during labor and delivery and the care of your newborn. This is so we can understand how delivery services are provided in this facility. Other patients in this facility are also being asked to participate.

BENEFITS

You will not be paid to help us and we will not pay you back for any costs of delivering at the health facility. You may not benefit from being in this study, but we will use what we learn to try to improve health care for women and newborns in Uganda.

RISKS

You may be uncomfortable having a stranger present at the birth, but you may ask me to leave at any time.

If you say yes, I will observe your birth and take notes on the care you receive, using a smartphone/ tablet computer.

Approval Date: February 9, 2015

Approved Consent Version No.: 2

PI Name: Cherrie Evans

IRB No. 00005383

CONFIDENTIALITY

Neither your name nor the date of services will be provided on any data shared with others. Your identity and any information about you will remain completely confidential. We will not let anyone outside our work see your health information. We will not keep your name on any documents once we leave the facility.

RIGHTS TO REFUSE OR WITHDRAW

Please know that your decision to allow me to observe your birth is your choice. Whether you agree to participate or not will not affect the care you receive at this facility.

Do you have any questions? You may contact the Principal Investigator, Cherrie Evans 410-537-1986 or Innocent Atukunda for Jhpiego in Uganda at 256.712.210802 about your questions or problems with this work. You may contact Dr. Suzanne Kiwanuka, the Chairperson, School of Public Health Institutional Review Board (MakSHS-IRB) Tel: (+256) 0772 886 377.

Do you have any other questions for me? Do I have your permission to be present while you are receiving services today?

May I begin?

Approval Date: May 21, 2015
Approved Consent Version No.:3
PI Name: Cherrie Evans
IRB No. 00005383

Oral Consent 3:
District Trainers and Clinical Mentors – In-depthInterviews
PI Name: Dr. Cherrie Evans
Study Title: *Saving Lives on the Day of Birth: Building and Sustaining Capacity of Frontline Health Workers in Uganda*
JHSPH IRB No.: 5383
PI Version/Date: Version 4, May 19, 2015

[Greeting]. My name is _____. I am from Jhpiego, an organization in Uganda and affiliated with Johns Hopkins University in USA working to improve maternal and newborn health. We would like to talk to you about your work.

STUDY PURPOSE

We have been doing a study to see if a new training package using simulators improves prevention and treatment of postpartum hemorrhage and neonatal asphyxia. We ask you to help us in our research study because you are assisted with this project as either a district trainer or a clinical mentor.

STUDY PROCEDURES

If you say yes, I will speak with you for about 30 minutes and ask your opinion about this program. I will make an audiorecording of the discussion if you agree, and I will take notes. The recording will be erased after I transcribe the recording. I will not include your name in the recording. We do not expect this project to cause you any risks or discomforts. The information collected during this study is not an evaluation of your job performance, but of the training program. Whether you participate or not in this study will have no effect on future job evaluations.

BENEFITS

You will receive no payment or monetary benefits for participating in the training or the data collection.

RISKS/CONFIDENTIALITY

There is a risk that someone outside the study will see your information. We will do our best to keep your information safe by not writing your name on study notes and excluding your name from any reports that are written based on this information.

RIGHTS TO REFUSE OR WITHDRAW

Your participation is entirely voluntary. You are free to withdraw at any time without any effect on your job. You may choose to answer some or all of the questions posed.

You may contact the Principal Investigator, Cherrie Evans in USA +1-410-537-1986 or Innocent Atukunda for Jhpiego in Uganda at +256 782 4545 99 about your questions or concerns with this study. You may contact Dr. Suzanne Kiwanuka, the Chairperson, Makerere University School of Public Health Institutional Review Board (MakSHS-IRB) Tel: Tel: (+256) 0772 886 377.

Do you have any questions?

Oral Consent 4 - Birth Attendants/Providers: Focus Group Discussions

PI Name: Dr. Cherrie Evans

Study Title: *Saving Lives on the Day of Birth: Building and Sustaining Capacity of Frontline Health Workers in Uganda*

Makerere University IRB No.:11353

PI Version/Date: 4/ May 19, 2015

[Greeting]. My name is _____. I am from Jhpiego, an organization in Uganda and affiliated with Johns Hopkins University in USA working to improve maternal and newborn health care. We would like to see if a new training package using simulators improves prevention and treatment of postpartum hemorrhage and neonatal asphyxia. We ask you to help us in our research study because you attend births regularly at this health facility. All birth attendants at this facility are being asked to participate in this study.

If you agree to join, you will participate in a focus group discussion with other health providers at this facility trained by Saving Lives at Birth project. We will ask about your experiences practicing with the simulator. The focus group will take about one hour.

I will make an audio recording of the discussion if you agree, and I will take notes. The recording will be erased after I transcribe it. I will not include your name in the recording.

We do not expect this project to cause you any risks or discomforts. The information collected during this study is not an evaluation of your job performance, but of the training program. Your level of participation in this study will have no effect on future job evaluations.

You do not have to help us in this study; it is your choice.

There is a risk that someone outside the study will see your information. We will do our best to keep your information safe by not recording your name on data collection forms. In a focus group discussion, we encourage participants to keep information confidential but there is no guarantee of this. Any reports on this study will not include any participant names.

You will receive no monetary benefits for participating today.

You may contact the Principal Investigator, Cherrie Evans in USA +1-410-537-1986 or Innocent Atukunda for Jhpiego in Uganda at +256 782 4545 99 about your questions or problems with this work. You may contact the Chairperson Dr. Suzanne Kiwanuka, Makerere University School of Public Health Institutional Review Board (MakSPH-IRB) (+256) 0772 886 377.

Do you have any questions?