

**Maternal Newborn Health Registry (MNH)**

Funding: *Eunice Kennedy Shriver* National Institute of Child Health and Human Development, Bethesda, MD

ClinalTrial.gov ID: NCT01073475

## **Model Consent: Global Network for Children's and Women's Research Network -Maternal and Newborn Health Registry**

**Title of Study:** Maternal and Newborn Health in Developing Countries

**Funding Source and/or Sponsor:** Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), United States National Institutes of Health (NIH)

### What are some general things you should know about research studies?

You are being asked to take part in a research study. It is voluntary to join this study. You may refuse to join, or you may withdraw your consent to be in the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. Deciding not to be in the study or leaving the study before it is done will not affect your relationship with the researcher, or your health care provider. You do not have to be in the research study in order to receive health care during your pregnancy.

You should ask the researchers or staff member who may assist them, any questions you have about this study at any time.

### What is the purpose of this study?

We are doing a study of newborn care that is given in communities in developing countries. This project is funded by the U.S. National Institutes of Health. Since you live or delivered in a participating community, we would like to collect some information about your pregnancy (and baby). This information will be kept confidential and will be coded without your name or any other identifying information about you.

### What will happen if you take part in the study?

A research assistant will ask about this pregnancy and your delivery. This will take about 15 minutes. At six weeks after delivery, we will also see or contact you about your baby. This visit will only take a few minutes of your time and may be during a routine visit, such as immunizations. In addition, a research staff may contact you within 6 months of delivery to ask about your experience with the study staff, this visit would take less than 10 minutes.

### What are the possible risks or discomforts involved from being in this study?

The only possible risk of participating in this project is that your or your baby's name might be seen by persons who are not part of the project. To prevent this, all information will be coded with a number rather than using your name. Although there may not be extra benefits to your baby by being part of the project, the project will help in planning other programs that may benefit other babies who are born in developing countries.

Information from this research study will be retained by (local institution) and RTI International in the United States (U.S.) and in the future may be included in a de-identified public use database managed by NICHD Data and Specimen Hub (DASH) in compliance with the U.S. National Institutes of Health (NIH) Public Access Policy. De-identified means that you and your baby will not be individually identified by name or other personal identifiers in the database. Your full name or any

address details will not be included. Information released will not identify you or your baby's participation in this research study.

If you have questions about this project or a project-related injury, you should contact [investigator contact]. If you have questions about your or your baby's rights as a project participant, please contact [ethics committee contact].

How will information about you be protected?

As a participant in this study, you will assigned a study number. Any information that is collected will be identified by this number and not your name. Your name will only be written in one place, in a book kept in the study office in your health center. No one other than an authorized member of the study team will have access to this book.

Participants in this study will not be identified in any report or publication about this study. Although every effort will be made to keep research records private, there may be times when federal or state laws require the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, (local institution) and (US partner institution) will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of these institutions, research sponsors, or government agencies for purposes of quality control or safety.

We have given you information about the project called "Maternal and Newborn Health in Developing Countries" in the community where your baby will be born. We have discussed the risks and benefits of the project and you understand that you do not have to agree to be in the project or may decide later not to be part of the project. This will not affect your baby's care in any way. If you have any questions, please call [insert senior investigator and ethics committee contact].

*Person requesting consent, please check applicable boxes:*

- Consent obtained (for adult respondent)
- Assent (for minor respondents)
- Permission from family member of minor respondent

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Signature of Person Obtaining Consent

Date

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Signature of Witness

Date

May we contact you for future studies by our study staff?

- Yes  No