Appendix 3: Informed consent form for interviews with women
[INSTITUTIONAL LETTER HEAD]

This informed consent form is for **women** in study sites in ***[country]***, who are invited to participate in **interviews** for the research project "Appropriate use of caesarean section through quality decision-making by women and providers" (QUALI-DEC)**.**

Principal Investigator: ***TBC***
Organization: ***TBC***
Sponsor: ***TBC***
Project: **Appropriate use of caesarean section through quality decision-making by women and providers" (QUALI-DEC)**
Version: **1**

This Informed Consent Form has two parts:

- **Information Sheet (to share information about the study with you)**
- **Certificate of Consent (for signatures if you choose to participate)**

You will be given a copy of the full Informed Consent Form

Part I: Information Sheet

Introduction
Good day. My name is _____, and I work for _____. I am doing research on childbirth care and caesarean section. I am going to give you some information and invite you to be a part of this research. You do not have to decide today whether or not you will participate in the research. Before you decide, you can talk to anyone you feel comfortable with about the research. This consent form may contain words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can ask them of me or of another researcher.

Purpose of the research
The purpose of this study is to better understand care during pregnancy and childbirth, including caesarean section. We would like to better understand how women feel about different methods of giving birth; that is, to give birth vaginally or by caesarean section. Women may have different opinions on the most appropriate way to give birth, and different factors that influence their opinions. In some places, caesarean section rates are high. We are concerned that sometimes women and their babies may not need a caesarean section, but they are receiving one anyway. We would like to understand why this happens, and what different factors influence how women give birth in [your setting].

Type of Research Intervention
This research will involve your participation in an interview that will take approximately 30 minutes (for quantitative questionnaire) to 60-90 minutes (for individual in-depth interview). Clinical data will be extracted from your medical records, unless you object to it.

Participant Selection
You are being invited to take part in this research because we feel that your pregnancy and childbirth experience can contribute much to our understanding of and knowledge about care during pregnancy and childbirth.

- ***Example of question to elucidate understanding:*** *Do you know why we are asking you to take part in this study? Do you know what the study is about?*

Voluntary Participation
Your participation in this research is entirely voluntary. It is your choice whether to participate or not. If you choose

not to participate, it will have no bearing on the type of care you receive throughout your pregnancy and childbirth. You may change your mind later and stop participating even if you agreed earlier.

- ***Examples of question to elucidate understanding:*** *If you decide not to take part in this research study, do you know what your options are? Do you know that you do not have to take part in this research study, if you do not wish to? Do you have any questions?*

Procedures
We are asking you to help us learn more about care during pregnancy and childbirth, including caesarean section. We are inviting you to take part in this research project. If you accept, you will be asked to participate in an interview with [***name of interviewer***] or myself. During the interview, I or another interviewer will sit down with you in a private, comfortable place at the [***location***]. If it is better for you, the interview can take place in your home or a friend's home. If you do not wish to answer any of the questions during the interview, you may say so and the interviewer will move on to the next question. No one else but the interviewer will be present, unless you would like someone else to be there.

The information recorded is confidential, and no one else except **[*name of person(s)]*** will have access to the information documented during your interview. The entire interview will be tape-recorded, but no-one will be identified by name on the tape. The tape will be kept [***explain how the tape will be stored***]. The information recorded is confidential, and no one else except [name of person(s)] will have access to the tapes. The tapes will be destroyed after _____number of days/weeks.

Duration
The research project will last for 60 months in total. This interview will be conducted once and will last 30 to 90 minutes. We will not contact you further after this interview.

- ***Examples of question to elucidate understanding:*** *If you decide to take part in the study, do you know how much time will the interview take? Where will it take place? Do you know how much time will the interview with other people take? If you agree to take part, do you know if you can stop participating? Do you know that you may not respond to the questions that you do not wish to respond to? Etc. Do you have any more questions?*

Risks
We are asking you to share with us some personal and confidential information, and you may feel uncomfortable talking about some of the topics. You do not have to answer any question or take part in the interview if you don't wish to do so, and that is also fine. You do not have to give us any reason for not responding to any question, or for refusing to take part in the interview

Benefits
There will be no direct benefit to you, but your participation will help us understand how childbirth care can be provided in your community.

Reimbursements
You will/will not [***TBC***] be provided any incentive to take part in the research.

- ***Examples of question to elucidate understanding:*** *Can you tell me if you have understood correctly the benefits that you will have if you take part in the study? Do you know if the study will pay for your travel costs and time lost, and do you know how much you will be reimbursed? Do you have any other questions?*

Confidentiality
The research being done may draw attention from other people in your local community and if you participate you may be asked questions by other people in the community. We will not be sharing information about you to anyone outside of the research team. The information that we collect from this research project will be kept private. Any

information about you will have a number on it instead of your name. Only the researchers will know what your number is and we will lock that information up with a lock and key. It will not be shared with or given to anyone.

- ***Example of question to elucidate understanding:*** *Did you understand the procedures that we will be using to make sure that any information that we as researchers collect about you will remain confidential? Do you have any more questions?*

Sharing the Results
Nothing that you tell us today will be shared with anybody outside the research team, and nothing will be attributed to you by name. The knowledge that we get from this research will be shared with you and your community before it is made widely available to the public. There will also be meetings in the community and these will be announced. Following the meetings, we will publish the results so that other interested people may learn from the research.

Right to Refuse or Withdraw
You do not have to take part in this research if you do not wish to do so, and choosing to participate will not affect the care you receive during pregnancy and childbirth in any way. You may stop participating in the interview at any time that you wish without your care being affected. I will give you an opportunity at the end of the interview to review your remarks, and you can ask to modify or remove portions of those, if you do not agree with my notes or if I did not understand you correctly.

Who to Contact
If you have any questions, you can ask them now or later. If you wish to ask questions later, you may contact any of the following:

[name, address/telephone number/e-mail]

This proposal has been reviewed and approved by [*name of the local IRB*], which is a committee whose task it is to make sure that research participants are protected from harm. If you wish to find about more about the IRB, contact [*name, address, telephone number*.]). It has also been reviewed by the Ethics Review Committee of the World Health Organization (WHO), which is supporting the study.

- ***Example of question to elucidate understanding:*** *Do you know that you do not have to take part in this study if you do not wish to? You can say No if you wish to? Do you know that you can ask me questions later, if you wish to? Do you know that I have given the contact details of the person who can give you more information about the study? Etc.*

You can ask me any more questions about any part of the research study, if you wish to. Do you have any questions?

Part II: Certificate of Consent

I have been invited to participate in a research interview about care during pregnancy and childbirth, including caesarean section.

(This section is mandatory)
I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions I have been asked have been answered to my satisfaction. I consent voluntarily to be a participant in this study

Print Name of Participant_____

Signature of Participant _____

Date _____
Day/month/year

If illiterate

Thumb print of participant 

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the following will be done:

1.
2.
3.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this ICF has been provided to the participant.
Print Name of Researcher/person taking the consent_____

Signature of Researcher /person taking the consent_____

Date _____
Day/month/year