

***Informed Consent Template for
Research Involving Children (Qualitative Studies)***

For use with Participant Observation, Focus Group Discussions (FGD), Interviews, and Surveys
(language used throughout form should be at the level of a local student of class 6th/8th)

Notes to Researchers:

1. Please note that this is a template developed by WHO ERC to assist the Principal Investigator in the design of their informed consent forms (ICF). It is important that Principal Investigators adapt their own ICFs to the outline and requirements of their particular study. **The logo of the collaborating institution must be used on the ICF and not the WHO logo.**

2. Do not be concerned by the length of this template. It is long only because it contains guidance and explanations which are for you and which you will not include in the informed consent forms that you develop and provide to participants in your research.

2. In this template:

- square brackets indicate where specific information is to be inserted
- bold lettering indicates sections or wording which should be included
- standard lettering is used for explanations to researchers only and must not be included in your consent forms
- italics are used to provide examples of phrasing. **These are only examples.** **Researchers should use wording which provides the best information about their particular research project and which is most appropriate to their research population.**

[YOUR INSTITUTIONAL LETTERHEAD]
Please do not submit consent forms on the WHO letterhead

[Informed Consent Form for _____]

Name the group of individuals for whom this consent is written. Because research for a single project is often carried out with a number of different groups of individuals - for example healthcare workers, patients, and parents of patients - it is important that you identify which group this particular consent is for.

Example: This informed consent form is for parents of adolescent girls and boys participating in the research titled, "What do we want: Adolescents and health systems."

[Name of Principle Investigator]

[Name of Organization]

[Name of Sponsor]

[Name of Project and Version]

This Informed Consent Form has two parts:

- **Information Sheet (to share information about the study with you)**
- **Certificate of Consent (for signatures if you agree that your child may participate)**

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

Part I: Information Sheet

Introduction

Briefly state who you are and explain that you are inviting them to have their child participate in research which you are doing. Inform them that they may talk to anyone they feel comfortable talking with about the research and that they can take time to reflect on whether they want their child to participate or not. Assure the parent that if they do not understand some of the words or concepts, that you will take time to explain them as you go along and that they may ask questions now or later.

Example: I am X, and I work at Y organization in _____. I am doing some research which might help your clinic/hospital do more to help teenagers become and stay healthier. In our research we will talk to many teenagers, both girls and boys, and ask them a number of questions. Whenever researchers study children, we talk to the parents and ask them for their permission. After you have heard more about the study, and if you agree, then the next thing I will do is ask your daughter/son for their agreement as well. Both of you have to agree independently before I can begin.

You do not have to decide today whether or not you agree to have your child participate in this research. Before you decide, you can talk to anyone you feel comfortable with.

There may be some 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

Explain in lay terms why the research is being done and what is expected from the results.
Explain why you need to conduct the research with children.

Example: *It is possible that the clinics and the hospital in this region are not providing some of the services that are important for teenagers. In this study we will talk to teenage girls and boys about what they know about caring for their bodies in a healthy way including sexual and reproductive health. We will invite them to share their knowledge and understanding with us so that we can find ways of meeting their needs at the local clinics and hospital.*

Type of Research Intervention

Briefly state the intervention. This will be expanded upon in the procedures section.

Example: *A questionnaire OR a focus group OR an interview*

Selection of Participants

State clearly why you have chosen their child to participate in this study. Parents may wonder why their children have been chosen for a study and may be fearful, confused or concerned.

Example: *We want to talk to many teenagers about their health and what information or services they want for themselves. One part of health that we want to talk to them about is sexuality. We would like to ask your daughter/son to participate because she/he is a teenager and lives in this region.*

Voluntary Participation

Indicate clearly that they can choose for their child to participate or not and reassure they will still receive all the services they usually do if they choose not to participate. Also inform them that their child will also have input into the decision. This can be repeated and expanded upon later in the form as well. It is important to state clearly at the beginning of the form that participation is voluntary so that the other information can be heard in this context. Participants may also be more alert at the beginning.

Example: *You do not have to agree that your daughter/son can talk to us. You can choose to say no and any services that you and your family receive at this centre will not change. We know that the decision can be difficult when it involves your children. And, it can be especially hard when the research includes sensitive topics like sexuality. You can ask as many questions as you like and we take the time to answer them. You don't have to decide today. You can think about it and tell me what you decide later.*

Protocol

Explain what each of the steps or procedures involves. Indicate when the research will take place and where. If there are surveys, indicate where and how the surveys will be collected and distributed.

1) the following applies only to focus group discussions:

Example: *Your daughter/son will take part in a discussion with 7-8 other teenagers, or a mix of teenagers and social service workers from the community. The girls and boys will be in separate groups. This discussion will be guided by [give name of moderator] or me.*

2) the following applies only to interviews:

Example: *Your daughter/son will participate in an interview with [name of interviewer] or myself.*

3) the following applies only to questionnaire surveys:

Example: *Your daughter/son will fill out a questionnaire which will be provided by [name of distributor of blank questionnaires] and collected by [name of collector of completed questionnaires]. **OR** The questionnaire can be read aloud and she/he can give me the answer which she/he wants me to write.*

Explain the type of questions that the participants are likely to be asked in the focus group discussion, interview or in the questionnaire. If the questions are sensitive, acknowledge this, try to anticipate parents' concerns and protective responses, and address these. Parents may be concerned that talking about sexuality may encourage sexual behavior. Other concerns may include disbelief that their child is ready to talk about sexuality, or parents may be personally embarrassed.

1) The following applies only to focus group discussions:

Example: *The group discussion will start with me, or the focus group guide (use the local word for group discussion leader), making sure that the participants are comfortable. We will also answer questions about the research that they might have. Then we will ask questions about the health system in this community. We will talk about where they go for information about health, and whether they get the information and services they need and want. We will encourage them to talk about sexual and reproductive health as well as other important health topics such as food and nutrition. These are the types of questions we will ask. We will not ask them to share personal stories or anything that they are not comfortable sharing.*

The discussion will take place in [location of the FGD], and no one else but the people who take part in the discussion and the guide or I will be present during this discussion. The entire discussion 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) with access to the tapes] will be allowed to listen to the tapes. [The tapes will be destroyed after ____period of time.]

2) The following applies only to interviews:

Example: *If your daughter does not wish to answer any of the questions during the interview, she may say so and the interviewer will move on to the next question. The interview will take place in [location of the interview], and no one else but the interviewer will be present unless your child asks for someone else to be there. The information recorded is confidential, and no one else except [name of person(s) with access to the information] will have access to the information documented during your interview.) [The tapes will be destroyed after _____period of time.]*

3) The following applies only to questionnaires and surveys:

Example: *If your daughter/son does not wish to answer some of the questions included in the questionnaire, she/he may skip them and move on to the next question. The information recorded is confidential, and no one else except [name of person(s) with access to the information] will have access to her questionnaire. [The questionnaires will be destroyed after ____period of time.]*

Duration

Include a statement about the time commitments of the study for the child and any time commitments on the part of the parent(s). Include both the duration of the study and follow-up, if relevant.

Example: *We are asking your child to participate in an interview which will take about 1 hour of her/his time. We can do this outside of school/work hours. There is also a questionnaire that we will either provide to your child or which we will do together with her/him. This also takes about an hour. Altogether, we are asking for about 2 hours of your child's time.*

Risks and Discomforts

Explain any risks or discomforts including any limits to confidentiality.

Example: *There is a slight risk that your son/daughter may share some personal or confidential information by chance or that he/she may feel uncomfortable talking about some of the topics. However, we do not wish this to happen, and he/she may refuse to answer any question or not take part in a portion of the discussion/interview/questionnaire if he/she feels the question(s) are too personal or if talking about them makes him/her uncomfortable.*

Your daughter/son may choose to tell you about the interview and the questionnaire but she does not have to do this. We will not be sharing with you either the questions we ask nor the responses given to us by your child.

Benefits

Describe any benefits to their child, to the community, or any benefits which are expected in the future as a result of the research.

Example: *There will be no immediate and direct benefit to your child or to you, but your child's participation is likely to help us find out more about the health needs of teenage girls and boys and we hope that these will help the local clinics and hospitals to meet those needs better in the future.*

Incentives

State clearly what you will provide the participants with as a result of their participation. WHO does not encourage incentives beyond reimbursements for expenses incurred as a result of participation in research. The expenses may include, for example, travel expenses and reimbursement for time lost. The amount should be determined within the host country context.

Example: *Your daughter/son will not be provided with any payment to take part in the research. However, she/he will be given with [provide a figure, if money is involved] for her/his time, and travel expense (if applicable).*

Confidentiality:

Explain how the research team will maintain the confidentiality of data, especially with respect to the information about the participant. Outline any limits there are to confidentiality. Note that with focus groups confidentiality cannot be guaranteed because what is said within the group becomes common knowledge. Participants can be asked not to share outside of the group but this does not guarantee confidentiality.

Example: *Because something out of the ordinary is being done through research in your community, it will draw attention. If your daughter/son participates, she and you may be asked questions by other people in the community.*

We will not be sharing information about your son or daughter outside of the research team. The information that we collect from this research project will be kept confidential. Information about your child that will be collected from the research will be put away and no-one but the researchers will be able to see it. Any information about your child will have a number on it instead of his/her name. Only the researchers will know what his/her number is and we will lock that information up with a lock and key. It will not be shared with or given to anyone except [name who will have access to the information, such as research sponsors, DSMB board, your clinician, etc].

The following applies to focus groups:

Example: *We will ask your child and others in the group not to talk to people outside the group about what was said in the group. We will, in other words, ask each participant to keep what was said in the group confidential. You should know, however, that we cannot stop or prevent participants who were in the group from sharing things that should be confidential.*

Sharing of Research Findings

Include a statement indicating that the research findings will be shared in a timely fashion but that confidential information will remain confidential. If you have a plan and timeline for the sharing of information, include the details. Also inform the parent that the research findings will be shared more broadly, for examples, through publications and conferences.

Example: *At the end of the study, we will be sharing what we have learnt with the participants and with the community. We will do this by meeting first with the participants and then with the larger community. A written report will also be given to the participants which they can share with their families. We will also publish the results in order that other interested people may learn from our research.*

Right to refuse or withdraw

Explain again the voluntary nature of consent. Also explain that their child will be asked to agree - or assent - and that the child's concerns and wishes will be taken very seriously.

Example: *You may choose not to have your child participate in this study and your child does not have to take part in this research if she/he does not wish to do so. Choosing to participate or not will not affect either your own or your child's future treatment at the Centre here in any way. You and your child will still have all the benefits that would otherwise be available at this Centre. Your child may stop participating in the discussion/interview at any time that you or she/he wish without either of you losing any of your rights here.*

Who to Contact

Provide the name and contact information of someone who is involved, informed and accessible (a local person who can actually be contacted. State also that the proposal has been approved and how.

Example: *If you have any questions you may ask them now or later, even after the study has started. 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 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.]

PART II: Certificate of Consent

Certificate of Consent

This section can be written in the first person. It should include a few brief statements about the research and be followed by a statement similar to the one in bold below. If the participant is illiterate but gives oral consent a witness must sign. A researcher or the person going over the informed consent must sign each consent. Because the certificate is an integral part of the information sheet and not a stand-alone document, the layout or design of the form should reflect this.

Example: I have been asked to give consent for my daughter/son to participate in this research study which will involve her completing one interview and one questionnaire .I understand that she/he will also be asked to give permission and that her/his wishes will be respected. I have been informed that the risks are minimal and may include only _____. I am aware that there may be no benefit to either my child or me personally and that we will not be compensated beyond travel expenses. I have been provided with the name of a researcher who can be easily contacted using the number I was given for that person.

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 that I have asked have been answered to my satisfaction. I consent voluntarily for my child to participate as a participant in this study and understand that I have the right to withdraw her/him from the study at any time without in any way affecting our care at this Centre.

Print Name of Parent or Guardian _____

Signature of Parent of Guardian _____

Date _____
Day/month/year

If illiterate

A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumb print as well.

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

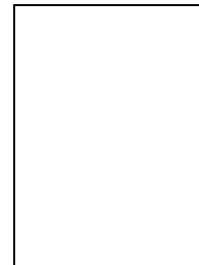
Print name of witness _____

AND

Thumb print of participant

Signature of witness _____

Date _____
Day/month/year



I have accurately read or witnessed the accurate reading of the consent form to the parent/guardian of the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of researcher _____

Signature of researcher _____

Date _____

Day/month/year

A copy of this Informed Consent Form has been provided to the parent or guardian of the participant ____ (initialled by researcher/assistant)

An Informed Assent Form will ____ OR will not ____ be completed.