	<u>Informed Consent Form for Qualitative Studies</u>	Document No.	IITB/IEC/ICF-C/2023
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Please delete the instructions marked in BLUE before submitting the proposal for review

Notes to Researchers:

1. This template is for **research interventions that use questionnaires, in-depth interviews or focus group discussions**. Hence, language used throughout form should be at the level of a local student of class 6th/8th.

Please note that this is a template developed by the 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.


2. The informed consent form consists of two parts: the information sheet and the consent certificate.

3. This template includes examples of key questions that may be asked at the end of each section that could ensure the understanding of the information being provided, especially if the research study is complex. These are just examples, and suggestions, and the investigators will have to modify the questions depending upon their study.

4. Please do not delete any sections. If any portion is not relevant to your study, please mark it as NA.

5. ICF should be drafted in simple language (*language used throughout form should be at the level of a local student of class 6th/8th*) – English, Hindi and other vernacular languages as applicable

TEMPLATE ON FOLLOWING PAGE...

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Informed Consent Form for _____ [Study Title]

Name the group of individuals for whom this informed consent form 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.

Name of Principal Investigator

Name of Organization

Name of Sponsor

Name of Proposal

This Statement of Consent consists of two parts:

- Information Sheet (to share information about unused samples with you)
- Certificate of Consent (to record your agreement)

You will be given a copy of the full Statement of Consent

PART I: Information Sheet

I. Introduction

Briefly state who you are and explain that you are inviting them to participate in the research you are doing.

II. Purpose of the research

Explain the research question in layman terms which will clarify rather than confuse.

III. Type of Research Intervention


Briefly state the type of intervention that will be undertaken.

IV. Participant Selection

Indicate why you have chosen this person to participate in this research. People wonder why they have been chosen and may be fearful, confused or concerned.

V. Voluntary Participation

Indicate clearly that they can choose to participate or not. State, only if it is applicable, that they will still receive all the services they usually do if they choose not to

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participate.

VI. Procedures

A. Provide a brief introduction to the format of the research study.

B. Explain the type of questions that the participants are likely to be asked in the focus group, the interviews, or the survey. If the research involves questions or discussion which may be sensitive or potentially cause embarrassment, inform the participant of this.

VII. Duration

Include a statement about the time commitments of the research for the participant including both the duration of the research and follow-up, if relevant.

VIII. Risks

Explain and describe any risks that you anticipate or that are possible. The risks depend upon the nature and type of qualitative intervention, and should be, as usual, tailored to the specific issue and situation.

IX. Benefits

Benefits may be divided into benefits to the individual, benefits to the community in which the individual resides, and benefits to society as a whole as a result of finding an answer to the research question. Mention only those activities that will be actual benefits and not those to which they are entitled regardless of participation.

X. Reimbursements


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 the research. These may include, for example, travel costs and reimbursement for time lost. The amount should be determined within the host country context.

XI. Confidentiality

Explain how the research team will maintain the confidentiality of data with respect to both information about the participant and information that the participant shares. Outline any limits to confidentiality. Inform the participant that because something out of the ordinary is being done through research, any individual taking part in the research is likely to be more easily identified by members of the community and therefore more likely to be stigmatized. If the research is sensitive and/or involves participants who are highly vulnerable - research concerning violence against women for example - explain to the participant any extra precautions you will take to ensure safety and anonymity.

XII. Sharing the Results

Your plan for sharing the findings with the participants should be provided. If you have a plan and a timeline for the sharing of information, include the details. You may also inform the participant that the research findings will be shared more broadly, for example, through publications and conferences.

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XIII. Right to Refuse or Withdraw

This is a reconfirmation that participation is voluntary and includes the right to withdraw. Tailor this section to ensure that it fits for the group for whom you are seeking consent.

XIV. Who to Contact

Provide the name and contact information of someone who is involved, informed and accessible (who is part of the investigating team – PI or Co-PI). State also that the proposal has been approved and how.

XV. This proposal has been reviewed and approved by IIT Bombay Institute Ethics Committee (IEC), 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 IEC, contact IEC Member secretary, Dr. Sreelekha P. Gopinathan, Technical Officer, IRCC at iec@ircc.iitb.ac.in

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Part II: Certificate of Consent

This section must be written in the first person. It should include a few brief statements about the research and be followed by a statement similar 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 informed consent and not a stand-alone document, the layout or design of the form should reflect this.

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

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.

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

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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 the requirements of the study as outlined in the Information Sheet.

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 Informed Consent Form has been provided to the parent or guardian of the participant.

Print Name of Researcher/person taking the consent _____

Signature of Researcher /person taking the consent _____

Date _____
Day/month/year

Print Name of Principal Investigator _____

Signature of Principal Investigator _____

Date _____
Day/month/year

[Note: This document should be signed by the PI / Researchers at the time of taking consent of participants]