
	<b>Informed Parental Consent Form Template for Research Involving Children (Clinical Studies)</b>	Document No	IITB/IEC/ICF/01
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**(For use with Participant Observation, Focus Group Discussions, Interviews, and Surveys)**  
(*language used throughout form should be at the level of a local student of class 6<sup>th</sup>/8<sup>th</sup>*)

Notes to Researchers:

1. 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 6<sup>th</sup>/8<sup>th</sup>*) – 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 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.

*(This informed consent form is for the parents of children between the ages of 1 and 4 years of age who attend clinic Z, and who we are asking to participate in research X )*

[Name of Principal Investigator]

[Name of Organization]

[Name of Sponsor]

[Name of Proposal 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.

**Purpose**


Explain the problem/research question in lay terms which will clarify rather than confuse.

**Type of Research Intervention**

Briefly state the intervention if you have not already done so. This will be expanded upon in the procedures section.

**Participant selection**

State clearly why you have chosen their child to participate in this study. Parents may wonder why their child has been chosen for a study and may be fearful, confused or concerned. Include a brief statement on why children, rather than adults, are being studied.

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### **Voluntary Participation**

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

Include the following section only if the protocol is for a clinical trial:

### **Information on the Trial Drug [Name of Drug]**

- 1) give the phase of the trial and explain what that means. Explain to the parent why you are comparing or testing the drugs.
- 2) provide as much information as is appropriate and understandable about the drug such as its manufacturer or location of manufacture and the reason for its development.
- 3) explain the known experience with this drug
- 4) explain comprehensively all the known side-effects/toxicity of this drug, as well as the adverse effects of all the other medicines that are being used in the trial

### **Procedures and Protocol**

It is important that the parents know what to expect and what is expected of them and their child. Describe or explain the exact procedures that will be followed on a step-by-step basis, the tests that will be done, and the drugs that will be given.

#### **A. Unfamiliar Procedures**

If the protocol is for a clinical trial:

1) involving randomization or blinding, the participants should be told what that means and what chance they have of getting which drug (i.e. one in four chances of getting the test drug). A very minimal statement is provided below to give you an example. You may need to be more explicit about what is exactly involved.


2) involving a placebo it is important to ensure that the participants understand what is meant by a placebo. An example for a placebo is given below.

3) which may necessitate a rescue medicine, then provide information about the rescue medicine or treatment such as what it is and the criterion for its use. For example, in pain trials, if the test drug does not control pain, then intravenous morphine may be used as a rescue medicine

#### **B. Description of the Process**

Describe the process on a step-by-step basis.

In case of a clinical research:

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Explain that there are standards/guidelines that must be followed. If a biopsy will be taken, then explain whether it will be under local anesthesia, sedation or general anesthesia, and what sort of symptoms and side effects the participant should expect under each category.

For any clinical study (if relevant):

If blood samples are to be taken explain how many times and how much in a language that the person understands. It may, for example, be inappropriate to tell a tribal villager that blood equal to a table-spoon full will be taken.

If the tissues/blood samples or any other human biological material will be stored for a duration longer than the research purpose, or is likely to be used for a purpose other than mentioned in the research proposal, then provide information about this and obtain consent specifically for such storage and use in addition to consent for participation in the study - (see last section)

If not, then explicitly mention here that the biological samples obtained during this research procedure will be used only for this research, and will be destroyed after \_\_\_ years, when the research is completed.

**Duration**

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

**Side Effects**

Parents should be told if there are any known or anticipated side effects and what will happen in the event of a side effect or an unexpected event.

**Risks**


A risk can be thought of as being the possibility that harm may occur. Explain and describe any such possible or anticipated risks. Provide enough information about the risks that the parent can make an informed decision. Describe the level of care that will be available in the event that harm does occur, who will provide it, and who will pay for it.

**Discomforts**

Explain and describe the type and source of any anticipated discomforts that are in addition to the side effects and risks discussed above.

**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.

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

### Confidentiality

Explain how the research team will maintain the confidentiality of data, especially with respect to the information about the participant, which would otherwise be known only to the physician but would now be available to the entire research team. 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 is therefore more likely to be stigmatized.

### Sharing of the results

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

### Right to Refuse or Withdraw

This is a reconfirmation that participation is voluntary and includes the right to withdraw. Tailor this section well to ensure that it fits for the group for whom you are seeking consent. The example used here is for a parent of an infant at a clinic.

### Alternatives to participating

Include this section only if the study involves administration of investigational drugs or use of new therapeutic procedures. It is important to explain and describe the established standard treatment.


### 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.

**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.]**

## PART II: Certificate of Consent

### Certificate of Consent

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This section should be written in the first person and have 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. The certificate of consent should avoid statements that have "I understand...." phrases. The understanding should perhaps be better tested through targeted questions during the reading of the information sheet (some examples of questions are given above), or through the questions being asked at the end of the reading of the information sheet, if the potential participant is reading the information sheet him/herself.

**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.**

**Print Name of Participant** \_\_\_\_\_

**Print Name of Parent or Guardian** \_\_\_\_\_

**Signature of Parent or 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 parent 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 witness** \_\_\_\_\_

**AND**

**Thumb print of parent**


**Signature of witness** \_\_\_\_\_

**Date** \_\_\_\_\_  
Day/month/year

**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**

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**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**

An Informed Assent Form will \_\_\_\_\_ OR will not \_\_\_\_\_ be completed.