**INDIAN INSTITUE OF TECHNOLOGY ROPAR**

**Office of the Dean of Research and Development**

**Institutional Ethics Committee (Humans)**

**Informed Consent Document (ICD) for Qualitative Studies involving Children**

**Form No. IEC-104**

**Notes**

* Use this ICD **template** for research employing the use of questionnaires, in-depth interviews, or focus group discussions involving children. Use simple language at the level of 6-8th grades. Where required, the ICD in English can be translated into Hindi or other languages (spoken in that region)
* The template was created by WHO ERC to help PIs in creating their informed consent forms (ICD). The PIs can modify the ICDs to fit the specifications of their specific research
* This ICD is divided into two sections: the information sheet and the consent certificate
* It includes examples of questions that may be asked at the end of each section to ensure the understanding of the information being provided. However, **these are just examples, and PI may modify questions depending upon their study**
* Please do not delete any sections, and mark “NA” in sections, which are not applicable to your research

**Informed Consent Form (ICD) for \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Study Title**

Specify the group of people on whose behalf this consent is being signed. It is important because research for one project involves a variety of distinct groups of people, like healthcare professionals, patients, and parents of patients.

**Name of the Principal Investigator**

**Name of the Organization**

**Name of the Sponsor**

**Name of the Project and Version**

Include the information that this ICD has two parts- **Information Sheet** (to share information about the study with you)and **Certificate of Consent** (for signatures, if you agree that your child may participate). PI will provide a copy of **full ICD** (and **translations**, where required).

**Part I: Information Sheet**

**Introduction**

Briefly introduce yourself and explain why you are inviting their child to participate in your research.

**Purpose**

In a simple language, explain why the research is being done and expected results. Describe why you need to do the study with children.

**Type of Research Intervention**

Describe the intervention that will be used- a questionnaire or a focus group or an interview.

**Selection of Participants**

Explain why you selected their child to take part in this study. Parents may be scared, confused, or anxious because their kids have been chosen for the study.

**Voluntary Participation**

Make it absolutely clear from the beginning that it is for the parents to decide whether their child will participate in the study, and they will receive all services they usually do even if they decide not to participate. Also, inform the parent that their child will participate in the decision-making process. The same must be repeated and expanded later in the ICD.

**Procedure**

Describe each step or method involved in the study, and indicate where and when the research will be done.

**Duration**

Include a statement about the time commitment of the child and/or parent(s) for the study, and include both the duration of the study and follow-up, if required.

**Risks and Discomforts**

Describe risks or discomforts, and any confidentiality restrictions.

**Benefits**

Outline benefits to the child, the community where the child lives, and others in the future as a result of this study.

**Reimbursements**

State what will be offered to participants in exchange for their involvement in the study. WHO does not encourage paying incentives beyond payment for expenses incurred as a result of their involvement in research (travel costs and compensation for the time lost).

**Confidentiality:**

Describe how your team will protect the confidentiality of data, in particular, the information about the participant, and include any limits to the confidentiality.

**Sharing of Research Findings**

Include a statement regarding the sharing of research findings while keeping the confidential information private, and include the details of a schedule and a plan for sharing or distributing information. Also let the parent know that the study's results will be communicated widely through publications and conferences.

**Right to refuse or withdraw**

Explain again the right of the child and his/her parent to refuse or withdraw from the study. In addition, inform the parent that the child’s worries and wishes will be respected.

**Who to Contact**

List the name and contact details of a team member (PI or Co-PI) who is involved and accessible.

Include the following information regarding the approval of the proposal.

**The [name of the body], a body tasked with ensuring that research subjects are safeguarded from harm, has evaluated and approved this proposal. To learn more about the body, contact [name, address, and phone number of member secretary].**

**PART II: Certificate of Consent**

This section must be written in first person. Include a few brief sentences regarding the research, and follow it up with a statement similar to the one written in bold below. Each ICD must be signed by the participant’s parents/guardian or a witness if the participant or his/her parent, being illiterate, has given an oral consent. Each ICD must be signed by the PI or the person who reviewed it.

**The information above has either been read to me or I have read it myself. I had the chance to inquire about it, and every inquiry I've made has received satisfactory answers. I voluntarily agree to give my child permission to take part in this stay as a participant.**

**Name of the Parent or Guardian (print):**

**Signature of the Parent or Guardian**

**Date (day/month/year):**

***If illiterate***

**I saw the ICD/permission document being correctly read to the parent/guardian of the prospective participant, who also got the chance to ask questions. I confirm that the person voluntarily gave the consent.**

**Name of the witness: and Thumb print of the participant**

**Signature of the witness:**

**Date (day/month/year):**

**Statement made by the researcher or consent-seeker**

**I did the best I could to make sure the potential participant understood the information sheet's requirements and that I had appropriately presented the information sheet to him or her.**

**I certify that the participant was given the chance to inquire about the study, and I have accurately and fully responded to all of the participant's inquiries. I confirm that the person's consent was freely provided and voluntarily given, and that it was not forced upon them*.***

**A copy of this ICD (translations, where required) has been given to the parent or guardian of the participant: Yes / No**

**Name of the Researcher****/Person taking the Consent (print):**

**Signature of the Researcher/Person taking the consent:**

**Date (day/month/year):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Name of the Principal Investigator (print):**

**Signature of the Principal Investigator:**

**Date (day/month/year):\_\_\_\_\_\_\_\_\_\_\_\_\_**