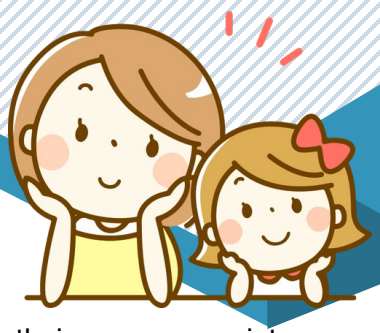

Information Sheet / Informed Consent Form for Research in Children or Minors

Since children's levels of perception and understanding depends largely on their age, appropriate amounts of information about the research conducted with them should be taken into consideration, as well as their willingness to participate along with their parents' decision.

MU-CIRB has prepared templates tailored to different age groups as follows:

Age of Participants *	Information Sheet for Children	Information Sheet for Parents	Remarks
Newborn – 6 years	Not required	Use the same form as the one used for adults with a change in the pronoun from "you" to "children under your care."	Children at this age do not have sufficient maturity to understand or make decisions on their own, so parents are allowed to think on their behalf. The only consent form required is the one completed by the parents.
7 – 12 years	The sheet should contain easy and short pieces of information that specifies only what children are required to do and an area where they sign or use any marks to show their consent.	Use the same form as the one used for adults with a change in the pronoun from "you" to "children under your care."	Children of this age meet the requirements of Primary school (grades 1–6) enrollment. Two forms required: one for children and one for the parents
13 – 17 years	Use the same form as that for parents.	Use the same form as the one used for adults with a change in the pronoun from "you" to "children under your care."	Similar to adults, children at the age eligible for entry into high school (grades 7–12) can understand information and its details. Therefore, only one form is used for both the children and their parents, requiring signatures from both. Use one form, but both signed together.
18 years and older	Use the adult consent form	None	In some countries, the age at which people can sign consent is 20, but in Thailand, it is 18. According to the patients' rights announced by the Medical Council, individuals at the age of 18 and over can give consent when receiving medical treatment.

*** The age is calculated based on the numbers of days and months after the birthday: for example, 6 years, 11 months, and 29 days is accounted as 6 years old.**

To recruit children aged 5 – 18 to participate in a research project, the age at which children are eligible for entry into schools from kindergarten through high school (grade 12).

Researchers must prepare information sheets as follows:

1. An information sheet for parents of children of all ages with a space for the signature of children aged 13 – 17 years to avoid too many forms. The title of this information sheet must be specified as “For parents and children aged 13 – 17 years”.
2. A document for children aged 7 - 12 includes both information and a consent statement in the same document.
3. For 18-year-old and older participants, use the same information sheet prepared for parents, but with the pronoun “you” to refer to them as readers and research participants. Unlike in the information sheet for parents, research participants are referred to as “children under your care”.

Researchers must prepare consent letters as follows:

1. A parental consent letter for parents to sign to give consent for their children to participate in the research. This is for children of all ages up to 17 years old; or
2. A consent letter for 18-year-old and older participants.

In other countries, information sheets and consent letters are included in the same document known as an “informed consent form”. The research information part and the consent statement part are clearly separated into different sections with different pronouns used to refer to readers as parents and children as research participants.

If the information sheet and the consent letter are prepared as two separate documents, researchers must prepare five documents. However, if researchers prepare an informed consent form, they will prepare only three documents with less confusion.

Researchers are allowed to use an informed consent form because the research participants will receive the same information. The form is convenient to use and record.