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Guidance for Assent for persons below ages eighteen

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Guidance for Assent from Children below age Eighteen

Definition of ‘Assent’

‘Assent’ indicates the young person’s willingness to participate in a research. It cannot be treated as mere formality and should be actively sought. Mere non-refusal to participate cannot signify assent and a researcher who requires participation from those aged below 18 years should seek the assent of such participants.

Method of Documenting Assent

Assent forms can be used to document a person’s willingness to participate, if they are between the ages 12-18 and eligible for participating in a research.

Persons who are 18 years and above are said to have attained majority under Indian law.(The Indian Majority Act, 1875) They can provide consent on their own. However, persons below age 18 have not attained majority under Indian law.

Assent from a participant below the age of 18 and above the age of 12 is considered because morally one feels that they are almost fully autonomous beings, capable of making choices regarding their bodies, even if the law does not recognise their capacities yet. For this reason, for persons between ages 12-18, a researcher is required to provide assent in the same way that they may provide consent. But in addition, they have to fulfill the legal requirement of taking consent from the legal guardian of the person aged 12-18. For most persons between the ages 12-18, parents are the legal guardians, unless of course they are ward of court or some one else has been appointed as the legal guardian. Then, in addition to obtaining assent, one is required to obtain consent from the parents/legal guardians of the participant, provided the individual wishes to participate.

Language to be used in Assent forms

There can be no difference in the information conveyed to the person below age 18 and that conveyed to their guardians. However, the language to be used in the assent form should be simplified to enable greater comprehension. This is particularly important when participants could be much younger than those giving consent. It is not merely a matter of literacy of the person providing consent/assent; it is an issue relating to their ability to make autonomous decisions about themselves after being informed of what participation in the research entails.

Sequence for Taking Assent and Consent

There is no specified sequence for taking assent and consent.

For minimal risk studies: For minimal risk studies, the sequence can be in any order – consent first and assent later or vice versa.

For more than minimal risk studies: For more than minimal risk studies, a researcher is advised to consider practical as well as potential legal issues relating to the sequence and apply their minds to this matter. The sequence in which assent and consent will be taken will have to be justified in the submission to the IEC.

Practical considerations for married women between the ages 12-18: Who is the legal guardian of married women below the age 18?

Married women above the age 18 are their own guardians and they will give consent on their own behalf.

When women are married before the age 18 and are respondents in studies obtaining legal consent is necessary. This consent is taken in addition to the assent that they will provide.

Usually parents are the legal guardians for women below age 18. However, going to parents for consent becomes a social problem in patrilocal societies (societies where women live with their in-laws after marriage) as married women will be found in their affinal homes (in-laws home). Sometimes, especially in research on gender based violence etc, it would be very difficult to ask women in their affinal homes (in-laws homes) to identify husbands as legal guardians (and these husbands may also be well below the age of 18 and not able to provide consent too). In these circumstances, the practice has been to ask women to identify an adult member of the household who they would consider appropriate to give consent on their behalf. Then, this adult member is sought out to provide consent (in addition to the assent that has already been obtained).

The number of forms required for research participants between ages 12-18

A researcher will have to provide two forms:

1. Assent form that gives information and takes the person's agreement to participate (for participants between ages 12-18) and
2. Consent form for the parents/ guardians of participants between the ages 12-18 that provides information and takes consent.

Persons below age 12:

For persons below age 12, the parental or guardian's consent is sufficient.

Special Caveats

Notwithstanding anything provided in the guidance for Assent, the IEC may require a researcher to obtain assent from children as young as 7 years of age or above, depending on the nature of risk and other considerations.

Definition of Legal Guardian

For children below age 18, the natural guardians are the parents, that is, the father and the mother. In the absence of both parents, consent should be sought from legal guardians. A legal guardian is appointed for a minor by a Court of Law, in the absence of the natural guardians.

When minors are residing in settings where natural guardians are not alive or present, the local guardian (a person who is looking after the affairs of the minor) is presumed to be the guardian. However, this condition of local guardian does not apply to institutionalized ¹minors.

¹ Institutionalised minors: This means, persons below the age 18, who are living in orphanages or residential schools or remand homes etc where a collective of such persons below the age 18 can be found.