

## Informed consent models

By default consent is active, requiring a deliberate act of the participant (“opt-in”). The type of informed consent to be used depends on the age of the participants and whether they are mentally competent.

*Mental competence is defined as taking decisions independently and being able to oversee the consequences of your decisions.*

### Model 1:

Intended for research involving participants 16 years and older that are mentally competent. For this study consent must be personally granted by those involved.

It may be good practice to inform the parents or guardians of participants that are 16 and 17 years of age. For some type of research, it is even needed to ask the consent of the parent or guardians (in such case, use consent model 3).

Consent for participants that are mentally competent can also be granted using an online form.

### Model 2:

Intended for research involving minors < 12 years and participants that are mentally incompetent:

- minors younger than 12 years, minors as of the age of 12 that are (temporarily) mentally incompetent. Consent for the minors must be granted solely by the parent(s) that exercise authority or the guardian;
- adults that are mentally incompetent. Consent must be granted by the legal representative or, if unavailable, by the person that has a written mandate from the person concerned, or if unavailable, by the spouse or other life partner of the person concerned.

### Model 3:

Intended for research involving minors between the age of 12 and 17 years. For this research consent must be personally granted by those involved and their parent(s) or guardians (in some cases this model can be used for the age of 16-17 years).

Also refer to the information provided by the cETO related to informed consent involving minors