

## Research on and with children and adolescents under the age of 18

### Guidelines for the provision of study information

**1.** If the trial subjects are **neonates, infants and toddlers**, it will not be possible to brief them. Their legal representatives (usually parents, legal guardians) receive all the information.

**2. Children with a developmental age 10 years or under** should be briefed verbally. Their legal representatives (usually parents, legal guardians) receive all the information.

The legal representatives should provide their consent on the same consent form as that used to confirm that a verbal briefing has been given (swissethics template: Declaration of consent).

**3. Children with a developmental age of 11-13 years** should be given a verbal briefing and written Patient Information that has been adapted to this age group's comprehension level and incorporates graphic elements if appropriate (HRA Art. 21).

Their legal representatives (usually parents, legal guardians) receive all the information. The legal representatives should provide their consent on the same consent form as that used to confirm that a verbal briefing has been given (swissethics template: Declaration of consent).

It should be drafted using the familiar form of address and should contain information on the following questions:

- What will be done and why? (brief summary of the study objective)
- Why you in particular? (participant selection)
- What should you expect? (study schedule, including key risks/unpleasant aspects)
- Do you have to take part? (voluntary basis: only if you and your parents agree, right to withdraw at any time without detriment)
- How will you benefit by taking part in the study? (benefits, remuneration)
- Who can you contact? (contact person)

Information on data protection, insurance cover and costs as well as detailed descriptions of side effects should not be included. Information on contraception (can be provided verbally if appropriate).

**4. Adolescents aged 14 and over** receive a verbal briefing and written information with the same content as that given to their legal representative (usually parents, legal guardians), but using the familiar form of address. If this is considered appropriate, the polite form of address may be used.

They sign the consent form. Should the research project entail more than minimal risks and burdens also the signature of their legal representative is required.

The form must be written in such a way as to address both the parents and the adolescent.