



Successful paediatric HRO research projects: From feasibility to sampling, age-dependent design and data reuse

Templates PatInfo/ ICF

- Question
 - How to write concise, meaningful **Informed Consent Forms (ICFs)** while adhering to the many requirements by the ECs (e.g. swissethics templates)?
- Answer:
 - ✓ Study-specific templates for PatInfo/ ICF are available on the swissethics webpage: swissethics.ch/en/templates/studieninformationen-und-einwilligungen (they include also templates for parents/ legal representatives)
 - ✓ In addition there are guidance notes and check lists for the research with children and the age-specific preparation of a meaningful PatInfo/ ICF document for them: swissethics.ch/en/templates/forschung-mit-kindern

General Consent

- Question
 - If you have samples from children in your biobank and they reach adulthood, do you need to obtain the **general consent**, that parents have given for them before, again?
- Answer:
 - ✓ Until the age of 18, the general consent (GC) (or any other consent concerning further use of data or samples) provided by the parents/legal representatives remains valid.
 - ✓ When the participant reaches the age of 18 (and has capacity of judgement and action), the institution is required to make reasonable efforts to re-contact the participant and give them the opportunity to decide for themselves whether to provide consent for the continued use of their data and/or samples or to object to such use.
- Question
 - What happens if the **young adult does not respond**?
- Answer:
 - ✓ This is an important point. Swiss legislation does not provide that parental consent automatically ceases to be valid when the participant reaches the age of 18. Institutions are expected to make reasonable efforts to re-contact the participant and offer them the opportunity to make their own decision regarding the continued use of their data and/or samples. If no response is received, the applicable procedures may depend on the wording of the General Consent (GC), institutional policies, and the position of the relevant ethics committee.