

Consent Form Requirements for Children and Adolescents

Bellberry generally requires specific consent/assent to a child's or young person's participation in research from the child or young person whenever he or she has the capacity to make this decision and either one or both parents (depending on the risk involved) or, where applicable, the guardian or person required by law. (per National Statement 4.2.7)

Bellberry will now accept the term 'assent' for children as long as it is defined to mean agreement by a minor to their enrolment in research. The Mature Minors Standard supports the use of this term.

A separate information sheet for children and adolescents is required.

The Committee requires reassurance that any participant turning 18 years of age during the study will be re-consented. This is legally necessary because the young person is then legally an adult and parental consent is no longer operative.