SPIRIT | CONSORT CHILDREN & ADOLESCENTS
Reporting Guidelines for Child Health Trials

SPIRIT-C 2026

Item 32a.1: Consent or assent

Provide information on whether developmentally appropriate materials with understandable information on the trial process will be provided to participants in obtaining informed consent or assent, and state where materials can be found or if available on request

Administrative information	1a.1	Title and structured summary
Open science	6.1	Data sharing
Introduction	9a.1	Background and rationale *Prevalence/incidence*
	9a.2	Background and rationale *Extrapolation*
	9a.3	Background and rationale *Research question or aim*
Methods	13.1	Trial setting
	14a.1	Eligibility criteria
	15a.1	Intervention and comparator *Dose/formulation*
	15a.2	Intervention and comparator *Adaptations*
	15a.3	Intervention and comparator *Intervention delivery*
	16.1	Outcomes
	17.1	Harms *Mitigation measures*
	17.2	Harms *Efforts to reduce risk*
	20.1	Recruitment *Impact of trial participation*
	20.2	Recruitment *Recognition for trial participation*
Ethics	32a.1	Consent or assent
	34.1	Ancillary and post-trial care

Key elements for reporting this item:

- Age group(s) or developmental stage(s) that the trial information material was prepared for
- How information and presentation of information will be developmentally appropriate for the target population
- Involvement/engagement of children/adolescents/family caregivers in preparation
- Where the developmentally appropriate materials can be found, or whether available on request.

Examples:

"Although written informed consent will be given by the parent or guardian, the child will be given age-appropriate information about the study and may confirm their assent during the completion of the consent form if they wish to do so. Consent will be taken by a member of the surgical team who has experience recruiting children to research studies and has completed appropriate good clinical practice training. A copy of the study consent form is included with the study protocol (see Additional file 1)."

Hutchings N, Wood W, Reading I, et al. CONTRACT Study - CONservative TReatment of Appendicitis in Children (feasibility): study protocol for a randomised controlled Trial. Trials 2018;19:153. doi:10.1186/s13063-018-2520-z

"Verbal consent for screening will be obtained from families and documented. For eligible parent/caregiver-child pairs who express interest in study participation, an [emergency department] ED physician will confirm eligibility, and the research nurse or designate will complete consent and assent, as appropriate (online supplementary appendix 1) . . . In keeping with the ethical requirements of the involved Canadian institutions, we will have consent forms for parent/caregivers, assent forms for children and mature minor consent forms for both accompanied and unaccompanied youth who are deemed to be mature minors. All of these forms are written in a manner to reflect the reading and comprehension capacity of the target groups."

Ali S, Rajagopal M, Klassen T, et al; KidsCAN PERC Innovative Pediatric Clinical Trials No OUCH Study Team. Study protocol for two complementary trials of non-steroidal or opioid analgesia use for children aged 6 to 17 years with musculoskeletal injuries (the No OUCH study). BMJ Open 2020;10:e035177. doi:10.1136/bmjopen-2019-035177.

See the E&E for more examples.

Statement (co-published in *The BMJ, JAMA Pediatrics, and The Lancet Child and Adolescent Health*): Baba A, Smith M, Potter BK, et al. SPIRIT-Children and Adolescents (SPIRIT-C) 2026 Extension Statement: Enhancing the Reporting and Usefulness of Paediatric Randomised Trial Protocols. BMJ 2026;392:e085062. doi: 10.1136/bmj-2025-085062

Explanation and Elaboration: Baba A, Smith M, Potter BK, et al. SPIRIT-C 2026 explanation and elaboration: recommendations for enhancing the reporting and impact of paediatric randomised trials. BMJ 2026;392:e085064. doi: 10.1136/bmj-2025-085064