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

SPIRIT-C 2026

Item 6.1: Data sharing

Describe whether individual participant data will be shared with others not directly involved in the trial, and how the child/adolescent's and/or family's confidentiality will be respected within the study

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:

- Whether individual participant data will be shared with others, or used in future projects
- How shared trial data will be anonymised or de-identified
- If participant data will be shared, measures taken to mitigate any possible risks associated with sharing
- Whether participants can opt out of the sharing of their personal data, or specific information
- The circumstances under which individual child data would be shared with their clinician/caregiver, why this is necessary and valuable, and steps taken to prevent harm associated with disclosure
- How study participants will be informed about data sharing methods and who will have access to the clinical data for data sharing purpose.

Examples:

"Data access: All deidentified individual participant data (including data dictionaries) will be made available immediately following publication with no end date to investigators whose proposed use of the data has been approved by an independent review committee identified for this purpose. Additional documents that will be available include the study protocol, statistical analysis plan and the informed consent forms. Proposals should be directed to [email redacted]. To gain access; data requestors will need to sign a data access agreement . . . Confidentiality: Participant confidentiality and privacy are strictly held in trust by the participating investigators, their staff and the sponsor. This confidentiality is extended to cover the clinical information relating to participants. Therefore, the study protocol, documentation, data and all other information generated will be held in strict confidence. No information concerning the study or the data will be released to any unauthorized third party without the prior written approval of the sponsor."

Freedman SB, Williamson-Urquhart S, Heath A, et al; KidsCAN-Pediatric Emergency Research Canada (PERC) Innovative Pediatric Clinical Trials DOSE-AGE Study Group. Multi-dose Oral Ondansetron for Pediatric Gastroenteritis: study Protocol for the multi-DOSE oral ondansetron for pediatric Acute GastroEnteritis (DOSE-AGE) pragmatic randomized controlled trial. Trials 2020;21:435. doi:10.1186/s13063-020-04347-6.

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