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SPIRIT-Children and Adolescents (SPIRIT-C) 2026 Extension Statement
Enhancing the Reporting and Usefulness of Pediatric Randomized Trial Protocols

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IMPORTANCE Key information is often omitted from pediatric randomized controlled trial (RCT) protocols, including details on dose adjustments of interventions based on age, body surface area, or weight; developmental appropriateness of trial outcome measures and processes; or strategies to minimize participants' anxiety and pain. These deficiencies impair the planning and implementation of potentially impactful trials for children and adolescents. Appropriate guidance is needed to support harmonized, comprehensive reporting of pediatric RCT protocols involving participants aged 0 to 19 years. Developed in partnership with young people (aged 10-24 years) and family caregivers, the Standard Protocol Items: Recommendations for Interventional Trials–Children and Adolescents (SPIRIT-C) 2026 consists of 17 new items recommended to be reported in addition to the SPIRIT 2025 items in pediatric RCT protocols.

OBJECTIVE To develop a pediatric reporting guideline extension to the SPIRIT 2025 guideline, SPIRIT-C 2026, that supports comprehensive and transparent reporting of pediatric RCT protocols.

EVIDENCE REVIEW The methodological framework for developing reporting guidelines published by the EQUATOR Network was implemented to develop a pediatric extension to the SPIRIT 2025 guidelines called SPIRIT-C 2026. A list of candidate reporting items was generated from the literature, and a Youth Advisory Group and a Family Caregiver Advisory Group contributed vital input throughout the project. An international Delphi study with a priori consensus thresholds, a consensus meeting, group writing of the explanation and elaboration paper, and pilot testing of the draft guideline were conducted.

MAIN OUTCOMES AND MEASURES SPIRIT-C 2026 details key reporting items applicable to pediatric RCT protocols involving children and adolescents aged 0 to 19 years. All relevant items are aligned with those in Consolidated Standards of Reporting Trials–Children and Adolescents 2026, a new reporting guideline for completed pediatric RCTs.

FINDINGS SPIRIT-C 2026 consists of a checklist with 17 new reporting items for reporting pediatric RCT protocols; 4 items are youth generated and 6 youth endorsed. These can be considered a minimum set of reporting items pertinent to pediatric RCT protocols that are relevant to various interest holders, including young people, family caregivers, researchers, pediatric trialists, ethics committees, regulators, funders, and journal editors. Widespread implementation and uptake of SPIRIT-C 2026 should enhance the quality and usefulness of protocols for RCTs that involve participants from birth through adolescence and ultimately foster high-quality pediatric trials.

CONCLUSIONS AND RELEVANCE Inclusion of these SPIRIT-C 2026 items supports comprehensive, meaningful, relevant, and transparent reporting, which can improve both the quality and usefulness of pediatric RCT protocols. RCT protocols contain essential details needed to understand and evaluate the trial's planned aims, design, data collection methods, monitoring, data analysis, and participants' safety.

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Randomized controlled trials (RCTs) that are appropriately designed and well conducted provide key information and evidence needed to reduce uncertainty about interventions and are pivotal in health care decision-making. Before the conduct of an RCT, a protocol that comprehensively describes the trial's design, planned data collection, and analysis methods and details various ethical, safety, and efficacy considerations should be available in the public domain. A comprehensive protocol can also mitigate downstream problems like selective reporting because it provides a clear record of what was originally planned in terms of outcomes and analysis.[1]

Despite the critical importance and various uses of protocols, inadequate reporting of key pediatric details is prevalent.[2] Studies show that incomplete reporting of pediatric trial protocols includes the omission of details on trial interventions, such as dose adjustments based on age, weight, or body surface area, developmental appropriateness of trial outcomes, and long-term harms monitoring.[3] Yet, methodological details are also poorly reported in pediatric trial protocols. For example, in a recent review of pediatric neuro-oncology trial protocols,[4] details on randomization, allocation sequence, implementation, and blinding were poorly reported; over half of the protocols assessed did not report whether blinding was done. Specifically important to children and adolescents, information on whether and how procedural pain and harm were minimized for study participants in both the experimental and comparator groups is commonly missing.[5]

To mitigate poor reporting in trial protocols, guidance has been available since publication of the 2013 Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guideline.[6] Yet, given the inadequate reporting that is continually observed in pediatric RCT protocols, it is evident that the existing reporting guidance for authors is not used or is insufficient in guiding appropriate reporting of pediatric-specific trial details. While updated in 2025,[7] the SPIRIT reporting guideline does not contain items on specific details for trials in children and adolescents. The pediatric population is heterogeneous and consists of multiple subpopulations—newborns, infants, children, and adolescents—who have ontogenetic variabilities in their biology, anatomy, pharmacokinetics, pharmacodynamics, cognitive abilities, and psychology.[8,9] Given these vast differences observed during this period of life, there are unique challenges that need to be considered when preparing a pediatric RCT protocol.[10] These include considerations about consent and assent, appropriate use of extrapolated data, age-appropriate trial interventions and formulations, preventing or minimizing distress and pain from trial procedures for all participants, selection and measurement of valid outcomes, and potential differences in treatment effects related to age, growth, and development.[11] Another key consideration pertains to the increased partnerships with young people and their families in the design and conduct of trials and the need to sufficiently report their engagement's impact on study design and conduct.[12,13]

Given the increased awareness about the importance of transparent and sufficient trial protocol reporting that may enhance the usefulness of the planned research, there have been recent calls in the literature for research reporting guidelines specifically for pediatric RCTs.[14] These calls complement the identified need for high-quality RCTs that produce pediatric-specific evidence.[15] Authors have stated that proper guidance for pediatric-specific issues should result in clearer and more useful RCT protocols[16,17] and can reduce avoidable research waste.[18]

We developed a pediatric-specific extension to SPIRIT 2025 with the intent to provide comprehensive guidance on a minimum set of essential reporting items applicable to pediatric RCT protocols, SPIRIT-Children and Adolescents (SPIRIT-C) 2026, for trials involving participants aged 0 to 19 years. In this statement, we describe the methods of the SPIRIT-C 2026 extension's development, present the newly developed reporting items, and detail the scope and the potential benefits of using this guideline. To facilitate the uptake and usability of the SPIRIT-C 2026 extension, we prepared an explanation and elaboration paper[19] that provides detailed guidance, real-world exemplars, and explanations for each reporting item.

Methods

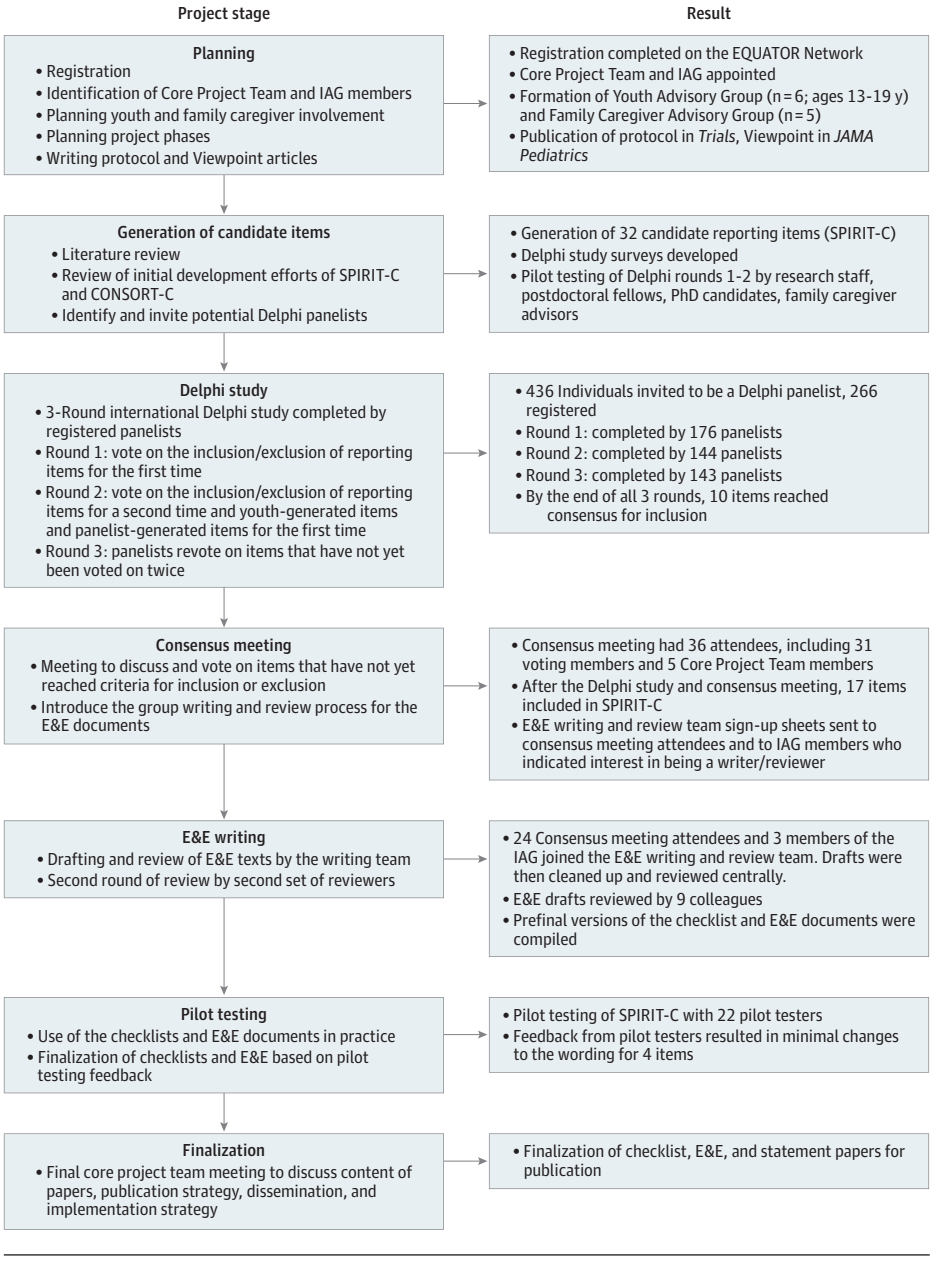
We initially registered the development of SPIRIT-C 2026 with the Enhancing the Quality and Transparency of Health Research (EQUATOR) Network in 2014,[20] then updated the registration in 2023 and 2024 to reflect the developmental steps described in this article. We closely followed EQUATOR guidelines on reporting guideline development,[21] reviewed identified methodological limitations attributed to the development of reporting guidelines,[22] and further improved our methods based on how other recent reporting guideline extensions were developed.[7,23-35] We published a study protocol, which includes details on the scope of the guideline, the development process, and the composition and role of each key group.[36] Briefly, for the purposes of this project, the term *pediatric* encompasses child and adolescent health, and the guidance pertains to trials that evaluate any intervention(s) (ie, drug and nondrug, including public and population health) in newborns, infants, children, and adolescents. Although heterogeneity exists in what constitutes *pediatric* and how different age groups are defined in the literature,[37,38] the SPIRIT-C 2026 extension pertains to newborns, infants, children, and adolescents (aged 0-19 years), which we based on published ranges by the United Nations Convention on the Rights of the Child and the World Health Organization.[39-42] In the context of this project, the term *children* includes newborns and infants.

Figure 1 shows the development process of SPIRIT-C 2026. We developed SPIRIT-C 2026 alongside Consolidated Standards of Reporting Trials–Children and Adolescents (CONSORT-C) 2026 to ensure consistency and harmonization in reporting from the trial protocol to the final report.[43] Key groups involved in the development of both guidelines included the Core Project Team, consisting of 6 individuals with expertise in pediatric research, trial methodology, reporting guidelines, patient and public involvement, and pediatric rare diseases, among others.

We engaged an International Advisory Group of pediatric trialists with representation from the following 4 countries: Canada, the United Kingdom, the US, and the Netherlands. The 14 members included clinical trialists, clinician scientists, epidemiologists, statisticians, and pediatric trial network representatives.

We involved young people (aged 10-24 years) and family caregivers (parents and guardians) in developing SPIRIT-C 2026 and CONSORT-C 2026. An International Youth Involvement Steering Committee was established to devise a strategy for the collection of input from young people in the project. The Committee consisted of 3 members of the Core Project Team and 4 youth facilitators who currently lead Young Person Advisory Groups in England,

Figure 1. Development Process of Standard Protocol Items: Recommendations for Interventional Trials–Children and Adolescents (SPIRIT-C) 2026 Checklist Items and Explanation and Elaboration (E&E) Papers



CONSORT-C indicates Consolidated Standards of Reporting Trials–Children and Adolescents; E&E, explanation and elaboration; EQUATOR, Enhancing the Quality and Transparency of Health Research; IAG, International Advisory Group.

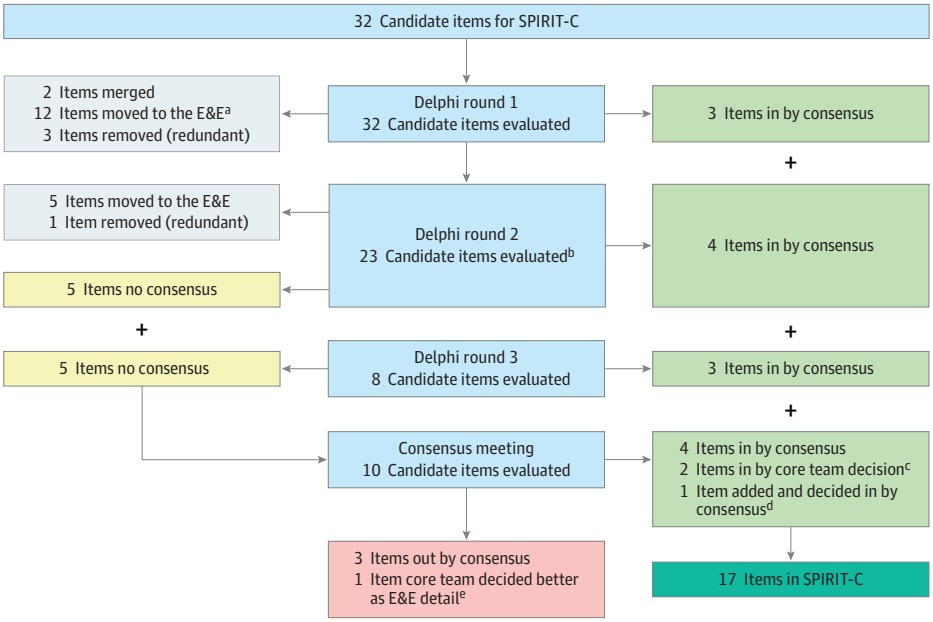
France, Scotland, and Spain as part of the European Young Person Advisory Group Network. We formed 2 pan-Canadian advisory groups: the Youth Advisory Group (advisors aged 13-19 years) and a Family Caregiver Advisory Group, who actively took part in several project stages, such as the Young Person Reporting Guideline workshops, the Delphi study, writing the explanation and elaboration papers, and developing materials for knowledge translation. Specifics on the rationale for the included age range, contributions of each advisory group, young people, family caregivers, and the impact on the final deliverables are detailed elsewhere.[44]

We describe minor amendments to the protocol in eAppendix 1 in Supplement 1. In eAppendix 2 in Supplement 1, we detail all contributors to the development of SPIRIT-C 2026 and CONSORT-C 2026. Detailed methods on the generation of candidate reporting items, Delphi study, consensus meeting, group writing process of the explanation and elaboration, and pilot testing and finalization are described in eAppendix 3 in Supplement 1.

Results

In collaboration with key partners, we developed SPIRIT-C 2026, harmonized with the SPIRIT 2025 update, from July 2023 to January 2025.[7]

Figure 2. Standard Protocol Items: Recommendations for Interventional Trials–Children and Adolescents (SPIRIT-C) 2026 Item Flow Diagram



See eTable 6 in Supplement 1 for detailed flow of each item. E&E indicates explanation and elaboration.

[a]These 12 items include 9 SPIRIT | Consolidated Standards of Reporting Trials (CONSORT)–Outcomes items that met consensus criteria to be included after round 1, which affirmed their importance as detailed in the statement paper. After concerns raised in round 1 by some panelists about including items not specific to pediatrics, these items were considered better as detail for the E&E and did not appear again in the Delphi study.

[b]These 23 items comprise 12 carried over from round 1 for second-round vote; 5 youth-generated items from Young Person Reporting Guideline workshops; 2 new panelist-suggested items from round 1; 2 additional items as a result of splitting an item from round 1; and 2 additional items considered only for CONSORT-Children and Adolescents (CONSORT-C) 2026 in round 1 but found appropriate for SPIRIT-C 2026 for round 2 onwards.

[c]No consensus for these items was reached even after voting at consensus meeting. The core team decided to include these items.

[d]Item originally only for CONSORT-C 2026 was discussed as relevant for SPIRIT-C 2026 during consensus meeting and added and voted in during meeting.

[e]No consensus was reached even after voting at consensus meeting. The core team decided to exclude this item and instead include as detail in E&E.

Delphi Study

Of the 436 invitees, 266 signed up for the Delphi study (response rate 61%). eTable 1 in Supplement 1 presents the number of Delphi panelists who completed each round, including their characteristics and whether they were directly invited or self-selected through snowball sampling. Round 1 was completed by 176 of 266 panelists (response rate 66%), round 2 was completed by 144 of 266 panelists (54%), and the final round was completed by 143 of 266 panelists (54%). In total, 10 family caregivers expressed interest in being a Delphi panelist; 5 were Family Caregiver Advisory Group members and 4 were young people (aged 19-24 years).

Figure 2 shows the flow of SPIRIT-C 2026 items throughout the project; eAppendix 5 in Supplement 1 provides details on the flow of items in rounds 1 through 3. eTable 6 in Supplement 1 presents the results of the Delphi study.

Consensus Meeting

Of 38 individuals invited to the consensus meeting, 31 (82%) attended; 4 (13%) were family caregiver advisors. In addition to the 31 attendees, 5 Core Project Team members and 1 notetaker were present, although they did not vote. eTable 2 in Supplement 1 describes characteristics of all consensus meeting attendees, including Core Project Team members.

Accounting for both SPIRIT-C 2026 and CONSORT-C 2026, we discussed 13 reporting items at the consensus meeting. Ten of these items were candidate reporting items for SPIRIT-C 2026, of which 4 were voted in and 3 were voted out. Discussions during the consensus meeting led to the consideration and voting in of 1 additional item that was originally not considered for SPIRIT-C 2026. Three items out of the original 10 discussed did not meet consensus criteria to be included or excluded;therefore, the Core Project Team discussed these items afterwards in the context of the consensus meeting discussions and the nature of the item. Ultimately, 2 of the 3 items were included and 1 item was incorporated as detail for the explanation and elaboration. eTable 7 in Supplement 1 describes voting results from the consensus meeting for each item.

The final SPIRIT-C 2026 extension contains 17 items for pediatric RCT protocols: 4 (items 6.1, 15a.3, 20.2, 32a.1) are youth-generated items and 6 (items 1a.1, 9a.3, 15a.1, 17.1, 17.2, 20.1) are youth-endorsed items.

Group Writing of the Explanation and Elaboration

We assembled an explanation and elaboration writing team (n = 27) with 24 individuals who attended the consensus meeting, which includes all 4 family caregivers. Members of the International Advisory Group (n = 3) who did not attend the consensus meeting also

signed up to contribute to identifying good reporting examples and drafting explanation text. On average, writing team members contributed to 6 items and signed up for both writing and reviewing tasks for various items. For the SPIRIT-C 2026 explanation and elaboration paper, writing team members contributed to all 17 SPIRIT-C 2026 items and 6 SPIRIT 2025 items (items 11, 15a, 16, 17, 20, 34). The 6 SPIRIT 2025 items were included in the explanation and elaboration paper to elaborate on pediatric considerations and facilitate comprehensive reporting for the following key topics: patient and public involvement, intervention and comparator, outcomes, harms, recruitment, and ancillary and posttrial care. After review and edits by 2 members of the Core Project Team (A.B., M. Offringa), the revised version was reviewed by 5 International Advisory Group members, a Core Project Team member (B.K.P.), and 3 colleagues who further reviewed and provided feedback on the explanation and elaboration paper. The explanation and elaboration papers were then prepared for pilot testing.

Pilot Testing and Finalization

Twenty-two pilot testers evaluated the SPIRIT-C 2026 checklist and explanation and elaboration paper, of whom 5 (23%) also pilot tested CONSORT-C 2026; eTable 3 in Supplement 1 summarizes their characteristics. Their feedback led to improvements in item wording for 4 reporting items (eTable 8 in Supplement 1); no modifications were made to the content. For some items, additional examples were identified and added.

At the final project meeting in December 2024, the guideline paper content, publication strategy, and plans for dissemination and implementation were discussed. The SPIRIT-C 2026 checklist and explanation and elaboration papers were finalized shortly after the meeting.

Scope and Use of SPIRIT-C 2026

SPIRIT-C 2026 includes 17 reporting items that are applicable to pediatric RCT protocols for any disease, condition, intervention, or outcome that involve children and adolescents (aged 0-19 years) (**Table 1**); aligning with the SPIRIT 2025 statement, SPIRIT-C 2026 is most focused on reporting the 2-group, parallel RCTs.[7] eTable 4 in Supplement 1 presents an expanded checklist that outlines all key elements for reporting each SPIRIT-C 2026 item.

The new reporting items address the title, data sharing, background and rationale, trial setting, eligibility criteria, intervention and comparator, outcomes, harms, recruitment, consent or assent, and ancillary and posttrial care. The **Box** describes the structure and use of SPIRIT-C 2026.

Although SPIRIT-C 2026 is intended to be used for pediatric RCT protocols, it can also be used in combination with other SPIRIT extensions depending on the condition, intervention, trial design, or outcome (eTable 5 in Supplement 1). SPIRIT-C 2026 can also be broadly applied to the reporting of nonrandomized pediatric trial protocols. Authors are invited to consider these guidelines for any type of pediatric trial protocol and apply reporting items as appropriate.

Additionally, SPIRIT-C 2026 reporting items should be considered and reported in protocols for pediatric adaptive trials, cluster RCTs, multi-arm RCTs, multistage RCTs, n-of-1 trials, and pilot and feasibility trials. SPIRIT-C 2026 is applicable to trials that plan to involve a mixed population, such as trials that enroll children and adults, trials that enroll parents or caregivers (ie, who deliver or receive the intervention) but assess outcomes in children or adolescents, or when parent-child dyads are recruited. Because SPIRIT-C 2026 is an extension, it should be used alongside SPIRIT 2025[7] for any pediatric RCT protocol.

Beyond pediatric trial protocol authors, SPIRIT-C 2026 can be used by several interest holders and knowledge users, including research funders; ethics committees and regulators; trial registries; trial or research staff; trainees; patients, public, and trial participants; academic institutions; journal editors and publishers; journal peer reviewers; and systematic reviewers and meta-researchers. **Table 2** details how these key users can implement SPIRIT-C 2026, along with the expected resulting benefits.

Discussion

SPIRIT-C 2026 provides guidance on the important details and content that should be reported in a well-written, high-quality, useful protocol and explains the level of detail needed. The international development effort described in this SPIRIT-C 2026 statement resulted in 17 essential reporting items that should be reported in pediatric RCT protocols. Consensus on this minimum set was based on the expertise and perspectives from various end users and interest holders—for example, young people (aged 10-24 years), family caregivers, pediatric trialists, clinicians, child health researchers, pediatricians, methodologists with pediatric clinical trial expertise, regulatory agencies, trainees, authors, and journal editors.

SPIRIT-C 2026 is an extension to the SPIRIT 2025 guideline and is focused on parallel-group RCT protocols involving children and adolescents (aged 0-19 years). This pediatric focus distinguishes it from other SPIRIT extensions, which are usually developed to address specific conditions, trial designs, interventions, or outcomes (eTable 5 in Supplement 1). However, available SPIRIT extensions may also highlight critical reporting items and are worth referring to if an appropriate extension is available, which would depend on the condition, trial design, intervention, or outcomes. For comprehensive trial intervention reporting, the Template for Intervention Description and Replication (TIDieR) for Children and Adolescents (TIDieR-C) describes pediatric considerations,[45] as further detailed in the accompanying explanation and elaboration paper.[19]

To best understand the rationale behind each reporting item and to be able to refer to good reporting examples, we recommend that the SPIRIT-C 2026 checklist and accompanying explanation and elaboration paper be used together. We recognize that owing to various editorial requirements, certain details may not necessarily be reported in the order presented in the checklist or even within the main text of the protocol. SPIRIT-C 2026 does not dictate exactly where details of each reporting item need to be included because the focus is on the inclusion of pertinent details. Therefore, clear indication in the protocol where readers can find the information, whether it be in the main text, supplementary material, citation, or link to the source, is helpful. Additionally, users of SPIRIT-C 2026 will benefit from referring to and using the CONSORT-C 2026 reporting guideline because both guidelines were developed in tandem and have been harmonized with the intent to provide consistent reporting guidance from the protocol to the final report.

Improving Research Practice

In August 2025, 676 reporting guidelines were registered on the EQUATOR Network database.[20] With the increasing number of re-

Table 1. Recommended Items to Report in Pediatric (Aged 0-19 Years) Trial Protocols From Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) 2025 and SPIRIT-Children and Adolescents (SPIRIT-C) 2026 Checklists

	SPIRIT 2025 statement		SPIRIT-C 2026 extension	
Section and topic	Item No.	SPIRIT 2025	Item No.	SPIRIT-C 2026
Administrative information				
Title and structured summary	1a	Title stating the trial design, population, and interventions, with identification as a protocol	1a.1[a]	Identify that it is a pediatric trial protocol, and include age group(s)/range(s), interventions, and, if applicable, trial acronym
	1b	Structured summary of trial design and methods, including items from the World Health Organization Trial Registration Data Set		
Protocol version	2	Version date and identifier		
Roles and responsibilities	3a	Names, affiliations, and roles of protocol contributors		
	3b	Name and contact information for the trial sponsor		
	3c	Role of trial sponsor and funders in design, conduct, analysis, and reporting of trial; including any authority over these activities		
	3d	Composition, roles, and responsibilities of the coordinating site, steering committee, end point adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable		
Open science				
Trial registration	4	Name of trial registry, identifying number (with URL), and date of registration. If not yet registered, name of intended registry		
Protocol and statistical analysis plan	5	Where the trial protocol and statistical analysis plan can be accessed		
Data sharing	6	Where and how the individual deidentified participant data (including data dictionary), statistical code, and any other materials will be accessible	6.1	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
Funding and conflicts of interest	7a	Sources of funding and other support (eg, supply of drugs)		
	7b	Financial and other conflicts of interest for principal investigators and steering committee members		
Dissemination policy	8	Plans to communicate trial results to participants, health care professionals, the public, and other relevant groups (eg, reporting in trial registry, plain language summary, publication)		
Introduction				
Background and rationale	9a	Scientific background and rationale, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	9a.1[a,b]	Describe the prevalence/incidence of the disease or condition in children/adolescents
			9a.2[b]	Describe the potential for extrapolation from other pediatric populations or adult data, or why extrapolation is not considered appropriate
			9a.3[a]	Include a description of the research question or aim with a justification for undertaking the trial in children/adolescents
	9b	Explanation for choice of comparator		
Objectives	10	Specific objectives related to benefits and harms		
Methods: patient and public involvement, trial design				
Patient and public involvement	11	Details of, or plans for, patient or public involvement in the design, conduct, and reporting of the trial		
Trial design	12	Description of trial design including type of trial (eg, parallel group, crossover), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)		
Methods: participants, interventions, and outcomes				
Trial setting	13	Settings (eg, community, hospital) and locations (eg, countries, sites) where the trial will be conducted	13.1[b]	Describe any adaptations put in place to support inclusion and participation of children/adolescents

(continued)

porting guidelines, more journals endorse their use as part of their instructions to authors,[46] although endorsement can be inconsistent across different journals and publishers.[47] While awareness and use of research reporting guidelines has increased in recent years, reporting guidelines usually focus on retrospective reporting on what has already happened and cannot rectify upstream deficiencies in

Table 1. Recommended Items to Report in Pediatric (Aged 0-19 Years) Trial Protocols From Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) 2025 and SPIRIT-Children and Adolescents (SPIRIT-C) 2026 Checklists (continued)

	SPIRIT 2025 statement		SPIRIT-C 2026 extension	
Section and topic	Item No.	SPIRIT 2025	Item No.	SPIRIT-C 2026
Eligibility criteria	14a	Eligibility criteria for participants	14a.1[a,b]	Provide a justification for including multiple age groups or children/adolescents at different developmental stages, and address potential age or development-related differences in treatment effects
	14b	If applicable, eligibility criteria for sites and for individuals who will deliver the interventions (eg, surgeons, physiotherapists)		
Intervention and comparator	15a	Intervention and comparator with sufficient details to allow replication including how, when, and by whom they will be administered. If relevant, where additional materials describing the intervention and comparator (eg, intervention manual) can be accessed	15a.1[a,b]	Describe whether there is an intervention dose and/or formulation appropriate for the trial population, and if there are any adjustments made based on age, weight, or body surface area
			15a.2[b]	Give rationale for adapting interventions used in other pediatric populations or adults for the present trial
			15a.3[a,b]	Describe whether the trial interventions will be delivered with help from a support person
	15b	Criteria for discontinuing or modifying allocated intervention/comparator for a trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)		
	15c	Strategies to improve adherence to intervention/comparator protocols, if applicable, and any procedures for monitoring adherence (eg, drug tablet return, sessions attended)		
	15d	Concomitant care that is permitted or prohibited during the trial		
Outcomes	16	Primary and secondary outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome	16.1[a]	Explanation of the validity, reliability, feasibility, and responsiveness of the outcome measurement instruments for the prespecified age groups
Harms	17	How harms are defined and will be assessed (eg, systematically, nonsystematically)	17.1[a,b]	Describe whether trial interventions and/or procedures will induce fear, pain, distress, or are invasive, and what measures are taken to mitigate this
			17.2	Describe all efforts to reduce the child/adolescent's risk associated with trial participation
Participant timeline	18	Time schedule of enrollment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure 1 in SPIRIT 2025)		
Sample size	19	How sample size was determined, including all assumptions supporting the sample size calculation		
Recruitment	20	Strategies for achieving adequate participant enrollment to reach target sample size	20.1	Describe the anticipated impact of trial participation on the child/adolescent's daily life
			20.2	Describe how participating children/adolescents will be given recognition for trial participation
Methods: assignment of interventions				
Randomization:				
Sequence generation	21a	Who will generate the random allocation sequence and the method used		
	21b	Type of randomization (simple or restricted) and details of any factors for stratification. To reduce predictability of a random sequence, other details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enroll participants or assign interventions		
Allocation concealment mechanism	22	Mechanism used to implement the random allocation sequence (eg, central computer/telephone; sequentially numbered, opaque, sealed containers), describing any steps to conceal the sequence until interventions are assigned		
Implementation	23	Whether the personnel who will enroll and those who will assign participants to the interventions will have access to the random allocation sequence		

(continued)

Table 1. Recommended Items to Report in Pediatric (Aged 0-19 Years) Trial Protocols From Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) 2025 and SPIRIT-Children and Adolescents (SPIRIT-C) 2026 Checklists (continued)

	SPIRIT 2025 statement		SPIRIT-C 2026 extension	
Section and topic	Item No.	SPIRIT 2025	Item No.	SPIRIT-C 2026
Blinding	24a	Who will be blinded after assignment to interventions (eg, participants, care providers, outcome assessors, data analysts)		
	24b	If blinded, how blinding will be achieved and description of the similarity of interventions		
	24c	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial		
Methods: data collection, management, and analysis				
Data collection methods	25a	Plans for assessment and collection of trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of trial instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be accessed, if not in the protocol		
	25b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols		
Data management	26	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be accessed, if not in the protocol		
Statistical methods	27a	Statistical methods used to compare groups for primary and secondary outcomes, including harms		
	27b	Definition of who will be included in each analysis (eg, all randomized participants), and in which group		
	27c	How missing data will be handled in the analysis		
	27d	Methods for any additional analyses (eg, subgroup and sensitivity analyses)		
Methods: monitoring				
Data monitoring committee	28a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and funder; conflicts of interest and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed		
	28b	Explanation of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial		
Trial monitoring	29	Frequency and procedures for monitoring trial conduct. If there is no monitoring, give explanation		
Ethics				
Research ethics approval	30	Plans for seeking research ethics committee/institutional review board approval		
Protocol amendments	31	Plans for communicating important protocol modifications to relevant parties		
Consent or assent	32a	Who will obtain informed consent or assent from potential trial participants or authorised proxies, and how	32a.1[b]	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
	32b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable		
Confidentiality	33	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial		
Ancillary and posttrial care	34	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	34.1[b]	Describe plans for assessing outcomes and harms beyond the formal study completion date

[a] New item pertains to both SPIRIT-C 2026 and Consolidated Standards of Reporting Trials–Children and Adolescents (CONSORT-C) 2026.[43]

[b] Report item if applicable or state explicitly that it is not applicable.

Box. Structure and Use of Standard Protocol Items: Recommendations for Interventional Trials–Children and Adolescents (SPIRIT-C) 2026 Extension

Structure

The SPIRIT-C 2026 extension includes a minimum set of items to report in pediatric randomized controlled trial (RCT) protocols, which are detailed in a checklist (**Table 1**). Reporting all items is recommended, except for 10 items with a footnote b (9a.1, 9a.2, 13.1, 14a.1, 15a.1, 15a.2, 15a.3, 17.1, 32a.1, 34.1), which should only be reported if applicable; if an item is not applicable, an explicit statement "not applicable" with an explanation, if relevant, is helpful. In the checklist, the 17 SPIRIT-C 2026 items are embedded within the framework of SPIRIT 2025. An explanation and elaboration paper was also prepared and published separately[19] and should be referred to when using the SPIRIT-C 2026 extension. Users should also refer to and report the SPIRIT 2025 items.

Intended users

Users of SPIRIT-C 2026 include pediatric RCT protocol authors, journal editors and publishers, peer reviewers, research funders, ethics committees and regulators, trial registries, systematic reviewers and meta-researchers, and academic end users. Evidence end users, such as young people, families, researchers, and health care providers, can also use this guideline. **Table 2** highlights each key group, their implementable actions, and resulting benefits.

Fillable checklist

As part of this statement paper, the downloadable, fillable checklist has been included in Supplement 2. Users may also access this checklist on the SPIRIT | CONSORT-C website (https://lab.research.sickkids.ca/enrich/reporting-standards/spirit-consort-c/), EQUATOR website (https://www.equator-network.org/), and new SPIRIT | CONSORT website (http://www.consort-spirit.org).

Additional resources

Educational resources, including a short informational video on the guideline and 1-page tip sheets for each reporting item, will be made available on the SPIRIT | CONSORT-C website (https://lab.research.sickkids.ca/enrich/reporting-standards/spirit-consort-c/). Summarized key elements are included alongside the SPIRIT-C 2026 checklist items in the expanded SPIRIT-C 2026 checklist (eTable 4 in Supplement 1).

Reference on guidance implementation

When using the SPIRIT-C 2026 extension, users should indicate that their pediatric RCT protocol is reported in accordance with the SPIRIT-C 2026 extension, in combination with other extensions as applicable.

Abbreviations: CONSORT-C, Consolidated Standards of Reporting Trials–Children and Adolescents; EQUATOR, Enhancing the Quality and Transparency of Health Research; RCT, randomized controlled trial.

trial design and conduct.[48] Theoretically, trials that are poorly designed and conducted can adhere to reporting guidance and report all items, despite core scientific deficiencies. Yet, at the protocol stage, sufficient detail and transparency can mitigate this. Therefore, an appropriately designed study described in a well-reported protocol adds value to research and avoids research waste, which is critical in pediatrics because recent studies show that many pediatric RCTs are not completed or published.[49,50]

Protocols provide a critical opportunity to mitigate downstream issues present at later stages of the research because they are typically drafted at the beginning of the trial process. When key details are missing from protocols, there are ramifications for the consistency of trial conduct across different study sites, the need to submit several amendments, and reduced transparency and reliability. In turn, users are restricted from being able to critically appraise and interpret the validity of study results in the finalized trial report. If details are not sufficiently described or planned at the protocol stage, selective reporting in the trial report may be undetectable. By contrast, well-written protocols can have significant influence downstream on the trial conduct and therefore on the quality and relevance of the evidence. SPIRIT-C 2026 places emphasis on the comprehensive reporting of pediatric-specific trial considerations. These considerations relate to the justification for undertaking the trial in the target pediatric age group; the use of intervention dose or formulation based on the child or adolescent's age, weight, or body surface area; appropriate reliability, validity, and feasibility of outcome measurement instruments for the pediatric population of interest; management of trial participants' stress and pain; and plans for long-term follow-up of outcomes and harms, among others.

We see several opportunities to improve research practice using SPIRIT-C 2026. First, because the implementation of transparent, connected, and early peer review efforts before trial conduct is needed,[48] we believe journals should be open to publishing protocols. Enabling consistent manuscript review, the reporting items in SPIRIT-C 2026 can be referred to by peer reviewers to check for detailed reporting. Although there is evidence of improved reporting since the publication of SPIRIT 2013, adherence in published protocols and in those approved by research ethics committees is not particularly high, and reporting of some items remains suboptimal.[2,51,52] Awareness, uptake, and implementation of SPIRIT-C 2026 can be increased in several ways. While endorsements from journals are key to raising awareness, consistency in the endorsement of reporting guidelines across different journals can be improved.[47] Additionally, mandating the submission of completed checklists can be coupled with verification of adherence by editorial staff (eg, for completeness) and peer reviewers (eg, for content) of submitted reporting guideline checklists.[53,54] This practice is implemented by some journals through dedicated editorial roles, such as protocol editors or assistant editors for transparent reporting,[55,56] but needs to be broadly adopted. We encourage (pediatric and child health) journals to be accommodating to the inclusion of details in protocols from this minimum set of reporting items, which are relevant to evidence end users and identified through international consensus.

Second, SPIRIT-C 2026 can be used by all who are involved in pediatric trial design and conduct. Table 2 highlights how interest holders of the SPIRIT-C 2026 extension can implement and benefit from SPIRIT-C 2026. When used widely, SPIRIT-C 2026 could ultimately lead to pediatric RCT protocols that are comprehensive, transparent, and useful, subsequently improving trial conduct and reporting and reducing research waste. Additionally, to make pediatric RCT reporting efficient and consistent from protocols to final reports, we have harmonized the reporting recommendations in SPIRIT-C 2026 with CONSORT-C 2026, a new guideline for reports of completed pediatric RCTs.[43] We recommend the SPIRIT-C 2026 and CONSORT-C 2026 extensions be referred to by authors pro-

Table 2. Implementable Actions of Key User Groups and Resulting Benefits From Use of Standard Protocol Items: Recommendations for Interventional Trials-Children and Adolescents (SPIRIT-C) 2026[a]

Key groups	Implementable actions	Potential benefits
Trial protocol authors	Adhere to the SPIRIT-C 2026 checklist and refer to the corresponding explanation and elaboration paper when writing trial protocols Cross-use with other existing SPIRIT extensions, depending on condition, design, intervention, and outcomes	Improved reporting of standardized minimum set of key elements, resulting in comprehensive, transparent, and useful trial protocols: improved appraisal, better implementation, and fewer amendments Inclusion of details that were identified as important by young people and family caregivers Better understanding of the minimum set of reporting items that needs to be included in trial protocols involving children and adolescents Downstream effects on trial conduct, analysis, and reporting Improved detection of selective (trial outcome) reporting Improved ability to synthesize results to generate recommendations for clinical guidelines
Research funders	Endorse or require applicants to use SPIRIT-C 2026 in the preparation of submitted trial funding proposals Use SPIRIT-C 2026 as a peer review tool when reviewing trial proposals	Set consistent standards on what trial protocols are expected to include Improved completeness, quality, and consistency of funding applications Improved understanding from investigators on details that should be included for efficient review of submitted trial protocols Reduce research waste by ensuring that trial protocol elements are comprehensively reported, replicable, and understandable
Ethics committees and regulators	Endorse or mandate SPIRIT-C 2026 use by applicants and reviewers	Improved comprehensiveness of reported details in trial protocols submitted for research ethics review Increased research ethics review efficiency by having consistent guidelines that trial protocols are expected to report details on
Trial registries	Refer to SPIRIT-C 2026 when preparing registration of key trial elements	Improved level of detail and consistency in registry entries Enhanced transparency enabling back-referral to understand trial evolution over time
Trial/research staff	Use SPIRIT-C 2026 as a training tool to increase awareness of and understanding of conduct, analysis, and reporting of pediatric trials	Improved understanding of trial concepts Reduce risk of bias that may result from trial conduct Improved adherence to the trial protocol and better implementation of the trial
Trainees (eg, graduate and medical students, residents, research fellows, clinical fellows)	Use SPIRIT-C 2026 as a training tool to increase awareness of and understanding of design, planning, and reporting of pediatric trials	Increased familiarity with the minimum set of reporting items to be reported in pediatric trial protocols Improved understanding and awareness by future generations in responsible research practice, including the use of research reporting guidelines, fostering comprehensive and useful study protocols
Patients, public, trial participants	Familiarize self with SPIRIT-C 2026 to know what information to expect when reading a trial protocol or participating in a pediatric trial Empower family caregivers to fully understand what the trial entails and support their child Advocate for the use of reporting guidelines, such as SPIRIT-C 2026, by authors, journals, funders, and institutions	Improved understanding of content that should be reported in trial protocols that facilitate the generation of high-quality knowledge that helps inform health care decision-making Increased awareness and empowerment of the general public in holding investigators and the research enterprise accountable for proper research conduct, reporting, and appropriate spending of funding Increased trust and accountability in research
Academic institutions	Increase training and awareness of SPIRIT-C 2026 to promote transparency in reporting, motivating investigators to use them Endorse or mandate use of SPIRIT-C 2026 for research ethics and funding applications	Improved understanding of the minimum set of reporting items to be reported in trial reports that involve children and adolescents Improved quality, accountability, reproducibility, replicability, and usefulness of produced research Fosters research integrity and transparency
Journal editors and publishers	Endorse use of SPIRIT-C 2026 in instructions to authors and in submission process for trial protocols that involve children and adolescents Verify accuracy of submitted SPIRIT-C 2026 checklists by authors who submitted their manuscript	Consistency in details reported across all submitted manuscripts, setting a minimum standard and fostering transparency for readers Quality check of reporting accuracy to ensure proper understanding of items that should be reported Improve efficiency in the peer review process and consistency in details across all published manuscripts Improve author's understanding of reporting items
Journal peer reviewers	Use SPIRIT-C 2026 during peer review to assess comprehensiveness of reporting	Improved transparency, consistency, and quality of peer review process Improved interpretation of trial protocols
Systematic reviewers and meta-researchers	Use SPIRIT-C 2026 to assess comprehensive reporting in included trial protocols and subsequent trial reports included in a systematic review	Improved detection of selective (trial outcome) reporting Improved ability to synthesize results to generate recommendations for clinical guidelines

[a] Table adapted and modified from SPIRIT-Outcomes 2022.[27]

spectively—that is, before drafting their protocol—rather than retrospectively as a checklist after a draft is written. This approach would be the most efficient to ensure that all key elements are considered at the right time. Outside of published protocols, SPIRIT 2025 and SPIRIT-C 2026 can both be used in preparing pediatric RCT protocols for grant applications, funding agencies, ethics submissions, and trial registration. Aside from journals, protocols can also be made openly available on preprint servers and as part of trial registration documentation.

Third, familiarity with and training in SPIRIT-C 2026 are also needed. A recent study found that using a structured template with SPIRIT items, along with a review of the items, facilitated better reporting by graduate students preparing protocols compared with those who did not receive the template.[57] This finding is consistent with the identified need for academic institutions to incorporate comprehensive training on research integrity, responsible research practice, and peer review.[58-60] The Box describes resources to enable better reporting.

Limitations

We acknowledge several limitations in developing SPIRIT-C 2026. The 2 systematic reviews conducted by our team that informed the development of the SPIRIT-C 2026 and CONSORT-C 2026 extensions were published in 2015.[11] Instead of conducting a full update, we reviewed recently published literature to inform the generation of additional candidate reporting items and referred to other evidence and reporting guidelines developed based on consensus, which includes SPIRIT and CONSORT 2025. However, this updated search was conducted by a single reviewer. We believe that the involvement of a large group of international experts in subsequent project phases, including the Delphi study and consensus meeting, reaffirmed the importance of the candidate items, and yielded limited new or missed pediatric reporting items. Involving young people and family caregivers also led to the generation and inclusion of reporting items that were relevant and meaningful to end users of pediatric RCT protocols and reports. Therefore, we believe it unlikely that we have missed important candidate reporting items.

We cannot exclude selection or nonresponse bias in the development of SPIRIT-C 2026 because contributors to the development of SPIRIT-C 2026 (ie, Delphi panelists, consensus meeting attendees, Young Person Reporting Guideline workshop attendees, advisory group members, pilot testers, explanation and elaboration writers and reviewers) were those who elected to be involved with the study. Despite our efforts to include family caregivers from outside of Canada through our international networks, only family caregivers from Canada expressed interest in contributing to the Delphi study. We recognize that of those invited to participate in the Delphi study, only 61% registered, and 54% completed all 3 rounds. However, we could still integrate the pediatric expertise of a variety of interest holders in the development of these guidelines. Relatedly, only 4 young people contributed as Delphi panelists despite our outreach efforts; this may be related to the time commitment needed. We also acknowledge that representation from low- and middle-income countries is low despite our efforts to involve a geographically diverse group of contributors. We did involve global health experts with experience in conducting trials in low- and middle-income country settings to mitigate this; however, we acknowledge that individuals from underrepresented areas may have different perspectives. We also acknowledge a language limitation because the study was conducted in English. To minimize the effect of these limitations, we implemented rigorous methods and involved a large and diverse group of end users and international experts.

Conclusions

SPIRIT-C 2026 contains 17 pediatric-specific reporting items to be addressed in pediatric RCT protocols. This minimum set of reporting items was generated through consensus by end users of pediatric RCTs, including young people, caregivers, pediatric trialists, and journal editors. Proper application by key users of the SPIRIT-C 2026 guidance should foster the preparation of useful pediatric trial protocols, which can enhance downstream trial conduct and reporting, strengthen the quality of the pediatric specific evidence base, and reduce research waste.

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Additional Information: The SPIRIT-C 2026 extension is being simultaneously published in *The BMJ*, *The Lancet Child and Adolescent Health*, and *JAMA Pediatrics*. Ethical approval was not required, as confirmed by The Hospital for Sick Children's research ethics committee. SPIRIT-C 2026 will be disseminated to participants and related patient and public communities through the SPIRIT | CONSORT-C website (https://lab.research.sickkids.ca/enrich/reporting-standards/spirit-consort-c/), where materials for patients and public members will be freely accessible. This article was not commissioned and was externally peer reviewed.

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