# SPIRIT 2025 Checklist

Scope: Standard Protocol Items: Recommendations for Interventional Trials.

Reference: See source/archetypes/spirit-2025.yml for canonical link and provenance.

## Instructions

* Use the boxes to confirm each reporting item.
* Add reviewer notes under each section as needed.

## Administrative information

* **1. Title:** Descriptive title that identifies the study as a randomised trial, the interventions, the trial acronym, and the SPIRIT item this protocol is based on.
* **2. Trial registration:** Trial identifier and registry name. If not yet registered, name of intended registry.
* **3. Protocol version:** Date and version identifier.
* **4. Funding:** Sources and types of financial, material, and other support.
* **5. Roles and responsibilities:** Names, affiliations, and roles of protocol contributors.

## Introduction

* **6. Background and rationale:** Description of research question and justification for undertaking the trial, including summary of relevant studies.
* **7. Objectives:** Specific objectives or hypotheses.

## Methods: Participants, interventions, and outcomes

* **8. Trial design:** Description of trial design including type of trial, allocation ratio, and framework.
* **9. Study setting:** Description of study settings.
* **10. Eligibility criteria:** Inclusion and exclusion criteria for participants.
* **11. Interventions:** Interventions for each group with sufficient detail to allow replication.
* **12. Outcomes:** Primary, secondary, and other outcomes.

## Methods: Assignment of interventions (for controlled trials)

* **13. Allocation:** Sequence generation, concealment mechanism, and implementation.
* **14. Blinding (masking):** Who will be blinded and how.

## Methods: Data collection, management, and analysis

* **15. Data collection methods:** Plans for assessment and collection of outcome, baseline, and other trial data.
* **16. Data management:** Plans for data entry, coding, security, and storage.
* **17. Statistical methods:** Statistical methods for analysing primary and secondary outcomes.

## Methods: Monitoring

* **18. Data monitoring:** Plans for data monitoring.
* **19. Harms:** Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct.
* **20. Auditing:** Frequency and procedures for auditing trial conduct.

## Ethics and dissemination

* **21. Research ethics approval:** Plans for seeking research ethics committee/institutional review board approval.
* **22. Protocol amendments:** Plans for communicating important protocol modifications to relevant parties.
* **23. Consent or assent:** Who will obtain informed consent or assent from potential trial participants or authorized surrogates, and how.
* **24. Confidentiality:** 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.
* **25. Declaration of interests:** Financial and other competing interests for principal investigators for the overall trial and each study site.
* **26. Access to data:** Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators.
* **27. Ancillary and post-trial care:** Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation.
* **28. Dissemination policy:** Plans for investigators and sponsors to authors and other stakeholders to share trial results.
* **29. Authorship eligibility:** Guidelines for authorship eligibility for trial publications.
* **30. Reproducibility:** Plans for sharing of original data and statistical code.

## Appendices

* **31. Informed consent materials:** Model consent form and other related documentation given to participants and authorized surrogates.
* **32. Biological specimens:** Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable.

Notes

## Provenance

* Source: See sidecar metadata in source/archetypes/spirit-2025.yml
* Version: 2025
* License: CC-BY-4.0