THE UNIVERSITY OF SYDNEY

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Quality of Life Office

SPIRIT-PRO Extension checklist: recommended items to address in a clinical trial protocol regarding patient-reported outcomes (PROs)*

Trial/CCTG/PI:
General comments: *e.g. if all QOL/PRO components are in one section, give section number and title.*

Protocol section	SPIRIT-PRO item		Protocol section number + specific comments
Administrative information			
Roles and responsibilities	SPIRIT-5a-PRO Elaboration	Specify the individual(s) responsible for the PRO content of the trial protocol.	
Introduction			
Background and rationale	SPIRIT-6a-PRO Extension	Describe the PRO specific research question and rationale for PRO assessment, and summarize PRO findings in relevant studies.	
Objectives	SPIRIT-7-PRO Extension	State specific PRO objectives or hypotheses (including relevant PRO concepts/domains).	
Methods: Participants, interventions, and outcomes			
Eligibility criteria	SPIRIT-10-PRO Extension	Specify any PRO-specific eligibility criteria (e.g. language/reading requirements or pre-randomization completion of PRO). If PROs will not be collected in the entire study sample, provide a rationale and describe the method for obtaining the PRO subsample.	
Outcomes	SPIRIT-12-PRO Extension	Specify the PRO concepts/domains used to evaluate the intervention (e.g. overall HRQOL, specific domain, specific symptom) and, for each one, the analysis metric (e.g. change from baseline, final value, time to event) and the principal time point or period of interest.	
Participant timeline	SPIRIT-13-PRO Extension	Include a schedule of PRO assessments, providing a rationale for the time points, and justifying if the initial assessment is not pre-randomization. Specify: time windows; whether PRO collection is prior to clinical assessments; and if using multiple questionnaires, whether order of administration will be standardized.	
Sample size	SPIRIT-14-PRO Elaboration	Where a PRO is the primary endpoint, state the required sample size (and how it was determined) and recruitment target (accounting for expected loss to follow-up). If sample size is not established based on PRO endpoint, then discuss the power of the principal PRO analyses.	

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Methods: Data collection, management, and analysis			
Data collection methods	SPIRIT-18a(i)-PRO Extension	Justify the PRO instrument to be used, and describe domains, number of items, recall period, instrument scaling/scoring (e.g. range and direction of scores indicating a good/poor outcome). Evidence of PRO instrument measurement properties, interpretation guidelines, and patient acceptability/burden should be provided or cited if available, ideally in the population of interest. State whether the measure will be used in accordance with any user manual and specify and justify deviations if planned.	
	SPIRIT-18a(ii)-PRO Extension	Include a data collection plan outlining the permitted mode(s) of administration (e.g. paper, telephone, electronic, other) and setting (e.g. clinic, home, other).	
	SPIRIT-18a(iii)-PRO Extension	Specify whether more than one language version will be used, and state whether translated versions have been developed using currently recommended methods.	
	SPIRIT-18a(iv)-PRO Extension	Where the trial context requires someone other than the trial participant to answer on their behalf (a proxy reported outcome), state and justify this. Provide/cite evidence of the validity of proxy assessment if available.	
	SPIRIT-18b(i)-PRO Extension	Specify PRO data collection and management strategies for minimising avoidable missing data.	
	SPIRIT-18b(ii)-PRO Elaboration	Describe the process of PRO assessment for participants who discontinue or deviate from their assigned intervention protocol	
Statistical methods	SPIRIT-20a-PRO Elaboration	State PRO analysis methods including any plans for addressing multiplicity/type 1 (α) error.	
	SPIRIT-20c-PRO Elaboration	State how missing data will be described and outline the methods for handling missing items or entire assessments (e.g. approach to imputation and sensitivity analyses).	
Methods: Monitoring			
Harms	SPIRIT-22-PRO Extension	State whether or not PRO data will be monitored during the study to inform the clinical care of individual trial participants and, if so, how this will be managed in a standardized way. Describe how this process will be explained to participants, e.g. in the participant information sheet and consent form.	
Appendices			
Questionnaires	N/A		

Calvert M, Kyte D, Mercieca-Bebber R, Slade A, Chan AW, King MT, et al. Guidelines for Inclusion of Patient-Reported Outcomes in Clinical Trial Protocols: The SPIRIT-PRO Extension. Jama. 2018;319(5):483-94.