**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.*

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| **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 |  |  |

(1)

1. 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.