**Patient-Reported Outcomes CHECKLIST for New CONCEPTS**

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| **Concept information** |  | |
| Concept date / version number | **\_ \_ - \_ \_ - \_ \_ \_ \_ /** Version number: | |
| Is this a CCTG-led or endorsed study? | 🞏 Yes  🞏 No - internationally led | If internationally-led, is the project funded?  🞏 Yes  🞏 No |
| Stage of review | 🞏 Early concept / idea  🞏 Synopsis / proposal developed for SAC review  🞏 Full protocol (trial unfunded or CTG funded) | |

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| **Question** | **Options** | **Comments** |
| 1. What is your study design? | *Trial*  🞏 Phase I  🞏 Phase II non-randomised  🞏 Phase II randomised  🞏 Phase III  🞏 Phase IV  *Other*  🞏 Cross-sectional  🞏 Prospective cohort  🞏 Registry development  🞏 PRO instrument validation  🞏 Other (please specify in the next column) |  |
| 2. Which aspects of HRQL are likely to be impacted by the study treatment/intervention (*choose all that apply*)? | 🞏 Symptoms of disease  🞏 Side effects of treatment  🞏 Psychological symptoms (e.g., anxiety, depression)  🞏 Functioning (e.g. physical, social, emotional, cognitive or role)  🞏 Sexual function  🞏 Body image  🞏 Satisfaction with healthcare  🞏 Financial wellbeing  🞏 Other (please specify in the next column) |  |
| 3. Do you plan to use a validated patient-reported outcome measure? (*noting that you may need to obtain permission, register use, pay fees, and check availability of language translations and e-versions*) | 🞏 Yes (please specify in the next column)  🞏 No (please indicate why in the next column)  🞏 Unsure |  |
| 4. Do you expect differences in HRQL between groups? | 🞏 Yes (please describe in the next column)  🞏 No |  |
| 5. Do you expect changes in HRQL over time? | 🞏 Yes (please describe in the next column)  🞏 No |  |
| 6. What are the assessment time-points during or following the intervention when HRQL is likely to be different between groups or over time (i.e. when are you likely to see the benefits, side-effects, or differences)? *(noting that you might need to consider electronic or telephone administration if key timepoints differ from clinical visits)* | Please describe in the next column |  |
| 7. Will HRQL be assessed by proxy (a parent, carer, or health professional) because the target patient population is too young, or may become too sick or cognitively impaired? | 🞏 Yes  🞏 No |  |

**Support available**

If you are assessing HRQL, you can get support from:

* [cquest@uts.edu.au](mailto:cquest@uts.edu.au) – The Quality of Life Technical Service to CTGs funded by Cancer Australia;
* Videos and checklists on writing grants, selecting PROMs, analysing PRO data and reporting PRO findings from the [PROTEUS website](https://theproteusconsortium.org/proteus-trials/).

When developing a full protocol, please refer to the [SPIRIT-PRO checklist](https://theproteusconsortium.org/proteus-trials/study-design/developing-protocols/), seeking support from CQUEST as required.

**Explanation of terms:**

* Patient-reported outcomes (PROs) are the constructs under investigation (e.g. fatigue, pain, sexual function).
* Patient-reported outcome measures (PROMs) are the questionnaires used to assess the PROs of interest (e.g. FACT-Fatigue, Brief Pain Inventory).
* Health-related quality of life (HRQL) is a multidimensional, over-arching PRO that includes all the impacts of disease and treatment on quality of life. HRQL questionnaires (e.g. EORTC QLQ-C30) are therefore PROMs.
* Quality of life is a much broader PRO than HRQL encompassing issues beyond disease and treatment that are often considered beyond the remit of healthcare.