**Cancer Symptom Trials (CST) - New Study Proposal Template**

In line with the purpose and aims of CST, new study concepts should meet the following criteria:

* Randomised controlled trials (RCTs)
* Small pilot studies for proof of concept (feasibility, safety, efficacy)
* Sub-studies embedded within a current study that adds value to the suite of currently running RCTs

Please complete the template and submit to [CST@uts.edu.au](mailto:CST@uts.edu.au).

*Your Concept Proposal document should NOT EXCEED FOUR A4 PAGES in length (excluding the table on page 1 and QOL Appendix A) and should address each of the headings below.*

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| --- | --- | --- | --- |
| **Date received** | *CST office use only* | | |
| **1. PERSONAL DETAILS OF APPLICANT** | | | |
| **Full name and title** |  | | |
| **Organisation** |  | | |
| **Address** |  | | |
| **Telephone** |  | | |
| **Email** |  | | |
| **Alternative email** |  | | |
| **2. STUDY DETAILS** | | | |
| **Full study title (50 word limit)** | | | |
| <Your text here> | | | |
| **Short study title** | | | |
| <Your text here> | | | |
| **Investigator team** | | | |
| <Concept proposer> | | | |
| <Investigator team> | | | |
| **Is this an investigator-initiated study? Yes/No**  <If no, please enter the company name and contact person> | | | |
| **Administering institution** *(if known)* | | | |
| <Your text here> | | | |
| **Collaborating partners** *(if known)* | | | |
| <Your text here> | | | |
| **Current status of study** *(please tick all that apply)* | | | |
| Concept stage1  Funding received  *(please complete 5.4)*  Includes QOL measures *(please complete Appendix A)* | | Protocol completed  Recruitment commenced  Includes health economic sub-study *(please see* [*CREST checklist*](https://www.uts.edu.au/sites/default/files/2021-06/Health%20economic%20checklist%20for%20clinical%20trials_2021_V2.pdf) *via hyperlink and complete 4.6)* | Ethics approval obtained  Other *(please comment):*  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

1CST protocol template provided upon request

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| **3. STUDY DESCRIPTION**  3.1 Background and rationale (including key references) (300 word limit – ½ page) |
| <Your text here> |

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| 3.2 Aims and hypotheses (200 word limit – ¼ page) |
| <Your text here> |

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| **4. METHODS**  4.1 What are the primary and secondary objectives? |
| <Your text here> |

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| 4.2 Define the study population (eligibility criteria) |
| <Your text here> |

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| 4.3 Outline the study design |
| <Your text here> |

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| 4.4 What is the relevant safety and/or toxicity information? Are there other potential risks, and how would these be mitigated? |
| <Your text here> |

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| 4.5 What is the primary outcome measure, the anticipated sample size and proposed analyses? |
| <Your text here> |

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| 4.6 If your proposal includes a health economic sub-study, please expand here |
| <Your text here> |

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| 4.7 In what ways might a qualitative sub-study contribute to your study? |
| Understanding the problem  Refining the intervention  Refining the measures (e.g. choice of measures)  Other  No sub-study to be considered  PaCCSC framework:  https://www.liebertpub.com/doi/10.1089/jpm.2020.0480?url\_ver=Z39.88-2003&rfr\_id=ori:rid:crossref.org&rfr\_dat=cr\_pub%20%200pubmed |

|  |
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| 4.8 Any other comments regarding the methods used |
| <Your text here> |

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| --- |
| 4.9 Include your table/diagram (if required) |
| <Your table/diagram here> |

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| --- |
| **5. POTENTIAL SUPPORT, RESOURCES, BUY-IN**  Briefly outline resources and support for this study which you have already identified, e.g. interested recruiters, potential CIs, mentors, institutional support etc. |
| <Your text here> |

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| **5.2.** Consumer Involvement: Briefly outline your plans for consumer involvement. |
| <Your text here> |

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| 5.3. Policy Maker Consultation: Briefly outline any discussions or engagement with policy makers. |
| <Your text here> |

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| 5.4. What Funding Sources Have Been Secured / Are Being Considered? Briefly outline funding sources applicable to support this study. |
| <Your text here> |

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

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:*

2. Which patient-reported outcomes (PROs) are likely to be impacted by the study treatment/ intervention (*choose all that apply*)?

Symptoms of disease. *Please specify:*

Side effects of treatment. *Please specify:*

Psychological symptoms *(e.g., anxiety, depression)*

Physical functioning *(e.g. mobility, activities of daily living)*

Role functioning *(e.g. ability to work)*

Social functioning

Sexual functioning

Body image

Satisfaction with healthcare

Financial wellbeing

Health-related quality of life (HRQL)

Overall quality of life (QOL)

Other

*Please specify:*

3. Do you plan to use one or more validated patient-reported outcome measure (PROM)? (*noting that you may need to obtain permission, register use, pay fees, and check availability of language translations and e-versions*)

Yes *Which one/s*?

No *Why?*

Unsure

4. Do you expect differences on PROMs between groups?

Yes *(please describe)*

No

*Description*:

5. Do you expect changes in PROMs over time?

Yes *(please describe)*

No

*Description*:

6. What are the time-points during or following the intervention when PROMs are likely to differ between groups and/or over time (i.e. benefits or detriments)? *(Noting that electronic or telephone PROMs may be needed if timepoints differ from clinic visits)*

*Description*:

7. Will PROMs be completed by proxy (e.g. carer or health professional) because the patient population is too young or may become too sick or cognitively impaired to self-report?

Yes

No

**Support available**

*You can obtain PRO-related methodological support for your study 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 protocols, selecting PROs, analysing PRO data, reporting PRO findings from the* [*PROTEUS website*](https://more.bham.ac.uk/proteus/tools-and-resources-for-using-pros-in-clinical-trials/)*.*

*In particular, when developing a full protocol, please refer to the* [SPIRIT-PRO Checklist](https://more.bham.ac.uk/proteus/tools-and-resources-for-using-pros-in-clinical-trials/)

**Explanation of terms:**

* Patient-reported outcomes (PROs) are the concepts 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 (QOL) is a much broader PRO than HRQL encompassing issues beyond disease and treatment that are often considered beyond the remit of healthcare.