**Palliative Care Clinical Studies Collaborative (PaCCSC) -
New Study Proposal Template**

In line with the purpose and aims of PaCCSC, 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 form below and submit to paccsc@uts.edu.au

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

|  |  |
| --- | --- |
| **Date received** | *PaCCSC 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* [*CHERE checklist*](https://www.uts.edu.au/sites/default/files/2021-06/Health%20economic%20checklist%20for%20clinical%20trials_2021_V2.pdf) *via hyperlink and complete 4.7)*  | [ ]  Ethics approval obtained[ ]  Other *(please comment):* \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 1PaCCSC protocol template provided upon request |
| **3. STUDY DESCRIPTION**3.1 Background and rationale (including key references) (300 word limit – ½ page) |
| <Your text here> |
| 3.2 Aims and hypotheses (200 word limit – ¼ page) |
| <Your text here> |
| **4. METHODS**4.1 What are the primary and secondary objectives? |
| <Your text here> |
| 4.2 Define the study population (eligibility criteria) |
| <Your text here> |
| 4.3 Outline the study design  |
| <Your text here> |
| 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. |
| 4.5 What is the primary outcome measure, the anticipated sample size and proposed analyses? |
| <Your text here> |
| 4.6 If your proposal includes a health economic sub-study, please expand here  |
| <Your text here> |
| 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 consideredPaCCSC 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> |
| 4.8 Any other comments regarding the methods used |
| <Your text here> |
| 4.9 Include your table/diagram (if required) |
| <Your table/diagram here> |
| **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, sources of pilot funding, mentors, institutional support etc. |
| <Your text here> |
| **5.2.** Consumer Involvement: Briefly outline your plans for consumer involvement. |
| <Your text here> |
| **5.3.** Policy Maker Consultation: Briefly outline any discussions or engagement with policy makers. |
| <Your text here> |
| **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* *– 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.