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

Your completion of this review is appreciated. When complete, please email to paccsc@uts.edu.au

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| --- |
| 1. **REVIEW DETAILS**
 |
| **Reviewer name** |  |
| **Date received** | *Date received by reviewer* |
| **Date reviewed** |  |
| **2. STUDY DETAILS** |
| **Full study title** |
| <PaCCSC will insert title prior to circulation> |
| **Short study title** *(if known)* |
|  |
| **Investigator Team** |
| <Concept proposer> |
| <Investigator team> |
| **Is this an investigator-initiated study? Yes/No**<If no, please enter the company name and contact person> |
| **3. STUDY DESCRIPTION**What is the background and rationale (including key papers)? Is the rationale for the study clearly articulated? What is the **unmet need** or is there a **gap** in the knowledge that this study will fill? Is the study answering important clinical question? |
| <Comments from the Reviewer> |
| 3.1 What are the aims and hypotheses? |
| <Comments from the Reviewer> |
| **4. METHODS** |
| 4.1 Do you have any specific comments relating to the primary and secondary objectives? |
| <Comments from the Reviewer> |
| 4.2 Do you have specific comments relating to the study population? |
| <Comments from the Reviewer> |
| 4.3 Do you have specific comments relating to the study design? Is the design appropriate to answer the primary and secondary objectives? |
| <Comments from the Reviewer> |
| 4.4 Does the design consider relevant safety and toxicity information? Were other significant risks mentioned, or, in your opinion, should there have been? |
| <Comments from the Reviewer> |
| 4.5 Are the proposed primary outcome measure, anticipated sample size and analyses appropriate to answer the study question? |
| <Comments from the Reviewer> |
| 4.6 Has a health economic sub-study been included in the proposal? If so, does the study propose collecting resource use information on the control (and experimental arm if relevant)? Does the outcome measure lend itself to inclusion in an economic evaluation (e.g. life years plus relevant QOL assessment? |
| <Comments from the Reviewer> |
| 4.7 Has a qualitative sub-study been included in the proposal?If so, do you have any specific questions and/or recommendations on the proposed methods? |
| <Comments from the Reviewer> |
| 4.8 Please add any other comments regarding the methods used. |
| <Comments from the Reviewer> |
| 4.9 Do you have specific comments relating to the table/diagram? (if included) |
| <Comments from the Reviewer> |
| **5. POTENTIAL SUPPORT, RESOURCES, BUY-IN**Are the supports for this study sufficient to achieve the outcomes? Are there any concerns re: potential recruitment/accrual of participants? Please make suggestions which may improve the support/resources/buy-in for the investigator team |
| <Comments from the Reviewer> |
| **5.2.** Consumer/End User Involvement: Are the plans for consumer/end-user involvement achievable/sufficient? What other consumer involvement may be of benefit to the study? |
| <Comments from the Reviewer> |
| **5.3.** Policy Maker Consultation: Is there evidence of consideration to engagement with policy makers? |
| <Comments from the Reviewer> |
| **5.4.** Funding: Are the funding sources proposed appropriate avenues to support this study? |
| <Comments from the Reviewer> |
| **6. REVIEWER RECOMMENDATION**Please check box next to your recommendation. |
| **PACCSC endorsed concept** (trial can be run by PaCCSC or in conjunction with a third-party entity (i.e. led or co-badged) |[ ]
| **Considerable further development** (concept requires further development and the investigator is requested to re-present at some point in the future) |[ ]
| **Not recommended** (concept is outside the program of PaCCSC) |[ ]
| **9.1 REVIEWER RECOMMENDATION COMMENTS**Please add any further comments relevant to your recommendation. |
| <Comments from the Reviewer> |