**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

|  |
| --- |
| 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 Is the design appropriate to answer 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 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> |
| 4.4 Are the proposed analyses appropriate to answer the study question? |
| <Comments from the Reviewer> |
| 4.5 Please add any other comments regarding the methods used. |
| <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> |
| **6. 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> |
| **7. POLICY MAKER CONSULTATION**Is there evidence of consideration to engagement with policy makers? |
| <Comments from the Reviewer> |
| **8. FUNDING**Are the funding sources proposed appropriate avenues to support this study? |
| <Comments from the Reviewer> |
| **9. 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> |