Standard Operating Procedures

6.0.1 New Study Ideas/Proposals – Cancer Symptom Trials

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<tr>
<td>Author/s</td>
<td>L Brown, B Fazekas, S Kochovska</td>
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Introduction / Background

PaCCSC and CST have a well-defined program of work across study phases and covering a number of nodes (Guidance 14) to enable ongoing work to be planned and to build expertise. PaCCSC/CST actively seek ideas for new clinical medication trials and non-pharmacological studies from the palliative care and cancer clinical research community and commercial interests that are in line with the existing program of work, and the Collaborative needs a mechanism to provide direction in relation to:

- The assessment of new study ideas/proposals brought to PaCCSC/CST; and
- The support structures available to researchers that (following acceptance of the new study idea/proposal) can be provided using PaCCSC/CST’s established clinical research infrastructure

Objective – FOR NEW CST STUDIES (studies in a cancer only population)

This SOP describes the process all new study concepts/ideas will go through in order to proceed towards pilot or full study recruitment.

Scope

This SOP applies to all individuals and/or organisations who have expressed interest in developing or undertaking new clinical studies with CST.

Ownership and Responsibility

Responsibilities of the Lead Investigator (of the new proposed study)

- To develop the study concept and submit for evaluation to the Scientific Advisory Committee (SAC)
- To develop the draft protocol for the new proposed study and present for review to the CST Scientific Advisory Committee
- To develop the full protocol for the proposed study and submit for approval to relevant Human Research Ethics Committees (HRECs).
- To apply for competitive research funding

Responsibilities of the PaCCSC/CST Coordinating Centre (UTS Based)

- To assist with the development of the draft protocol and full protocol of new proposed studies by providing teleconference facilities and practical implementation advice as required
- To provide governance and operationalisation support for new proposed studies
Responsibilities of the CST Scientific Advisory Committee

- To provide a forum for the presentation of all new study ideas/proposals by the Investigators proposing the new study at a meeting of the SAC (either face to face or via virtual means)
- To evaluate new study ideas/proposals, nominating two members of the SAC to provide written feedback for the benefit of all SAC members and the Investigators proposing the new study at its first presentation to the SAC.
- To determine the carriage or otherwise of all new study proposals/ideas under the auspice of CST through formal endorsement (minuted acceptance of the study)
- To provide guidance to the Investigators proposing the new study, and assisting with the resolution of any scientific/study design related issues where appropriate
- To receive a subsequent presentation of all new study ideas/proposals within one year of their first presentation to the SAC to determine ongoing progress and endorsement.
- To approve protocols for progression to HREC approval/funding submission.
Procedure

All new study applications are made to the PaCCSC/CST National Manager, using the New Study Proposal template (Template 31). CST undertakes to formally review applications for new studies on an as needed basis.

In line with the purpose and aims of CST, new study support will be considered for:

- 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

New studies that do not fit within the criteria listed and within the existing program of work are unable to be considered for support unless there are specific advantages to the larger CST community to move forward with a proposal.

Applications for new clinical research study ideas/proposals undertake the following staged process in order to be taken into pilot and/or subsequent Phase III clinical study development under the governance and management of CST.

1. **Proposal**

- Presentation of new ideas/proposals can be presented at the Scientific Advisory Committee meeting (which can be held out of session if needed) to inform the development of a concept or to formulate a trial development group which can progress a concept.

- The study concept is formally presented (15 minute presentation followed by 15 minute feedback) at the Scientific Advisory Committee meeting.

- Presentations are given by the Lead Investigator for the new study idea/proposal.

- The new study idea/proposal is evaluated by two members of the SAC and written feedback provided using the Template

- The new study idea/proposal requires the review of a consumer/s if there is no such representation on the investigator team.

- The new study idea/proposal Investigator is informed of the outcome of the evaluation by the SAC by the Chair.

Figure 1 below details the proposal and development process for CST new study ideas.
Figure 1 CST new idea proposal and development process
2. Development

- The Lead Investigator for the proposed study develops a draft protocol (refer SOP 6.0: Protocol Development) for the study on the appropriate PaCCSC/CST Protocol Template (pilot or full Phase III study template).

- If the protocol is not developed and ready for presentation to the CST SAC within one year of the initial presentation to the CST SAC, the idea goes back to stage 1 for re-presentation to subsequent CST SAC.

- Prior to presentation of the draft protocol to the SAC, two spokespersons, who are members of the SAC, are nominated to provide written review of the study (template provided) and provide carriage of the study at the meetings of the SAC and if needed provide feedback to the study investigators. The members will continue as the spokesperson throughout the life of the study and/or their term on the SAC.

- The protocol is presented at the next SAC meeting (held twice annually), or if required can be reviewed out of session at the discretion of the Chair.

Figure 1 above details the proposal and development process for CST new study ideas.

3. Ongoing support from CST, If CST led:

- All new studies supported by CST are conducted under the direction of the CST governance framework.

- All new studies supported by CST are undertaken within the PaCCSC/CST Standard Operating Procedures and other policy documents for the duration of the study.

- All new studies supported by CST are operationally supported by the PaCCSC/CST Coordinating Centre.

3.1 CST Support Role (Collaborative Research Group / Sponsor)

CST is the Collaborative Research Group (CRG) / sponsor for all new studies (whether pilot or phase III) receiving approval from the CST SAC to be CST-led. (Co-badged or endorsed studies will vary in terms of the support provided by CST. This will be determined on an individual study basis).

- CST, through its legal entity The University of Technology Sydney (UTS), acts as sponsor of the study for the purposes of the Therapeutic Goods Administration’s (TGA) Clinical Trial Notification (CTN) Scheme or CTX Scheme (or any successor scheme) and is responsible for preparing and submitting all documents required by the TGA to file an application for initiating and conducting the study.

- The provision to each Principal Investigator, and (through the Principal Investigator) all institutions participating in the clinical study and the reviewing HREC, of all current and relevant information regarding the investigational product/study medication as reasonably required to justify the nature, scope and duration of the study.
CST implements and maintains quality assurance and quality control systems with written SOPs to ensure that the study can be conducted and data generated, documented, recorded and reported. CST’s assistance include data management, Case Report Form (CRF) development and review, data checking and study monitoring.

CST designates appropriately qualified personnel to advise on study-related medical questions or problems.

CST monitors the study and the application of the investigational product/study medication in PaCCSC/CST sites throughout Australia and advises, via the Principal Investigator, all participating sites and TGA of the cessation elsewhere of any relevant trial, or the withdrawal of the investigational product/study medication from any other market for safety reasons.

CST notifies all participating sites of any adverse events (including serious adverse events) that occur during the course of the study (either at the study site or other study sites, including overseas sites) which may require alteration of the conduct of the study, or which may affect the rights, interests, safety or well-being of study participants.

CST facilitates cooperation between participating institutions and/or the reviewing HREC in investigating any adverse event (including serious adverse event) arising out of or in connection with the study.

CST maintains insurance, or ensures that there is a named insurer for each participating site, with respect to its activities and indemnity obligations under any agreement.
Other related SOPs

6.0 Protocol Development

All CST supported studies are required to operate in accordance with the PaCCSC/CST suite of SOPs and other work instructions and policy documents as developed by PaCCSC/CST.

Other related documents

Template 31: New Study Proposal
Template 32: New Study Proposal Evaluation
Guidance 14: Symptom Nodes and Study Matrix

References

Nil
## History

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<tr>
<td>1.0</td>
<td>27/08/2013</td>
<td>L Devilee</td>
<td>To document the process and support provided by PaCCSC for new study ideas/proposals</td>
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<tr>
<td>1.1</td>
<td>9/06/2015</td>
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<td>To clarify some minor discrepancies since development of the pilot protocol within the phase III protocol template</td>
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| 1.3     | 28/02/2018 | B Fazekas, S Kochovska | Periodic review  
Publication of the ICH GCP E6 (R2) |
| 1.4     | 28/11/2018 | L Brown         | Update following the establishment of the CST.                |

## Approval

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