UTS IMPACCT Trials Coordination Centre

Standard Operating Procedure

6.0.1b New Study Proposals - CST

Version	V1.5
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Introduction / Background

Cancer Symptom Trials (CST), funded by the Cancer Australia, was established in 2017 to address the unmet symptom management of Australians living with cancer through investigator-initiated or academic (industry-independent) clinical trials.

CST now has a well-defined program of work across study phases and covering eight symptom nodes to enable ongoing work to be planned and to build expertise. CST actively seeks ideas for new clinical medication and non-pharmacological intervention studies from the cancer / oncology and palliative care clinical research communities and commercial interests that are in line with the existing program of work, and CST needs a mechanism to provide direction in relation to:

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

Objective

This Standard Operating Procedure (SOP) describes the process all new study proposals will go through 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 Coordinating Principal Investigator (CPI) (of the new proposed study)

- To develop the study concept or draft protocol and submit for evaluation and/or present for review to the CST Annual Forum or the CST Scientific Advisory Committee (SAC)
- 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 IMPACCT Trials Coordination Centre (ITCC)

- To assist with the process of the new study proposals review by the CST SAC
- 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 SAC

- To evaluate and endorse new study proposals, including studies that have been amended and re-submitted to the CST SAC for additional review
- To assist with the study design, refinement, and development
- To provide guidance regarding investigator team members and other issues where

appropriate

- To review and endorse major changes to previously endorsed studies, including updated protocol summaries (*refer* Template 28, section 2).

Procedure

All new study applications are made to the CST National Manager, using the New Study Proposal template (Template 31b). The CST SAC formally reviews applications for new studies twice per annum. New applications can be reviewed out of session as required.

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 proposals undertake the following staged process to be taken into pilot and/or subsequent Phase III clinical study development under the governance and management of CST.

1. Proposal

- Informal discussions of new proposals can be tabled at any CST SAC meeting to inform the development of a concept or to formulate a trial development group which can progress a concept in preparation for formal presentation.
- The study concept is formally presented (15-minute presentation) at a CST SAC meeting.
- Presentations are given by the CPI for the new proposal.
- The new study proposal is evaluated by the CST SAC members using the CST Protocol New Study Review template (Template 32b).
- Out of session reviews: Reviewers are allocated by the CST National Manager comprising of least two medical health professionals, one consumer, the health economics team (CREST) and the QOL office (CQUEST)
    - Reviewer feedback is requested within 10 business days
    - A new reviewer will be assigned if an allocated reviewer does not have the capacity to complete
    - Reviews are collated and sent back to CPI prior to presentation to the SAC
- The CPI is informed of the outcome of the evaluation by the CST SAC by the CST National Manager or delegated representative.

Figure 1 below details the proposal and development process for CST new study proposals.

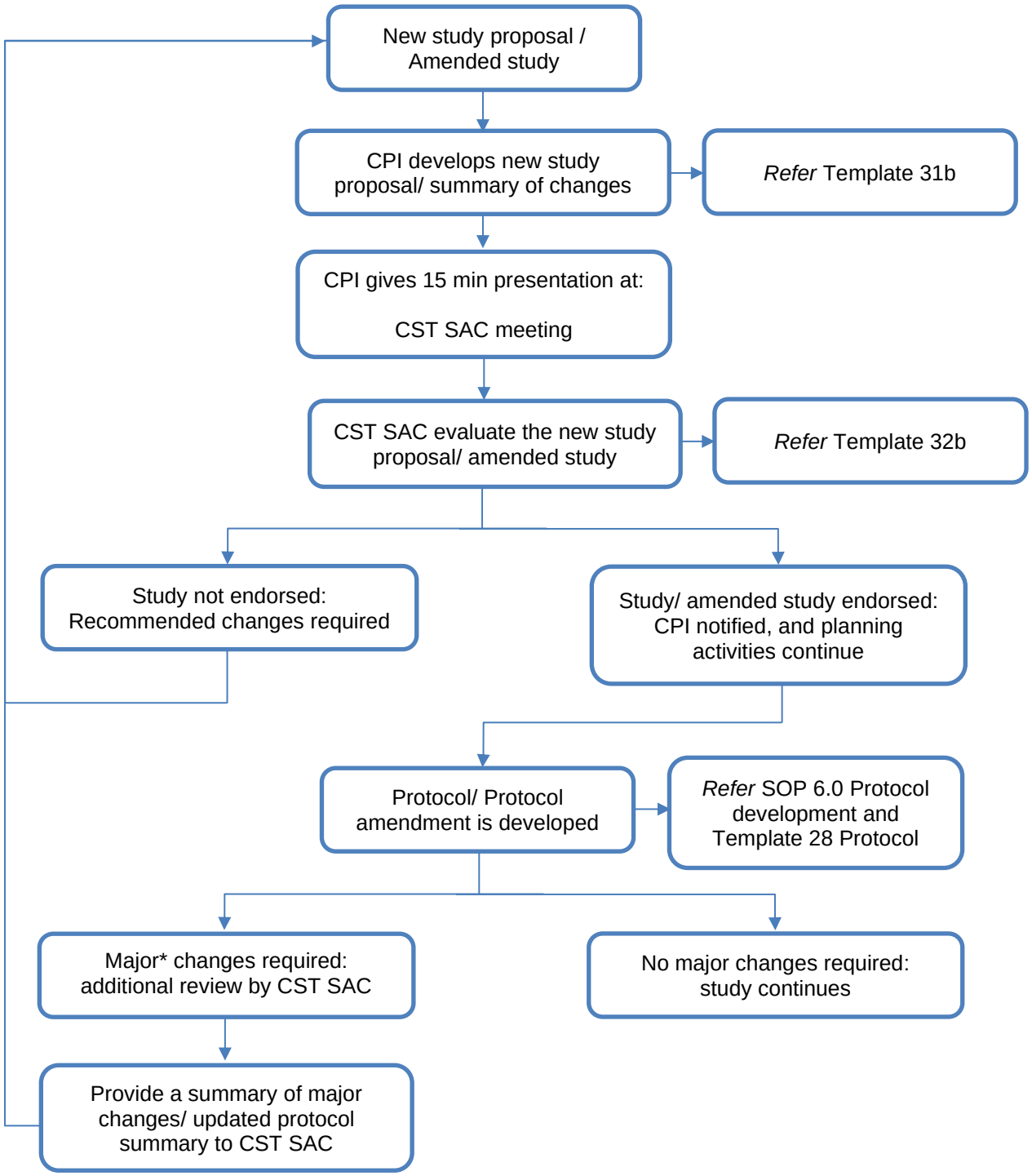

Figure 1 CST new study proposal and development process

***Major changes** (can occur at any stage of study development and implementation)**:**

1. Changes to study intervention, including dosing changes
2. Changes to study design
3. Significant safety issues bringing about change (such as eligibility criteria)
4. Change in sponsor

2. Development

- The CPI for the proposed study develops a draft submission outlining the study design using the CST New Study Proposal Template (*refer* Template 31b).
- If the New Study Proposal is not endorsed by CST SAC within one year of the initial presentation to the CST SAC, it can be presented again to CST SAC meeting.
    - Any study that undergoes a major change(s) at any stage of project development or implementation is required to submit a summary of changes (outlined in new study concept template [*refer* Template 31b]) or as a protocol summary [*refer* Template 28, section 2]).
    - Major changes include, but are not limited to, 1) Changes to study intervention, including dosing changes; 2) Changes to study design; 3) Significant safety issues bringing about change (such as eligibility criteria); 4) Change in sponsor.

3. Ongoing support from CST and ITCC

- 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 CST/ITCC SOPs and other policy documents for the duration of the study.
- All new studies supported by CST are operationally supported by the ITCC

4. CST and ITCC 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.

- CST acts as sponsor of the study for the purposes of the Therapeutic Goods Administration's (TGA) Clinical Trial Notification (CTN) Scheme or Clinical Trials Approval (CTA) 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 CPI, and (through the CPI) all institutions participating in the clinical study and the reviewing HREC, of all current and relevant information regarding the investigational product/study medication/non-pharmacological intervention as reasonably required to justify the nature, scope, and duration of the study.
- CST/ ITCC, 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/ITCC assistance includes data management, Data Collection Worksheet and Case Report Form (CRF) development and review, data checking and study monitoring.
- CST/ITCC designates appropriately qualified personnel to advise on study-related medical questions or problems.
- CST/ITCC monitors the study and the application of the investigational product/study medication/non-pharmacological intervention in 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/non-pharmacological intervention from any other market for safety reasons.

- CST/ITCC 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/ITCC 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/ITCC 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.

Related SOPs

6.0 Protocol Development

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

Related documents

Template 28:	Protocol Template Including Pilot
Template 31b:	New Study Proposal - CST
Template 32b:	New Study Proposal Evaluation - CST

References

Nil

History			
Version	Date	Author	Reason
1.0	27/08/2013	L Devilee	To document the process and support provided by PaCCSC for new study ideas/proposals
1.1	9/06/2015	C Hope	Periodic review
1.2	13/08/2015	L Devilee	To clarify some minor discrepancies since development of the pilot protocol within the phase III protocol template
1.3	28/02/2018	B Fazekas, S Kochovska	Periodic review Publication of the ICH GCP E6 (R2)
1.4	26/02/2020	V. Yenson	Periodic review – CST
1.5	18/01/2022	V. Yenson	Periodic review – CST. Changes to procedure for studies requiring significant changes

Approval		
Version	Approval Name	Approval Signature
1.5	Meera Agar