UTS IMPACCT Trials Coordination Centre

Standard Operating Procedure

6.0.1a New Study Ideas/Proposals - PaCCSC

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Approved	M Agar
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Introduction / Background

Initial studies for the Palliative Care Clinical Studies Collaborative (PaCCSC), funded by the Australian Government Department of Health, were defined by the Palliative Care Medicines Working Group as priority medications for the generation of evidence into their net effect.

Additional new studies have come under the umbrella of PaCCSC where competitive grant funds have been secured to support the conduct of the studies.

PaCCSC 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. PaCCSC actively seeks ideas for new clinical medication studies from the palliative care 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; and
- The support structures available to researchers that (following acceptance of the new study idea/proposal) can be provided using PaCCSC' established clinical research infrastructure

PaCCSC is located within the Centre for *Improving Palliative, Aged and Chronic Care through Clinical Research and Translation* (IMPACCT) at the Faculty of Health, University of Technology Sydney (UTS).

Objective

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 PaCCSC.

Ownership and Responsibility

Responsibilities of the Coordinating Principal Investigator (CPI) (of the new proposed study)

- To develop the study concept and submit for evaluation to the PaCCSC Annual Forum or the IMPACCT (including PaCCSC) Scientific Advisory Committee (SAC)
- To develop the draft protocol for the new proposed study and present for review to the IMPACCT (including PaCCSC) 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 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 IMPACCT (including PaCCSC) SAC

- To evaluate new study ideas/proposals
- To assist with the protocol refinement and development
- To provide guidance regarding investigator team members, and other issues where appropriate
- To review draft protocols for new proposed studies
- To approve protocols for progression to HREC

Procedure

All new study applications are made to the PaCCSC National Manager, using the New Study Proposal template (Template 31a). The IMPACCT (including PaCCSC) Scientific Advisory Committee (SAC) formally reviews applications for new studies twice per annum.

In line with the purpose and aims of PaCCSC, 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 PaCCSC 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 PaCCSC.

1. Proposal

- Informal discussions of new ideas/proposals can be tabled at any IMPACCT (including PaCCSC) 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 IMPACCT (including PaCCSC) SAC meeting.
- Presentations are given by the Coordinating Principal Investigator (CPI) for the new idea/proposal.
- The new study idea is evaluated by the IMPACCT (including PaCCSC) SAC members using the New Study Evaluation template (Template 32a).
- The CPI is informed of the outcome of the evaluation by the IMPACCT (including PaCCSC) SAC by the PaCCSC National Manager or delegated representative.

Figure 1 below details the proposal and development process for PaCCSC new study ideas.

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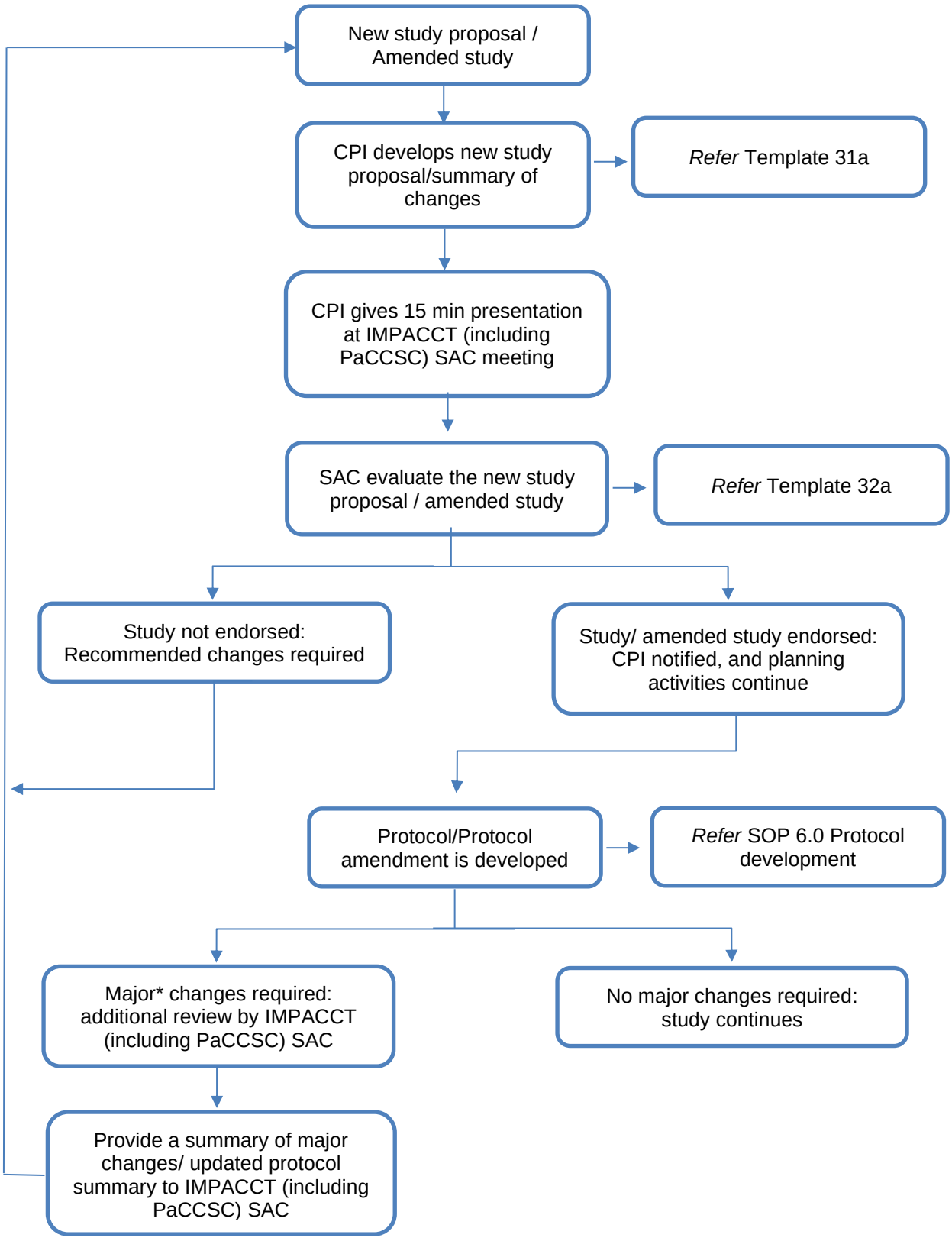

Figure 1 PaCCSC new idea proposal and development process

***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 IMPACCT (including PaCCSC) New Study Proposal Template (*refer* Template 31a).
- If the New Study Proposal is not endorsed by IMPACCT (including PaCCSC) SAC within one year of the initial presentation to the IMPACCT (including PaCCSC) SAC, it can be presented again to IMPACCT (including PaCCSC) 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 31a]) or as a protocol summary).
    - 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 PaCCSC/ITCC

- All new studies supported by PaCCSC are conducted under the direction of the IMPACCT governance framework.
- All new studies supported by PaCCSC are undertaken within the ITCC Standard Operating Procedures and other policy documents for the duration of the study.
- All new studies supported by PaCCSC are operationally supported by the ITCC.

3.1 PaCCSC/ITCC Support Role (Collaborative Research Group / Sponsor)

PaCCSC is the Collaborative Research Group (CRG) and the University of Technology Sydney (UTS) is the sponsor for all new studies (whether pilot or phase III) receiving approval from the IMPACCT (including PaCCSC) SAC.

- 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 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 as reasonably required to justify the nature, scope, and duration of the study.
- PaCCSC/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. The ITCC assistance include data management, Case Report Form (CRF) development and review, data checking and study monitoring.
- PaCCSC/ITCC designates appropriately qualified personnel to advise on study-related medical questions or problems.

- PaCCSC/ITCC monitors the study and the application of the investigational product/study medication in PaCCSC/ITCC 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.
- PaCCSC/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.
- PaCCSC/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.
- PaCCSC/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 PaCCSC supported studies are required to operate in accordance with the ITCC suite of SOPs and other work instructions and policy documents as developed by the ITCC.

Other related documents

Template 31a: New Study Proposal

Template 32b: New Study Proposal Evaluation

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	01/04/2020	S Kent	Periodic review
1.5	12/01/2022	G Prael	Periodic review

Approval		
Version	Approval Name	Approval Signature
1.5	Meera Agar