



UTS

IMPACCT
Trials Coordination
Centre

Principal Investigator Manual (PI Manual)

Principal Investigator Manual

Purpose

This manual has been created for organisations who are recruiting patients to clinical trials being coordinated by the IMPACCT Trials Coordination Centre (ITCC) including the Palliative Care Clinical Studies Collaborative (PaCCSC) and/or Cancer Symptom Trials (CST).

The purpose of this manual is to give an overview of available resources to support the administration of clinical trials at each participating site.

If you have any questions that are not answered by the resources included in this manual, please contact the email address below, or refer to the [Contacts](#) section for details about who to contact for specific queries.

Contact us

IMPACCT Trials Coordination Centre (ITCC)

Level 3, 235 Jones St, Ultimo NSW 2007

PO Box 123, Broadway NSW 2007, Australia

E: itcc@uts.edu.au

W: uts.edu.au/impacct/itcc

Palliative Care Clinical Studies Collaborative (PaCCSC)

E: paccsc@uts.edu.au

W: uts.edu.au/paccsc

Cancer Symptom Trials (CST)

E: CST@uts.edu.au

W: uts.edu.au/cst

Version control

DATE	VERSION	COMMENTS	WHO
15/02/2019	1.0	Final approved	L James, L Brown, B Fazekas
11/03/2020	2.0	Two-year review	L Brown
07/05/2020	2.1	Edited	L James
01/04/2022	3.0	Periodic review, Updated Site Investigator Forum information	V Yenson, L Brown



Improving Palliative Aged and Chronic Care Through Research and Translation (IMPACCT)

W: uts.edu.au/impacct

PaCCSC and CST are located within the IMPACCT Trials Coordination Centre (ITCC) at the University of Technology Sydney (UTS). IMPACCT's transdisciplinary research program is dedicated to improving the care, outcomes, and quality of life of people affected by a range of chronic conditions or who have palliative care needs.

Location

W: <https://maps.uts.edu.au/map.cfm>

W: <https://maps.uts.edu.au/directions.cfm>

IMPACCT and the ITCC are located in Building 10 on the UTS campus in Ultimo NSW. A UTS campus map is available at the above UTS maps web page. Type 'CB10' into the 'Search maps' field on the maps web page, and press 'enter' to see more details about building access points and amenities, including mobility access ramps.

If you are visiting the campus, please read the *Directions to UTS* web page at the directions link above. It includes information about public transport options and parking.

Parking is limited to metered street parking and user-pay parking stations, other than for people with disabilities and those with special permits. Visitors with mobility impairments can access parking on campus by calling UTS Security on 1800 249 559.

Palliative Care Clinical Studies Collaborative (PaCCSC)

PaCCSC is an Australia-wide research network that aims to improve the wellbeing of people with life-limiting illness through:

- The generation of high-quality research evidence to support effective palliative care clinical interventions including medications
- Building capacity within the health workforce in the conduct and understanding of high-quality palliative care clinical research
- The translation of palliative care research results into clinical practice and policy

Public health and clinical advances have led to people living longer and consequently having a higher likelihood of warning of death. Our role is to engage in high quality research that provides the evidence base to underpin and optimise quality healthcare practice for people with life-limiting illness.

PaCCSC is a national, member-based research network comprised of a participating network of hospitals and health services, where the benefits of our research can be applied directly to patients and, more broadly, to health policy.

Cancer Symptom Trials (CST)

Cancer Symptom Trials (CST) is one of fourteen Cancer Cooperative Trials Groups (CCTGs) funded by Cancer Australia. CST is a research collaborative within the IMPACCT research centre at UTS.

Our work is important for the significant number of Australians who are diagnosed with cancer every year. Through our clinical trials, we research options for improved management of symptoms that can occur due to a cancer diagnosis and related treatments.

Our goal is to ensure the best quality of life possible for people with cancer. We do this by identifying accessible, affordable, and appropriate medicines and therapies for people with cancer, including those living at home.

We acknowledge the significant role that carers play in the lives of people with cancer. They are critical contributors in decisions about management of symptoms. We welcome their inclusion and participation in our research.



Membership

As a Principal Investigator, you are a member of PaCCSC and/or CST, depending on the clinical trial/s that you are conducting at your site. Please submit your details to our membership database via the online membership forms available at the websites below. A Confidentiality Agreement is required upon joining, and members receive quarterly newsletters for ongoing trial updates, notification of available opportunities (such as grants, conferences and our annual Forum), and the achievements of fellow members.

PaCCSC membership

W: uts.edu.au/paccsc/membership

CST membership

W: uts.edu.au/cst/membership

Committees and meetings

As a Principal Investigator, you will be a member of the 1) Site Investigator Forum which meets 4 times per year, and 2) study-specific Trial Meetings held from trial initiation to close of recruitment. These are monthly teleconference meetings conducted with all recruiting sites.

Resources

W: uts.edu.au/itcc/researcher-resources

You can find a range of resources available for clinical trials' sites on the ITCC Researcher Resources web page above. Available resources include Standard Operating Procedures (SOPs), guidelines, templates, and information about new study proposals, referral resources and research data management.

Standard Operating Procedures

Standard Operating Procedures (SOPs) enable operationalisation of the principles required by International Council for Harmonisation (ICH) guidelines for Good Clinical Practice (GCP). They are designed to be applied across ITCC/PaCCSC/CST trials and support the study-specific study protocols.

Our SOPs are available as a single combined document, or you can download individual SOPs that are relevant to you. We recommend that you become familiar with the available SOPs and that the above link be a first port of call for any operational queries.

Each SOP is supported by a range of guidelines to further explain the detail of the SOP, and templates to enable the SOP to be applied in specific situations.

If you can't find the information you need, please contact us for advice.

Guidelines and Templates

Our guidelines and templates have been developed to ensure consistency in the way information is disseminated, collected and documented through the SOPs. They will help you to ensure that your site is compliant with each studies clinical trial protocol. The ITCC Protocol template is available on request by those wanting to develop a new trial and be the Coordinating Principal Investigator (CPI). This comprehensive document includes guidance from ICH GCP and other industry sources for a complete and high-quality protocol for your research.

Referral resources

We have two plain-English FAQs brochures available at the above web page with information for potential trial participants. You are welcome to download and print these for use at your site.

Research data management systems

We use purpose-built clinical trials data management systems. Access is granted to our members to support their research conducted with the ITCC. Please direct enquiries about these systems to our National Project Officer, Ms Belinda Fazekas.

Contacts

Name/role	Queries	E-mail	Telephone
Linda Brown National Manager, PaCCSC/CST	Clinical Trials Agreements, membership	Linda.Brown@uts.edu.au	0437 816 884



Belinda Fazekas National Project Officer	Clinical studies Protocols	Belinda.Fazekas@uts.edu.au	0414 190 084
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