Palliative Care Clinical Studies Collaborative (PaCCSC) and Cancer Symptom Trials (CST)

Principal Investigator Manual
Principal Investigator Manual

Purpose

This manual has been created for organisations who are recruiting patients to clinical trials run by 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

Palliative Care Clinical Studies Collaborative (PaCCSC)
Level 3, 235 Jones St, Ultimo NSW 2007
PO Box 123, Broadway NSW 2007, Australia
E: paccsc@uts.edu.au
W: www.uts.edu.au/paccsc

Cancer Symptom Trials (CST)
Level 3, 235 Jones St, Ultimo NSW 2007
PO Box 123, Broadway NSW 2007, Australia
E: CST@uts.edu.au
W: www.uts.edu.au/cancer-symptom-trials

Version control

<table>
<thead>
<tr>
<th>DATE</th>
<th>VERSION</th>
<th>COMMENTS</th>
<th>WHO</th>
</tr>
</thead>
<tbody>
<tr>
<td>15/02/2019</td>
<td>1.0</td>
<td>Final approved</td>
<td>L James, L Brown, B Fazekas</td>
</tr>
</tbody>
</table>
Improving Palliative Aged and Chronic Care Through Research and Translation (IMPACCT)


PaCCSC and CST are located within IMPACCT 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

IMPACCT is in Building CB10 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.

Please note that 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)

W: https://www.uts.edu.au/paccsc/message-chief-investigator

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.

Governance

The PaCCSC Chief Investigator, Professor David Currow, provides leadership to the collaborative, supported by the National Manager, Ms Linda Brown.

PaCCSC is governed by a Management Advisory Board, a Scientific Committee, a Trials Management Committee and study specific Data and Safety Monitoring Committees.

Engagement with health professionals, researchers and the general community is a high priority for PaCCSC. We have a diverse national membership and encourage active participation in our research from colleagues and the community.
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 Improving Palliative, Aged and Chronic Care through Research and Translation (IMPACCT) research centre at the University of Technology Sydney.

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.

Governance

Cancer Symptom Trials (CST) is led by Professor Meera Agar, supported by the National Manager, Ms Linda Brown.

The CST is governed by a Management Advisory Committee, a Scientific Advisory Committee, study-specific Trial Management Committees and a Data and Safety Monitoring Committee.

Engagement with the community is a high priority for CST and consumers play a vital role in ensuring our research is relevant and meaningful to people living with cancer.

Please see Appendix A IMPACCT Governance for an overview of our governance structure.

Membership

As a Principal Investigator, you are a member of PaCCSC and/or CST, depending on the clinical trial that you are running. Please submit your details to our membership database via the online membership forms available at the websites below.

PaCCSC membership


CST membership


Committees and meetings

As a Principal Investigator, you will be a member of a Trial Management Committee. A similar forum is held for site coordinators.

For PaCCSC, a single over-arching Trials Management Committee has oversight of all clinical trials. For CST, a study-specific Trial Management Committee will be established for each study.

Trials Management Committees meet monthly via teleconference with an annual face-to-face meeting in March to align with the Annual Research Forum.
Resources

W: https://www.uts.edu.au/paccsc/researcher-resources

You can find a range of resources available for both PaCCSC and CST clinical trials’ sites on the PaCCSC 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

W: https://www.uts.edu.au/paccsc/research-support-resources/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 both PaCCSC and 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 clinical trial protocols.

Referral resources

W: https://www.uts.edu.au/paccsc/research-support/referral-resources

We have several plain-English posters and 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 PaCCSC and/or CST. Please direct enquiries about these systems to our National Project Officer, Ms Belinda Fazekas.

Contacts

<table>
<thead>
<tr>
<th>Name/role</th>
<th>Queries</th>
<th>E-mail</th>
<th>Telephone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Linda Brown</td>
<td>Clinical Trials Agreements</td>
<td><a href="mailto:Linda.Brown@uts.edu.au">Linda.Brown@uts.edu.au</a></td>
<td>0437 816 884</td>
</tr>
<tr>
<td>National Manager, PaCCSC and CST</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Belinda Fazekas</td>
<td>Clinical studies Protocols</td>
<td><a href="mailto:Belinda.Fazekas@uts.edu.au">Belinda.Fazekas@uts.edu.au</a></td>
<td>08 7421 9796 or 0414 190 084</td>
</tr>
<tr>
<td>National Project Officer, PaCCSC</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Louise Fazekas-Giles</td>
<td>Membership Meetings General enquiries</td>
<td><a href="mailto:Louise.Fazekas-Giles@uts.edu.au">Louise.Fazekas-Giles@uts.edu.au</a></td>
<td>08 8275 1926 or 02 9514 4862</td>
</tr>
<tr>
<td>Administration Officer, PaCCSC</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Christine Bassiri</td>
<td>Membership Meetings General enquiries</td>
<td><a href="mailto:Christine.Bassiri@uts.edu.au">Christine.Bassiri@uts.edu.au</a></td>
<td>02 9514 2858</td>
</tr>
<tr>
<td>Executive Assistant, CST</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

11 December 2018
Appendix A IMPACCT Governance chart