UTS IMPACCT Trials Coordination Centre

Standard Operating Procedure

6.15.1 Dissemination of Study Results

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Introduction / Background

The IMPACCT Coordination Centre (ITCC) (incorporating the Palliative Care Clinical Studies Collaborative (PaCCSC) and Cancer Symptom Trials (CST)) recognises the importance and responsibility to disseminate the results of its clinical studies in accordance with the Australian Code for Responsible Conduct of Research.

ITCC also recognises the importance of maintaining clinician engagement with contributing sites and shares information in line with contractual requirements and processes described in this Standard Operating Procedure (SOP).

Centralised management of the dissemination of study results is required in order to:

- protect the integrity of the study results and their interpretation;
- prevent duplication of publication of study results;
- reduce the risk of individual site data appearing to conflict with aggregated study results;
- prevent re-identification of participants in local study populations and;
- reduce the potential for clinician recall bias in results dissemination;

Objective

This SOP describes the processes for managing the dissemination of study results following study closure.

Scope

This SOP applies to all staff involved in clinical studies conducted by ITCC/PaCCSC/CST irrespective of individual organisational employment, role, or position.

Ownership and Responsibility

Responsibility for dissemination rests with the Coordinating Principal Investigator (CPI), who is supported by the ITCC. The CPI responsibilities regarding dissemination can be delegated to the PaCCSC/CST National Manager where agreement has been reached for this to occur between the parties. The Principal Investigator (PI) at the site is responsible for all processes and procedures at the site.

Responsibilities of the CPI or delegated PaCCSC/CST National Manager

- To assist with the development of the study Dissemination Plan
- To monitor the execution of the Dissemination Plan once it is mobilised
- To liaise with the Executive Author to ensure timely execution of the study Dissemination Plan
- To liaise with the relevant Scientific Advisory Committee during the review and ratification of the study Dissemination Plan

Responsibilities of the PI and/or other designee(s) as documented in the Staff Signatures and Delegation Log (refer SOP 4.2.4 Delegation of Duties)

- To participate in the development of the study Dissemination Plan

Responsibilities of relevant Scientific Advisory Committee

- The review and ratify the Dissemination Plan for each study
- To determine the timing and form of presentations, publications, press releases and other information for dissemination

Procedure

1. Timing

- The CPI and the relevant Scientific Advisory Committee determine the timing and form of presentations, publications, press releases and other information for dissemination.
- The **full disclosure of study results** will only be made, other than verbally, presenting the results by the CPI or their delegate at leading scientific meetings, **after the main study manuscript is accepted for publication in an appropriate peer-reviewed scientific journal**.
- An **embargo** is placed on individual site data being released back to the site until the main study manuscript is published in an appropriate peer-reviewed scientific journal.
- Dissemination of results proceeds in accordance with the study's Dissemination Plan.

2. Study Dissemination Plan

- A Dissemination Plan for each ITCC/PaCCSC/CST sponsored study is developed by the CPI and/or PaCCSC/CST National Manager. Ideally, the Dissemination Plan is developed concurrently with the study protocol.
- The Dissemination Plan is developed using the Dissemination Plan Template (Template 24).
- The Dissemination Plan is shared with the Protocol Investigators who are invited to comment.
- The Dissemination Plan is reviewed and ratified by the relevant Scientific Advisory Committee.
- The Dissemination Plan is mobilised immediately upon initial publication of the main study results:
    - 60% of actions are completed by 3 months from mobilisation
    - 90% of actions are completed by 12 months from mobilisation
    - 100% of actions are completed by 18 months of mobilisation

3. Journal Publications

- Manuscripts for publication are developed in line with SOP 6.15 Authorship.
- The PaCCSC/CST National Manager is notified of an intention to develop a manuscript for publication via email from the executive author.
- The executive author submits the full manuscript to the agreed authorship team (consistent with SOP 6.15 Authorship) for comment (and amendment) prior to submission for publication.
- Any conflicts are resolved using the Conflict Resolution process detailed in SOP 6.15 Authorship.

4. Scientific Meeting Presentations

- National and international scientific meetings are targeted for the dissemination of ITCC/PaCCSC/CST study results.
- Submissions of abstracts for scientific meetings are consistent with the Dissemination Plan and SOP 6.15 Authorship.
- Prior to submission of an abstract for presentation at a scientific meeting:
    - The PaCCSC/CST National Manager is notified of an intention to develop a manuscript for publication via email from the executive author.
    - The executive author is required to circulate the draft abstract/publication with the authorship team as per SOP 6.15 Authorship.
- Following acceptance of an abstract for presentation at a scientific meeting:
    - The abstract author shares the abstract with the PaCCSC/CST National Manager.
    - The PaCCSC/CST National Manager distributes the abstract to the Protocol Investigator team.
    - The abstract is discussed either by email or if timing allows at the next scheduled relevant Scientific Advisory Committee (the abstract author must be present), and the presentation's content is agreed upon.
    - **Full disclosure of the results must wait until the main paper has been accepted for publication in a peer-reviewed journal.**
- Following presentation of the study results at the scientific meeting:
    - The abstract author (presenter) sends an email of the presentation details to the PaCCSC/CST National Manager.
    - Upon acceptance for publication, the main paper is disseminated to members of the relevant Scientific Advisory Committee.
- Restrictions on results dissemination and the role of individual site contributions:
    - Individual site data must remain aggregated until after publication. It cannot be subject to a separate or secondary analysis or published as a stand-alone item without the written permission of ITCC/PaCCSC/CST and the CPI. This is because:
        - most journals do not permit the release of a manuscript’s content in advance of publication. Simultaneous release of the publication in line with the dissemination plan is preferred;
        - there is an inherent risk that an individual site’s data may appear differently to the aggregated study results and/or the individual site findings may not support the overall study findings;
        - the local population could potentially be re-identified;
        - rules regarding unblinding during the trial should remain in place until publication of the study results; and

- recall bias becomes a risk – a clinician's (local site investigator's) desire to see whether their clinical suspicion about which arm a patient was randomised is difficult and drawing conclusions is not possible without prospective documentation of clinical opinion during the participant's time on study, exploration an individual case with any accuracy about individual decision making is problematic.

- ITCC/PaCCSC/CST recognises the importance of maintaining clinician engagement with contributing sites and will wherever possible continue to share information in line with the above process.
- Participant and consumer feedback will be conducted as per the Dissemination Plan for each study.
- **An embargo on individual site data remains in place until publication of the full study results.**

5. Impact measurement

- The impact of the Dissemination Plan and dissemination activities is measured using any of the following strategies:
  - Impact
    - Star rating of the peer-reviewed journal
    - Positive evaluation of outsourced critical appraisal workshops
    - External audit
  - Number of citations
    - Measured at 6 months post-publication
    - Measured at 12 months post-publication
  - Responses received from organisations/groups contacted for any means
    - No response
    - Response without action from responder
    - Response indicates action will be taken
    - Response actioned (i.e. published article/letter, reference on website, link to study report etc.)
  - Monitoring of timelines set out in this SOP
  - Change to health professional practice
    - Survey sites after one-year post-publication of study results

Related SOPs

4.2.4 Delegation of Duties

5.18.2 Study Closure

6.15 Authorship

5.5.10 Data Ownership and Utilisation

Related documents

Template 24: Dissemination Plan

SOP 6.15.2 Journal Publications for Impact

References

Australian Code for the Responsible Conduct of Research 2007 (accessed 20/10/2017) https://www.nhmrc.gov.au/guidelines-publications/r39

National Statement on Ethical Conduct in Human Research (2007) - Updated March 2014 - (accessed 19/10/2017) http://www.nhmrc.gov.au/guidelines-publications/e72

History			
Version	Date	Author	Reason
1.0	18/08/2015	C Hope, L Devilee	New procedure
1.1	9/06/2016	L Devilee	Update following March 2016 governance meetings
1.2	28/02/2018	B Fazekas, S Kochovska	Periodic review Publication of the ICH GCP E6 (R2)
1.3	01/04/2020	L Brown	Periodic review
1.4	01/04/2022	L Brown	Periodic review

Approval		
Version	Approval Name	Approval Signature
1.4	Meera Agar