UTS IMPACCT Trials Coordination Centre

# Standard Operating Procedure

## 5.5.10 Data Ownership and Sharing

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| Version | V1.7 |
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| Approved | M Agar |
| Effective date | 01/04/2022 |
| Review date | 01/04/2024 |

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## Introduction / Background

The Australian Code for the Responsible Conduct of Research (2018) requires research institutions to have policies that address the ownership of data, including their retention beyond the end of the project and appropriate access to them by the research community.

Furthermore, The Australian Code of the Responsible Conduct of Research (2018) requires research collaboratives to have agreed arrangements in place for data ownership prior to the commencement of the project.

In addition, there are now national and international expectations that research data is used to its full capacity, to avoid duplication of trials, and to make the best use of the funding and grants. This can be achieved by sharing data from clinical trials with external organisations and researchers to enable additional analysis to be undertaken, and for data to be combined with other similar data for meta-analysis. Trial registries and approving HREC seek details around proposed data sharing to be transparent and pre-determined.

Data ownership is different from data storage and data management. The data owner is the person(s) (or entity) identified as having overall responsibility for the research data. Research data may be stored at multiple research sites during and following the research project.

## Objective

This SOP defines and describes how data ownership and sharing arrangements are determined within the IMPACCT Trials Coordination Centre (ITCC) which includes data of the Palliative Care Clinical Studies Collaborative (PaCCSC) and Cancer Symptom Trials (CST) to ensure its integrity, safety, and use, now and in the future.

## Scope

This SOP applies to all individuals involved in clinical studies conducted by ITCC (including PaCCSC and CST members where the University of Technology Sydney (UTS) is the sponsor) irrespective of individual organisational employment, role, or position.

## Ownership and Responsibility

*Responsibilities of the PaCCSC/CST National Manager*

- To negotiate data ownership agreements between commercial sponsor and ITCC on behalf of University of Technology Sydney
- To manage requests for sharing of ITCC (UTS) held data
- To liaise with Coordinating Principal Investigator (CPI) and the Chairs of the relevant Scientific Advisory Committee regarding requests for data sharing.
- To maintain a log of requests for data sharing
- To provide the log for review when requested at meetings of the relevant Scientific Advisory Committee

# Data Ownership Outline and Procedure

## 1. PaCCSC/CST-sponsored studies

- Data created in any ITCC sponsored study are owned by ITCC (legal entity is University of Technology Sydney) and are managed by the relevant Scientific Advisory Committee with advice from the CPI.
- The data relating to any ITCC sponsored study will be owned by ITCC (University of Technology Sydney) unless the study is conducted as per items 2 or 3 below.
- ITCC is the data custodian for all ITCC sponsored studies.
- The data owner is documented in the Clinical Trial Research Agreement (CTRA) (as per the Medicines Australia Standard Agreement), held between ITCC and each participating site for each ITCC sponsored study.
- Data ownership is reviewed and updated whenever appropriate, including (but not limited to):
  - If the agreed, documented data owner leaves the collaboration.
  - If the agreed, documented data owner moves from one institution / organisation to another.
  - Following completion of the project.
- Requests for sharing of data from any party (recruiting site, other research centre or collaboration, etc.) are referred to the relevant Scientific Advisory Committee
- Data collected by individual trial sites in relation to a specific trial/study is referred to in the CTRA for each individual study and referred to as Study Materials. For information regarding ownership, rights and use of such materials the CTRA for the site/study should be referred to.

## 2. Joint ownership

- As well as sponsoring studies, ITCC also conducts and coordinates clinical research trials in collaboration with other Universities and research collaboratives. These are referred to herein as joint ownership research.
- Prior to agreement to conduct external collaborative research, data ownership is negotiated between the parties by UTS Legal Services on behalf of University of Technology Sydney. Specific data ownership issues negotiated include (but are not limited to):
  - Arrangements if the research is terminated early;
  - Arrangements if one party withdraws from the study;
  - Arrangements for data ownership at the completion of the study;
  - Process for addressing requests for sharing data from external parties.
- The agreed data ownership arrangements are documented in the head Research Collaboration or Multi-institutional Agreement (or equivalent) between the external party

and University of Technology Sydney. This Agreement is produced by one party, usually the Grant Holder, and negotiated between the parties.

- The Research Collaboration or Multi-institutional Agreement is reviewed by UTS Legal Services and once agreement is reached the contract is fully executed.

## 3. Commercial studies

- As well as sponsoring studies, ITCC also conducts and coordinates clinical research trials on behalf of commercial organisations (e.g., the pharmaceutical industry). These are referred to herein as commercially sponsored trials.
- Prior to agreement to conduct a commercially sponsored trial, data ownership is negotiated between the commercial sponsor and the Coordinating Principal Investigator and PaCCSC/CST National Manager on behalf of University of Technology Sydney. Specific data ownership issues negotiated include (but are not limited to):
    - Arrangements if the commercially sponsored trial is ceased;
    - Arrangements if the data owner withdraws from the study;
    - Arrangements for data ownership at the completion of the study;
    - Process for addressing requests for sharing data from external parties.
- In most commercially sponsored trials, data ownership sits with the commercial entity and University of Technology Sydney (ITCC/PaCCSC/CST) is given rights to use the data for the purposes of publishing study results. However, these arrangements are individually negotiated for each study.
- Data ownership arrangements are documented in the head Clinical Trials Research Agreement (or equivalent) between the commercial sponsor and University of Technology Sydney. This Agreement is produced by the commercial sponsor and negotiated between the parties.
- The head Clinical Trials Research Agreement is reviewed by UTS Legal Services and once agreement is reached the agreement is fully executed.
- ITCC initiates Clinical Trials Research Agreements for all the participating recruiting sites in the commercially sponsored trial. The data ownership arrangements are included in these Agreements. The participating sites retain no ownership over the data in commercially sponsored trials.

Data ownership arrangements are regularly reviewed in accordance with the requirements of the Australian Code for the Responsible Conduct of Research (2018).

Disputes regarding data ownership are referred to the relevant Scientific Advisory Committee for consideration and engagement of legal representation from UTS Legal Services if deemed necessary.

## Data Sharing Outline and Procedure

Data sharing is becoming a frequent request by other investigators in order to undertake secondary analysis, and/or to combine into larger data sets for meta-analysis.

HREC submission documents and trial registries require the scope of the data sharing to be explicit within the study documentation. In order for data sharing decisions to be clear and consistent, a Data Sharing Statement should be included within the study protocol and the patient information and consent form to state:

1. The data can be used for other future purposes
    a. The scope and description of the data that can be shared should be detailed as described below
2. The data will not or cannot be used for future purposes.
    a. CPIs will require a reason in relation to item 2 above (for insertion into the Trial Registration platform) and can appropriately include feasibility and pilot studies stating that the methods, design and participant level data are not suitable for sharing.
3. There is no statement either way.
    a. Lack of any statement should be avoided

## What data in particular will be shared?

There are two levels of research data that should be considered.

1. Individual Participant Data - Specify which de-identified participant data will be shared, e.g. all of the individual participant data collected during the trial, individual participant data of published results only, individual participant data of primary outcomes only. More detail is available from ANZCTR Data Field Explanations.
2. Other research outputs such as:
    a. Aggregate data including CONSORT, summary results
    b. Study protocol
    c. Participant information and consent form (PICF)
    d. Data dictionary
    e. Data management plan
    f. Statistical analysis plan
    g. Guidelines or recommendations emerging from the trial
    h. Publications or reports

**When will data be available (start and end dates)?**

Specify the end date for when the data will or will not be available, e.g. no end date, available for 5 years after publication, etc.

**How or where can data be obtained?**

Provide a method of contact for the Sponsor/ data custodian, e.g. provide email address, etc.

*Note: All CST and PaCCSC data will be provided to the Australian Research Data Commons via the Health Studies Australia National Data Asset (HeSANDA) when requested to do so and in keeping with any Data Sharing statements (as agreed by participants) and/or in any Data Sharing Agreement executed by UTS with other entities for PaCCSC/CST trials.*

**Procedure for handling of requests for sharing ITCC data (including all PaCCSC/CST sponsored trial data and secondary data storage repositories)**

- Requests for the sharing of ITCC data are to be made to the PaCCSC/CST National Manager (NM).
- A data sharing agreement will be executed between the parties.
- The NM will keep a log of requests (Template 25), including dates, names, outcome of Chair approval, date data provided to requester, date for 12-month follow up of requester where required.
- The NM will provide a descriptive outline of the request to the following:
    - Chair of the relevant Scientific Advisory Committee
    - Coordinating Principal Investigator (CPI)
- The Chair and CPI will liaise accordingly to discuss the request and provide a response to the NM. This will be on a case by case basis.
- If sharing is agreed by the Chair and CPI, the NM will:
    - Ask the requester to sign the University of Technology Sydney Confidentiality Agreement (unless one is already in place).
    - Liaise with UTS Research office and provide the requester with a Data Sharing Agreement for their review and execution including the proposed use of the data; inserting a requirement for HREC approval for the research and any provisions to recover costs involved in providing the data to the requester.
    - Following full execution of the Data Sharing Agreement liaise with the requester with the data to be shared via the transfer process as follows:
    - Data will be transferred following SOP 5.5.2 Electronic Data Transfer
    - Complete the log.

- If the Chairs determine access cannot be given to the requester, the NM will:
  - Advise the requester of the decision
  - Complete the log.
- The NM will provide the 'log' file for review at each meeting of the relevant Scientific Advisory Committee.

## Related SOPs

6.15 Authorship
6.15.1 Dissemination of Study Results
5.5.1 Electronic Data Handling
5.5.2 Electronic Data Transfer
8.4.1 Archiving of Research/Project Materials
8.4.2 Record Destruction

## Related documents

Template 25: Data Requests Log

## References

Australian Code for the Responsible Conduct of Research 2018 (accessed 07/02/2020) https://www.nhmrc.gov.au/guidelines-publications/r39

National Statement on Ethical Conduct in Human Research 2007 **(**Updated 2018) - (accessed 07/02/2020) http://www.nhmrc.gov.au/guidelines-publications/e72

Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95). Annotated with TGA comments 2000 (accessed 07/02/2020)

https://www.tga.gov.au/sites/default/files/ich13595an.pdf

Practical Data Management: A Legal and Policy Guide Version 1. Queensland University of Technology 2008

University of Technology Sydney Code of Conduct (accessed 07/02/2020) http://www.gsu.uts.edu.au/policies/code-conduct.html

University of Technology Sydney Research Ethics and Integrity Policy (accessed 07/02/2020) http://www.gsu.uts.edu.au/policies/research-ethics-integrity-policy.html

University of Technology Sydney Intellectual Property Policy (accessed 07/02/2020) http://www.gsu.uts.edu.au/policies/intellectual-property-policy.html

Australian Research Data Commons via the Health Studies Australia National Data Asset (HeSANDA), publications currently under finalisation as of Feb 2022

| **History** | | | |
|---|---|---|---|
| Version | Date | Author | Reason |
| 1.1 | 1/06/2015 | L Devilee | New procedure |
| 1.2 | 28/01/2016 | L Devilee | Updated draft to include comments from Scientific Committee August 2015 |
| 1.3 | 9/06/2016 | L Devilee | Updated draft to include comments from Scientific Committee June 2016 |
| 1.4 | 28/02/2018 | B Fazekas,<br>S Kochovska | Periodic review<br>Publication of the ICH GCP E6 (R2) |
| 1.5 | 06/12/2018 | L Brown | Update to include CST and © |
| 1.6 | 07/02/2020 | J Lourdesamy | Periodic review |
| 1.7 | 02/02/2022 | L Brown | Periodic review and to maintain currency with developments internationally |

| **Approval** | | |
|---|---|---|
| Version | Approval Name | Approval Signature |
| 1.7 | Meera Agar |  |