

# Standard Operating Procedure

## 4.2 Confidentiality

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## Introduction / Background

The IMPACCT Trials Coordination Centre (ITCC) is committed to maintaining confidentiality of all its research data and related materials that is consistent with confidentiality requirements, legislation, privacy rules and other guidelines.

## Objective

This SOP describes the process for managing confidentiality of all study materials held or created by the ITCC project or its members.

## Scope

This SOP applies to all Palliative Care Clinical Studies Collaborative (PaCCSC) and/or Cancer Symptom Trials (CST) members and all staff involved in clinical studies conducted by ITCC irrespective of individual organisational employment, role, or position.

## Ownership and Responsibility

### *Disclosure of 'Confidential Information'*

1. The University of Technology Sydney (UTS) has confidentiality obligations which flow from the ITCC Agreements, Confidentiality Deeds or other applicable contracts\*. This means that UTS must maintain the confidentiality of all information which can be considered 'Confidential Information' under these agreements. It must be ascertained from the relevant agreement what the Confidential Information is.
2. UTS must, prior to disclosing any information which may be considered 'Confidential Information' under the relevant Agreements, form a view about whether the disclosure is in fact permitted under the confidential obligations set out in the relevant contract. This can only be determined by reference to the terms of the relevant contract. This is UTS responsibility.
3. If disclosure is not permitted under the terms of the relevant contract, UTS will need to obtain the other party/parties' approval, prior to any disclosure (i.e., the Commonwealth or parties to Confidentially Deeds or other applicable contracts).
4. If disclosure is permitted under the terms of the relevant contract, UTS can disclose the information provided a number of steps are taken.

\* *Contracts and agreements include (but not limited to): Commonwealth Department of Health, National Health and Medical Research Council, Cancer Council, Cancer Australia, philanthropic organisations, a variety of Universities, and commercial agreements.*

## Procedure

### 1. Making confidential information available to another party

- A UTS Confidentiality Deed is required to be executed with the receiving party prior to disclosure of any ITCC study protocols or other information considered confidential.
- UTS have two standard Confidentiality Deed templates (one mutual and one unilateral) which can be used for this purpose.
- The PaCCSC/CST National Manager must authorise the disclosure of the confidential information and the use of the template.

### 2. Confidentiality statements

- A simple non-disclosure statement on the study protocol or other document does not in itself create a legally binding obligation on the receiver of the confidential information. However, a generic statement is more practical, and the UTS recommended statement is as follows:

*The information in this document is strictly confidential. By accepting or reviewing this document, you agree to hold the information in confidence and not to disclose it to others (except with the prior written authorisation of the University of Technology Sydney or where required by applicable law). The information is provided for the exclusive use of investigators involved in the study and, subject to the foregoing, may only be disclosed to other persons involved in the study who have a need to know with the obligation not to further disseminate the information. In the event of any actual or suspected breach of these obligations, the University of Technology Sydney should be promptly notified.*

**This statement is to be inserted on all new study protocols at the development stage.**

In summary:

- You must ascertain from the relevant agreement what the confidential information is;
- You must ascertain from the agreement what may be disclosed and what you need permission to disclose;
- You must seek permission where necessary;
- You should have the receiver of the information sign a standard Confidentiality Deed;
- Just putting a 'confidentiality statement' on the front of a document does not bind the receiver of the information.

## **2.1 Examples of when Confidentiality Deeds should be used**

The standard UTS Confidentiality Deed template is used in all instances where UTS wish to bind a party to confidentiality obligations. In relation to IMPACCT/ITCC/PaCCSC/CST, this includes a range of reasons/events such as:

- Prior to attending the IMPACCT Incubator Sessions and IMPACCT Concept Development Workshops
- Prior to engaging a service provider where confidential information will be shared as part of the service provision
- Prior to the release of PaCCSC/CST owned data for any reason (see SOP 5.5.10 Data Ownership and Utilisation for more information on data sharing)
- Prior to new members joining PaCCSC/CST
- By all members of the PaCCSC/CST governance committees

## **3. Breach of Confidentiality**

Any breach of confidentiality will be investigated and managed appropriately.

## Related SOPs

SOP 5.5.10 Data Ownership and Utilisation

## Related documents

N/A

## References

Australian Code for the Responsible Conduct of Research 2018 (accessed 06/02/2020)

<https://www.nhmrc.gov.au/guidelines-publications/r39>

National Statement on Ethical Conduct in Human Research 2007 (Updated 2018) (accessed 06/02/2020) <http://www.nhmrc.gov.au/guidelines-publications/e72>

University of Technology Sydney Code of Conduct (accessed 06/02/2020)

<http://www.gsu.uts.edu.au/policies/code-conduct.html>

University of Technology Sydney Research Ethics and Integrity Policy (accessed 06/02/2020)

<http://www.gsu.uts.edu.au/policies/research-ethics-integrity-policy.html>

University of Technology Sydney Intellectual Property Policy (accessed 06/02/2020)

<http://www.gsu.uts.edu.au/policies/intellectual-property-policy.html>

History			
Version	Date	Author	Reason
1.0	18/08/2015	L Devilee	New procedure
1.1	25/01/2016	L Devilee	Update to procedure following August Scientific Committee
1.2	5/07/2016	L Devilee	Update to procedure following March Scientific Committee
1.3	28/02/2018	B Fazekas, S Kochovska	Periodic review Publication of the ICH GCP E6 (R2)
1.4	06/12/2018	L Brown	Update to include CST and ©
1.5	06/02/2020	J Lourdesamy	Periodic review
1.6	17/01/2022	L Brown	Periodic review

Approval		
Version	Approval Name	Approval Signature
1.6	Meera Agar	