

Standard Operating Procedure

4.1 Conflict of Interest

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Introduction / Background

A conflict of interest exists where there is a divergence between the individual interests of a person and their professional responsibilities, such that an independent observer might reasonably conclude that the professional actions of that person are unduly influenced by their own interests (Australian Code for the Responsible Conduct of Research 2018).

A conflict of interest in the context of research exists where a person's individual interests or responsibilities have the potential to influence the carrying out of his or her institutional role or professional obligations in research; or an institution's interests or responsibilities have the potential to influence the carrying out of its research obligations (Australian Code for the Responsible Conduct of Research 2018).

The perception that a conflict of interest exists in a research project can be as serious as an actual conflict of interest.

The Australian Code for the Responsible Conduct of Research (2018) is supported by the *Disclosure of interests and management of conflicts of interest* guide. The Code and guide require research institutions to have policies that facilitate the disclosure of interests, and to identify and manage any conflicts of interest that may be apparent or that may emerge during the research project.

Objective

This SOP describes the process for facilitating the disclosure of interests and managing actual, potential, and perceived conflicts of interest that occur in the IMPACCT Trials Coordination Centre (ITCC) research.

Scope

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

Ownership and Responsibility

All:

- recruiting site-based staff,
- staff at the ITCC,
- individual members of the various governance committees of PaCCSC and CST, and
- all invited researchers or experts who contribute to the research conducted under the auspice of the ITCC, PaCCSC or CST

are responsible for disclosing any actual, potential, or perceived conflicts of interest prior to the commencement of a committee meeting, being provided with new study information, the

commencement of a study at the recruiting site and/or immediately as they emerge during the course of the usual business of the Collaborative.

Procedure

1. Disclosure

- Committee members will be asked to disclose any actual, potential, or perceived conflicts of interest to the meeting Chair at the beginning of the meeting. All meetings of committees include a standard agenda item pertaining to conflict of interest and this is captured in the minutes.
- Study site team members disclose any actual, potential, or perceived conflicts of interest to the Principal Investigator at their site.
- ITCC staff and non-site-based staff and/or researchers and/or stakeholders (e.g., statisticians) disclose any actual, potential, or perceived conflicts of interest to the Lead Investigator (or delegate, for e.g., the PaCCSC/CST National Manager).
- Full public disclosure of all details regarding the conflict of interest is strongly encouraged. If the individual is not willing to disclose full details publicly, an opportunity to provide details to the Lead Investigator (or delegate) is offered. If the individual is not willing to disclose full details to the Lead Investigator (or delegate), the individual is withdrawn from any involvement in the meeting/study.
- Study team members must also comply with individual institutional (e.g., local hospital) policies and procedures regarding disclosure of actual, potential, or perceived conflicts of interest.

2. Management of Conflict of Interest

Conflicts of interest are managed by an appropriate governance committee. The Lead Investigator (or delegate) refers the conflict of interest to the governance committee best placed to address it, such as the Scientific Advisory Committee depending on the nature of the conflict of interest and the individual with the conflict of interest.

The committee assigned to address the conflict of interest (herein referred to as 'the Committee') develops an action plan. Actions will vary according to the nature of the conflict of interest and the potential impact on the research.

- Conflicts of interest are tabled at a Committee meeting. If it is an emergent issue, a meeting is convened as soon as it is practical.
- The conflict of interest is presented by the Lead Investigator of ITCC or the Principal Investigator of the site, whichever is appropriate, regarding where the conflict of interest has been identified.

- The individual with the conflict of interest may contribute to the discussions of the Committee but the individual is not involved in the decision-making process around the management of the conflict of interest.
- The Committee:
 - may decide that the declared conflict of interest does not exist. In such circumstances, the decision is clearly documented in the meeting minutes that are distributed to all stakeholders.
 - evaluates the risk of potential impact on the integrity of the research, based on the following:
 - the nature of the interest
 - how closely the interest is related to the research
 - the degree to which the interest may affect the research and/or participants
 - may seek additional information or advice from other parties for e.g., the ITCC Data Monitoring and Safety Committee or legal counsel provided by University of Technology Sydney (UTS).
- A management plan, consistent with the evaluated risk (as above), for the conflict of interest is agreed by the Committee. The management plan may include (but is not limited to):
 - withdrawal of the individual from all research related activities
 - withdrawal of the individual from recruitment of participants
 - withdrawal of the individual from all financial decisions and decisions that may impact the research project budget
 - withdrawal of the individual from the analysis of data and study results
 - education of research staff
 - disclosure of the conflict of interest to study participants.
- In exceptional circumstances (where the risk to the integrity of the research or risk of harm to participants is high), the management plan may include (but is not limited to):
 - ceasing the research at the study site where the conflict of interest exists
 - modification of the research protocol.
- The conflict of interest and management plan is documented and kept at the study site where the conflict of interest exists. A copy is also held by the ITCC.
- If appropriate, the relevant Human Research Ethics Committees (HRECs) are informed of the conflict of interest and management plan. If an HREC requires additional actions in relation to the conflict of interest, the management plan is updated by the ITCC and redistributed to the relevant site.

- The decision regarding the management of the conflict of interest by the Committee (subject to HREC review) is final.

Related SOPs

N/A

Related documents

N/A

References

Australian Code for the Responsible Conduct of Research 2018 (accessed 03/02/2020)

<https://www.nhmrc.gov.au/about-us/publications/australian-code-responsible-conduct-research-2018>

National Statement on Ethical Conduct in Human Research 2007 (updated 2018) (accessed 03/02/2020)

<https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018>

History			
Version	Date	Author	Reason
1.0	17/08/2015	C Hope	New procedure
1.1	28/02/2018	B Fazekas, S Kochovska	Periodic review Publication of the ICH GCP E6 (R2)
1.2	06/12/2018	L Brown	Update to include CST and ©
1.3	03/02/2020	J Lourdesamy	Update to new version of reference materials
1.4	17/01/2022	L Brown	Periodic review

Approval		
Version	Approval Name	Approval Signature
1.4	Meera Agar	