UTS IMPACCT Trials Coordination Centre

Standard Operating Procedure

5.18.1 Site Closure

Version	V1.4
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Approved	M Agar
Effective date	01/04/2022
Review date	01/04/2024

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Introduction / Background

While participation in IMPACCT Clinical Trial Coordination Centre (ITCC) clinical trials and membership of PaCCSC/CST may bring benefits to individual sites, there may be circumstances where ongoing participation may not be in the site or the Collaborative's best interests, and therefore the site closes. Reasons for site closure include (but are not limited to):

- Voluntary withdrawal from ITCC/PaCCSC/CST due to:
    - lack of interest or support from the clinical teams/institution/trials teams in research at site
    - lack of clinical support to undertake ITCC/PaCCSC/CST studies
    - competing research demands from non-ITCC/PaCCSC/CST funded/sponsored studies
    - financial hardship due to enforcement of ITCC/PaCCSC/CST non-performance penalties
    - completion of all ITCC/PaCCSC/CST studies at site
- Enforced withdrawal from ITCC/PaCCSC/CST due to:
    - persistent non-compliance with ITCC/PaCCSC/CST polices and Standard Operating Procedures (SOPs)
    - breach of agreement with ITCC/PaCCSC/CST
- Hospital / service shutdown

Objective

This SOP describes the process for managing site closure.

Scope

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

Ownership and Responsibility

Responsibility for site closure rests with the Chief/Coordinating Principal Investigator (CPI), who is supported by the ITCC.

The CPI responsibilities are delegated to the PaCCSC/CST National Manager.

The Principal Investigator (PI) is responsible for all processes and procedures at the site.

Responsibilities of the PaCCSC/CST National Manager (or delegate)

- To liaise with the PI (or delegate(s)) at the closing site
- To liaise and communicate with other relevant ITCC investigators
- To liaise with regulatory bodies and the Department of Health (Federal Government)
- To prepare a paper regarding the impact of the site closure on ITCC
- To prepare a Site Closure Plan (including timeline); this will be via email and is site and study specific

- To organise any outstanding monitoring of the closing site
- To ensure all finances are acquitted prior to final sign off that site is closed

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 communicate with the PaCCSC/CST National Manager in a timely way
- To fulfil the required activities at the site to achieve site closure
- To fulfil the requirements of the local Human Research Ethics Committee (HREC)
- To provide financial information as requested

Procedure

1. Decision to shut down

- Voluntary withdrawal of site:
  - The PI notifies the PaCCSC/CST National Manager of their intention to withdraw from ITCC/PaCCSC/CST. Notification is given in writing with at least 30 days of notice.
  - If further information is required, the PaCCSC/CST National Manager contacts the PI.
  - The PaCCSC/CST National Manager prepares a report regarding the implications of the site shut down for ITCC/PaCCSC/CST.
  - The PaCCSC/CST National Manager informs other ITCC/PaCCSC/CST CPI and PIs of the withdrawal of the site.
  - The PI informs the HREC of the closure as an ITCC/PaCCSC/CST site.
  - In consultation with the PI, the PaCCSC/CST National Manager prepares a Closure Plan for the site, detailing specific tasks and responsibilities.
- Enforced closure of site:
  - The decision to enforce closure of a site from ITCC/PaCCSC/CST is taken by the CPI
  - The PaCCSC/CST National Manager informs the PI in writing, giving a minimum of 30 days of notice.
  - The PaCCSC/CST National Manager informs other PaCCSC/CST stakeholders and other interested parties such as external sponsors or funding agencies of the withdrawal of the site.
  - The PI informs the HREC of the closure as an ITCC/PaCCSC/CST site.
  - In consultation with the PI, the PaCCSC/CST National Manager prepares a Closure Plan for the site, detailing specific tasks and responsibilities.

2. Ceasing Studies

- Recruitment for all studies currently undertaken at the site is ceased on the date of notification to withdraw/close study site.
- Under the direction of the ITCC (and following site audit), the following activities are completed by the PI (or delegate):
  - Any remaining investigational products are destroyed or returned to the manufacturer as per individual site or state guidelines.
  - Checking and storage arrangements of the site pharmacy folders and the study files held on site.
  - Checking and completion of the Investigator Site File.
  - Final reports are made to the local and institutional HRECs.

3. Site Audit

- The PaCCSC/CST National Manager determines if the site requires an internal (monitoring) or external audit prior to closure (*refer* SOP 5.18 Monitoring).
- The PaCCSC/CST National Manager arranges an audit visit to the site to ensure all work conducted prior to the notification to withdraw has complied with the ITCC Standard Operating Procedures, policies, and study protocols.

4. Financials

- All study specific funding ceases on the date of notification to withdraw from ITCC/PaCCSC/CST or date of notification to close the study site.
- The site provides ITCC/PaCCSC/CST with a financial audit detailing the ITCC/PaCCSC/CST related income and expenditure.
- All unspent funds are returned as set out in the funding agreement between ITCC/PaCCSC/CST and the site.

5. Archiving of Research Materials

- All research materials for all ITCC/PaCCSC/CST studies are archived according to SOP 8.4.1 Archiving of Research/Project Materials.

6. Additional notes

- Ongoing employment of the research staff at the closing site is the responsibility of the site.
- Ongoing representation of the PI of the closing site on ITCC/PaCCSC/CST committees (for e.g., relevant Scientific Advisory Committees) will be at the discretion of the PaCCSC/CST National Manager.
- It is the responsibility of the PI at the closing site to ensure all HREC reporting requirements are met and the HREC are fully informed of the site closure.

Related SOPs

4.2.4 Delegation of Duties
5.18.2 Study Closure
5.18 Monitoring
8.4.1 Archiving
8.0 Essential Documents

Related documents

N/A

References

National Statement on Ethical Conduct in Human Research (2007) – Updated 2018- (accessed 31/03/2020) https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018

History			
Version	Date	Author	Reason
1.0	10/06/2015	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	31/03/2020	C Strauss	Periodic review Updated to IMPACCT Trials Coordination Centre
1.4	06/01/2022	C Strauss	Periodic review

Approval		
Version	Approval Name	Approval Signature
1.4	Meera Agar