Standard Operating Procedure

5.18.2 Study Closure

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Introduction / Background

The purpose of study closure is to finalise all follow-up activities to enable final reporting of the study and archiving of study materials.

Objective

This SOP describes:

- The activities that are undertaken
- The closure process and follow-up

Scope

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

Ownership and Responsibility

Responsibilities of the Coordinating Principal Investigator (CPI)

- To prepare and submit a final report to the approving Human Research Ethics Committee (HREC) and receive formal acknowledgement of study closure
- To approve data base lock

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

- To finalise the Investigator Folder
- To reconcile and finalise all accounts and payments
- To prepare and submit final report to the approving Research Governance Office (RGO)
- To complete and sign the Study Closure Checklist (Template 29) and return to the ITCC.
- To inform participants (or proxies) of the study results, where appropriate

Responsibilities of the IMPACCT Trials Coordination Centre (ITCC)

- To prepare and execute Site Pharmacy monitoring recommendations regarding remaining Investigational Product(s)
- To guide and facilitate in the preparation and execution of study closure activities
- To check the Study Closure Checklist (Template 29) is completed and returned by each site
- To complete for each site the Study Closure Checklist (*each site*) (Template 29a)
- To complete for the entire study the Study Closure Checklist (*all sites*) (Template 29b) once the Study Closure Checklists have been returned by all sites and have been

checked. Once completed, the entire study checklist is filed in the Trial Master File to indicate that each site has now completed all closure activities and the entire study is now ready for archive.

Procedure

1. Timeframe

Study closure occurs when:

- recruitment for the study is completed,
- all site monitoring visits at all study sites are completed, and
- the main study results are accepted for publication in an appropriate journal

Study closure may also occur if the study is ceased before the above criteria are met or if a site is to be closed for any reason (*refer* SOP 5.18.1 Site Closure).

2. Personnel involved

- PaCCSC/CST National Manager, ITCC National Project Officer, Principal Investigators

3. Preparation

The following activities are completed in preparation for study closure:

- All outstanding monitoring activities are completed
- Data entry of all data is completed
- Data base is locked
- Notification (update) is provided to the ANZCTR
- All follow-up for ongoing Adverse Events (AEs) and database resolutions are completed
- Safety database is reconciled with electronic Case Report Form (eCRF) database so that all AEs and Serious Adverse Events (SAEs) are entered and reported appropriately
- All study documents are retrieved
- Diagnostics is completed and all data is cleaned
- Unblinding occurs (*refer* SOP 4.7.2 Unblinding)
- Analysis is completed by the study Statistician
- A manuscript of the draft results is written

4. Site activities

Each site undergoes a series of activities in order to close the study at that site. These activities are completed by the site under the direction of the ITCC via email and teleconference:

- Final site pharmacy monitoring
    - Clearance is given by the monitor to destroy any remaining Investigational Product as per state regulations.

- Supply of the site pharmacy folder and the study files to the Principal Investigator for incorporation into the Investigator Folder/Essential Documents (*refer* SOP 8.0 Essential Documents)
- Finalisation of the Investigator Folder
- Accounts and payments are reconciled, including final payment
- Submission of final report to the approving RGO as acknowledged by the HREC, using the reporting template required by the RGO
- Participants (or proxies) are informed of the study results via a letter if appropriate and under the direction of the Coordinating Principal Investigator, using the following procedure:
    - Each site is provided with a list of the participant ID numbers for that site along with the allocation of each participant by the ITCC.
    - The site writes a letter, based on the template letter provided, completing the specific details such as names, dates and allocation. The study summary is attached to each letter.
    - The completed personalised letters are checked by the associated clinical team in order that names and addresses are confirmed as correct.
    - The letter is sent to the most appropriate person (next of kin, carer, etc.) as known to the clinical service and entirely at the discretion of the clinical team according to their knowledge of the family and circumstances.
- Study Closure Checklist is completed (Template 29)
    - The checklist can be completed by any of the study staff
    - The checklist is signed by the Principal Investigator
- Archiving of files is completed (*refer* SOP 8.4.1 Archiving)

5. ITCC activities

The ITCC undertakes a series of activities in order to close the study at each site and centrally. These activities involve a number of communications with each site to ensure site responsibilities are upheld. When all site closure responsibilities are completed, the ITCC undertakes the following activities:

- Final payment is sent to every site
- Accounts and payments are reconciled
- Study Closure Checklist (each site) (Template 29a) – is completed by the PaCCSC/CST National Project Officer to confirm completion of closure activities at each site
- Study Closure Checklist (all sites) (Template 29b) – is completed when all sites have indicated completion of the closure activities and these have been checked by ITCC

- Coordinating Principal Investigator is informed in writing of study closure
- Written confirmation of study closure from the Coordinating Principal Investigator is attached to the checklist and archived
- Archiving of PaCCSC/CST/ITCC study files

A number of activities may continue after the study is closed at all sites and at the ITCC including:

- Continued analysis of secondary data
- Further development and completion of the Clinical Study Report
- Dissemination of findings
- Reporting to funding agency
- Study report submission to the TGA

Related SOPs

4.2.4 Delegation of Duties

4.7.2 Unblinding

5.18.1 Site Closure

8.0 Essential Documents

8.4.1 Archiving

Related documents

Template 29: Study Closure Checklist

Template 29a: Study Closure Checklist (each site)

Template 29b: Study Closure Checklist (all sites)

References

Australian Code for the Responsible Conduct of Research 2018 (accessed 31/03/2020) https://www.nhmrc.gov.au/about-us/publications/australian-code-responsible-conduct-research-2018

International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2). November 2016 (accessed 31/03/2020)

https://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R2__Step_4.pdf

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

Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95). Annotated with TGA comments 2000 (accessed 17/10/2017)

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

History			
Version	Date	Author	Reason
1.0	30/08/2012	B Fazekas, L Devilee	New procedure
1.1	19/05/2015	C Hope	Periodic review
1.2	28/02/2018	B Fazekas, S Kochovska	Periodic review Publication of the ICH GCP E6 (R2)
1.3	06/12/2018	L Brown	Update to include CST and ©
1.4	31/03/2020	C Strauss	Periodic review Publication of Australian Code for Responsible Conduct of Research (2018) and National Statement on Ethical Conduct in Human Research (2007) Updated 2018. Updated to include IMPACCT Trials Coordination Centre
1.5	24/11/2021	B Fazekas	Periodic review

Approval		
Version	Approval Name	Approval Signature
1.5	Meera Agar