Standard Operating Procedure

5.7 Site Initiation

Version	V1.3
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Effective date	01/04/2022
Review date	01/04/2024

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Introduction / Background

All studies conducted through the IMPACCT Trials Coordination Centre (ITCC), including Palliative Care Clinical Studies Collaborative (PaCCSC) and Cancer Symptom Trials (CST), must undergo a set process for study start-up, following Human Research Ethics Committee (HREC) and Governance approval, and before subject recruitment.

Objective

This SOP describes the procedure for initiating a study sponsored or hosted by the ITCC at a recruitment site.

Scope

This SOP applies to Principal Investigators running a research study (both Investigational drug studies and non-drug studies, conducted in Australia) sponsored or hosted by the ITCC. It applies to all members of staff who manage, coordinate, or advise on clinical research.

Ownership and Responsibility

Responsibilities of IMPACCT Trials Coordination Centre (ITCC)/Sponsor

- The responsibility for setting up sites lies with the external sponsor, on behalf of the lead investigator team

Responsibilities of the site 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 provide adequate training and preparation at the site for which they are responsible

Procedure

After successful completion of the Site Feasibility Checklist (Template 5), Study Feasibility Checklist (Template 21) and the Site Risk Assessment Toolkit (Template 6) (*refer* SOP 5.6.1 Site Selection):

- The study Coordinating Principal Investigator determines (in consultation with the PaCCSC/CST National Manager) when a new site is ready to be initiated into the study.
- The decision to initiate a new site is emailed to the Principal Investigator of the new site.
- The initiation of a new site is communicated (by email, meeting minutes or telephone) to all other sites participating in the study, and the appropriate Committees.
- The Principal Investigator is invited to attend the relevant Scientific Advisory Committee.

1. Site initiation Meetings

All sites undergo site initiation prior to the trial starting. The site initiation training is delivered virtually using a web-based video conferencing platform (e.g. Zoom or Microsoft Teams) and may also include completion of self-paced training by site staff. Face to face meetings will only be conducted in exceptional circumstances and with the approval from the Coordinating Principal Investigator and PaCCSC/CST National Manager. The site initiation agenda is determined by each site's previous exposure to conducting studies and their prior involvement with PaCCSC/CST/ITCC.

1.1 Existing sites

- Existing sites (i.e. sites that have participated in an PaCCSC/CST/ITCC study prior to the study in question) will need to attend virtual training session(s) presented by members of the ITCC as well as complete self-paced training modules following the appropriate Agenda (Template 33).

1.2 New sites

- New sites (i.e. sites that participate for the first time in an PaCCSC/CST/ITCC study) undergo a series of virtual training sessions with members of the ITCC following the appropriate Agenda (Template 34).

Site initiation meetings will take the following format:

- The site initiation meeting is arranged for all research staff involved, including Pharmacy, and supporting services as appropriate, once all the agreements and approvals are in place.
- The ITCC will schedule the virtual site initiation training sessions (particularly the protocol training session) so that all participating sites can attend at the same time. There will be limited capacity to schedule multiple training sessions due to restricted Coordinating Principal Investigator availability. Site staff who are not able to attend a scheduled virtual training session will be required to self-review the training slides. A follow-up Question and Answer session with the ITCC can be organised as needed and upon request.
- The primary virtual training session will be presented by the Coordinating Principal

Investigator and members of the ITCC team and will cover a review of the study protocol highlighting study specific procedures and elements including randomisation and study drug, schedule and questionnaires, site implementation and recruitment, sub-studies and other topics as applicable.

- Additional training sessions will also be provided highlighting an overview of the principles of Good Clinical Practice (GCP), relevant legislation, roles and responsibilities of investigators and site staff and drawing attention to ITCC Standard Operating Procedures (SOPs). These sessions will also cover monitoring and study management including record keeping and essential document filing and maintenance, informed consent, contracts and invoicing, and data management including data collection worksheets and data entry. For new sites, these additional training modules will be presented virtually by the ITCC over a series of 1.5 to 2 hour sessions, per the agenda outlined in Template 34. For existing sites, these training modules will constitute part of the self-training program (refer to Template 33) and self-review of the training slides will be required. Sites will be able to access the training slides from the study Forms and Documents project in REDCap (Template 47).
- A separate virtual training session covering pharmacy procedures will also be provided by members of the ITCC to site pharmacies or external third-party pharmacy staff as well as relevant site staff (e.g. study coordinator) prior to site activation.
    - The virtual format of the site initiation training sessions allows for audio and/or video recording of the training presented so it can later be reviewed by current or new site staff as needed.
    - After the virtual site initiation training sessions are completed, the final attendance list and training slides and recordings (if applicable) are uploaded by the ITCC team to the study Forms and Documents project in REDCap (Template 47) and made accessible to all sites for download.
        - The agenda, attachments (training slides) and attendance list are to be filed in the Trial Master File (refer to Template 20) and as part of the Investigator Site File (refer to Template 39).
- Following completion of all required site initiation training as outlined in the relevant agenda (Template 33 or 34), study staff will be required to complete the delegation log and confirm their Curriculum Vitae (CV) is signed and on file.

2. Approvals

- It is the responsibility of the Principal Investigator to ensure that appropriate regulatory and ethics approvals are in place before the Site Initiation/Study Start-up Sessions and recruitment starts. This includes a Therapeutic Good Administration (TGA) Clinical Trials Notification (CTN) acknowledgement or a Clinical Trial Exemption (CTX) approval, along with HREC and/or RGO approval.
- It is the responsibility of the Principal Investigator at each site to ensure that local Governance approval is in place before recruitment begins.

- The Principal Investigator is also responsible for ensuring that the sponsor and the site agreements (for multi-centre studies) are in place before recruitment begins.
- For Investigational Drug studies, Governance approval will not be issued until appropriate regulatory approvals and sponsorship agreements are in place.

3. Establishing an Investigator Site File (ISF)

- An Investigator Site File (ISF) must be established for all research sites before recruitment begins. It is the responsibility of the Principal Investigator at each site (if multi-centre) to ensure that all required documents are collected and filed in the ISF.
    - This file is electronic and provides a structure within which the study related files and documents can be held at each site. The electronic folder (15. Investigator Site File, from Template 20: Trials Master File Index) will be emailed to the Principal Investigator or delegate during study start-up and prior to Site Initiation. It must then be saved to a network-based, password-protected computer drive to enable access to the study team members only.
    - It is appropriate for an alternative ISF format or dedicated ISF portal (e.g SiteDocs) to be used if this is the standard procedure at the site.
    - The study 'Forms and Documents' project in REDCap will be used as a repository and share point for all study documents. Access to this project will be granted to the PI or their delegate for retrieval and download of the required essential documents to populate the ISF.
    - This task may be delegated to another member of the research team, but this delegation should be formally documented in the study Staff Signature and Delegation Log.
    - Once established, the ISF should be kept in a secure location and be updated as the study progresses.
    - Refer to SOP 8.0 Essential Documents

4. Site commencement

- The Principal Investigator will receive a follow-up email from the ITCC within 14 days of the last site initiation training session providing:
    - A final agenda listing the individuals who attended each session
    - A listing of any follow-up actions required either by the Principal Investigator or by ITCC to be completed prior to commencement
    - A planned resolution date for the follow-up items, and then a planned date of commencement to the study, this is the date from which participants can be approached regarding the study, no study related activities can commence prior to the date of commencement
- The Principal Investigator must not commence recruitment until a formal site activation and commencement notification has been received from the ITCC.
- The following requirements must be met before a site can be activated and a formal

notification of recruitment commencement to be sent:

- All regulatory approvals in place (CTN acknowledgement, HREC approval, RGO approval) and confirmed present in the ISF.
- Completion of all required study training by site staff (at minimum the Principal Investigator, and one Study Nurse/Coordinator and Pharmacy staff) and delegation of relevant study tasks and duties to site staff:
  - Copies of relevant training records and the site signature and delegation log must be provided to the ITCC for verification and confirmation.
- For Investigational Drug studies: Confirmation that the initial shipment of study drug has been received at the site pharmacy or third-party pharmacy.
- Randomisation and Electronic Data Capture system access is granted to relevant delegated site staff (as applicable).

- A copy of the formal notification of site activation and recruitment commencement must be filed in the Trial Master File and the ISF.

Related SOPs

4.1 Investigator Responsibilities

4.2.4 Delegation of Duties

8.0 Essential Documents

Related documents

Template 5: Site Feasibility Checklist

Template 6: Site Risk Assessment Toolkit

Template 20: Trial Master File Index

Template 21: Study Feasibility Checklist

Template 33: Site Initiation One Day Program

Template 34: Site Initiation Two Day Program

Template 39: ISF Index

Template 47: Forms and Documents

References

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 23/10/2017)

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

Praxis Australia

History			
Version	Date	Author	Reason
1.0	21/11/2017	B Fazekas, S Kochovska	New procedure
1.2	April 2020	B Fazekas, S Kochovska	Two-yearly review
1.3	17/01/2022	C Strauss	Periodic review Incorporation of remote site initiation program and virtual training procedures. Clarification of site activation and recruitment commencement requirements.

Approval		
Version	Approval Name	Approval Signature
1.3	Meera Agar