Standard Operating Procedure

4.0 Investigator Roles and Responsibilities

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Introduction / Background

Good Clinical Practice defines the requirements to ensure that all patients on clinical trials are safe and that their rights are protected. The care and safety of the patient is the responsibility of the Principal Investigator and any clinical sub or co-investigator as delegated. The Principal Investigator (and/or suitably delegated sub or co-investigator) also has responsibility for the overall management of the clinical trial.

While trial-related tasks and duties can be delegated to other appropriately qualified and trained staff, the responsibility for the clinical trial cannot be delegated and remains with the Principal Investigator. The Principal Investigator is responsible for supervising any individual or party to whom they have delegated study tasks/duties.

Objective

This SOP defines the Principal Investigator responsibilities and provides instruction when performing clinical study(s) under applicable regulatory requirements. It is applicable to all phases of clinical investigation of medicinal products.

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

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).

Procedure

The Principal Investigator must:

- Ensure that clinical studies are carried out according to International Conference on Harmonisation of Good Clinical Practice (ICH GCP) guidelines, regulatory authorities' requirements and any other local requirements.
- Have an understanding that when a trial is sponsored by an agency/pharmaceutical company, they may be requested to follow their procedures in order to comply with company obligations. Agreement between all parties must be discussed before initiating the trial (*refer* Clinical Trial Research Agreement (CTRA)).
- Inform the participant's primary clinician about the participant's participation in the trial if the participant has a primary clinician and if the participant agrees to the primary clinician being informed.
- Declare any conflicts of interest, payments etc. from other parties.
- Ensure that the financial aspects of a trial are documented in an agreement between the Sponsor and the investigator/institution.
- Maintain a list of any delegated duties with respect to the trial, and the persons and qualifications of those persons to whom the duties are assigned.
- Ensure that mandatory ICH GCP training is current for all staff involved in clinical trials or research involving humans. Accredited courses are recommended and required no more than three years prior to the commencement of a given trial, and every three years thereafter.
- Ensure that they provide appropriate supervision, oversight, and management to all staff/parties to whom specific trial related duties have been delegated (*refer* SOP 4.2.4 Delegation of Duties). This includes the implementation of procedures to ensure the integrity of the trial related duties and functions performed and any data generated.
- Ensure they provide regular, appropriate, and timely training to all staff. All training must be clearly documented in a training log and filed in the Investigator Site File (*refer* SOP 8.0 Essential Documents).
- Be able to demonstrate that adequate participant recruitment is likely to be possible as agreed upon within the Clinical Trials Research Agreement (CTRA), with necessary time and resources available to conduct the study to Good Clinical Practice (GCP) requirements, and with adequate facilities and trial staff.
- Ensures medical care, to trial participants during routine visits or as a result of any adverse events, is performed as per protocol, and in reference to ICH GCP guidelines. Additionally, a report for any protocol deviation or serious adverse event that causes immediate harm to the participant requires review by the Sponsor, HREC and Governance office within a 24 hour period of the investigator/delegate being aware of the incident (*refer* SOP 5.17 Adverse Event Reporting).

- Provide medical care to trial participants that is necessary as a result of any adverse events experienced during or following the trial that are related to the trial and must be responsible for all trial-related medical decisions.
- Possess, prior to trial commencement, a favourable HREC endorsement of trial protocol, patient information and consent documents, recruitment procedures, consent form updates and any other information given to participants (*refer* SOP 6.12 Ethical Approval, Review and Reporting).
- Present all trial related documents to the HREC for review including the investigator's brochure as well as updates.
- Ensure that the trial is conducted according to the approved protocol.
- Document any deviation from the protocol for later review (*refer* SOP 4.5 Protocol Violation and SOP 4.5.3 File Notes).
- Ensure that no deviation from the protocol occurs without HREC endorsement, unless it is required to prevent imminent harm to participants.
- Maintain adequate and accurate source documents and trial records that include all pertinent observations on each site's trial participants. Source data must be attributable, legible, contemporaneous, original, accurate and complete (*refer* SOP 4.9.2 Source Data and Documentation).
- Ensure the accuracy, completeness, legibility, and timeliness of the data recorded in the data collection worksheets and reported to the sponsor in the case report forms (CRF) and in all required reports (*refer* SOP 5.23.2 Data Collection Worksheet Completion).
- Maintain the trial documents as specified in the essential documents for the conduct of a clinical trial (*refer* SOP 8.0 Essential Documents).
- Provide adequate storage and ensure accountability of the investigational product(s) at the trial site(s) (refer SOP 5.14.1 Investigational Product Handling).
- Ensure that participants have made fully informed, written consent, with all trial procedures and risks adequately explained and that the principles and essential elements of informed consent are upheld and included in the information document (*refer* SOP 4.8 Informed Consent).

Note: *Although a participant is not obliged to give his/her reason(s) for withdrawing prematurely from a trial, the investigator must make a reasonable effort to ascertain the reason(s), while fully respecting the participant's rights.*

- Be thoroughly familiar with the appropriate use of the investigational product(s), as described in the protocol, in the current Investigator's Brochure, in the product information and in other information sources provided by the sponsor.
- Ensure that all persons assisting with the trial are adequately informed about the protocol, the investigational product(s), and their trial-related duties and functions.

- Submit written summaries of the trial status to the HREC annually, or more frequently, if requested by the HREC.
- Provide written reports to the sponsor, the HREC, and where applicable, the institution, promptly on any changes significantly affecting the conduct of the trial, and/or increasing the risk to participants.
- Comply with the applicable regulatory requirement(s) related to the reporting of unexpected serious adverse drug reactions to the regulatory authority(s) and the HREC.
- Promptly inform the trial participants if the trial is prematurely terminated or suspended for any reason as well as the institution and must assure appropriate therapy and follow-up for the participants, and where required by the applicable regulatory requirement(s), inform the regulatory authority(s).

Note: *If the investigator terminates or suspends a trial without prior agreement of the sponsor, they must inform the institution where applicable, and the investigator/institution must promptly inform the sponsor and the HREC and provide the sponsor and the HREC a detailed written explanation of the termination or suspension.*

- Upon completion of the trial, where applicable, inform the institution; the investigator/institution must provide the HREC with a summary of the trial's outcome, and the regulatory authority(s) with any reports required.

Related SOPs

4.2.4 Delegation of Duties
4.5 Protocol Deviations and Violations
4.5.3 File Notes
4.8 Informed Consent
4.9.2 Source Data and Documentation
5.14.1 Investigational Product Handling
5.17 Adverse Event Reporting
5.23.2 Data Collection Worksheet Completion
6.12 Ethical Approval and Reporting
8.0 Essential Documents

Related documents

Clinical Trial Research Agreement (CTRA)

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
1.1	10/01/2006	Contributing authors	New procedure
1.2	25/02/2007	S Whicker	Administrative update
1.3	11/07/2007	B Fazekas	Update prior to MAB review
1.4	13/08/2007	B Fazekas	Changes ratified by MAB
1.5	16/10/2007	B Fazekas	Update after David Currow review
1.6	7/06/2010	B Fazekas, T Shelby-James	Periodic review
2.0	20/01/2011	B Fazekas, T Shelby-James	Changes ratified by MAB
2.1	13/05/2015	C Hope	Periodic review
2.2	28/02/2018	B Fazekas, S Kochovska	Periodic review Publication of the ICH GCP E6 (R2)
2.3	16/03/2020	C Strauss	Periodic review
2.4	24/11/2021	J Hao	Periodic review

Approval		
Version	Approval Name	Approval Signature
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