



Standard Operating Procedures

4.0 Investigator Roles and Responsibilities ©2007

History			
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1.1	10 th Jan 2006	Contributing authors	New procedure
1.2	25 th Feb 2007	S Whicker	Administrative update
1.3	11 th July 2007	B Fazekas	Update prior to MAB review
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Approval				
Version	Author	Signature	Approval Name	Approval Signature
1.5	B Fazekas	<i>B. Fazekas</i>	D Currow (CI)	<i>David Currow</i>

Scheduled review

Date August 2009

Responsible person PaCCSC National Project Officer

4.0 Investigator Roles and Responsibilities

Purpose

To outline the roles and responsibilities of clinical trial/study investigators in conducting research with participants.

Investigators are responsible for ensuring that a clinical trial is properly conducted and that participants are adequately protected. Investigators must be properly qualified and trained with adequate experience to undertake the clinical trial in line with the requirements of the protocol. The site investigator may delegate significant clinical trial related duties to appropriately qualified and trained staff. It is ultimately the responsibility of the site investigator to ensure that all members of the clinical trial team understand and apply their obligation to ensure the protection of the rights, safety and well-being of participants.

Other related SOPs

Archiving of Research/Project Materials
Adverse Event Reporting
Essential Documents
Ethical Approval, Review and Reporting
Data Management
Record Destruction

Attachments

Staff Signature Sheet for delegation of responsibilities

References

NHMRC National Statement on Ethical Conduct in Research Involving Humans 1999 (accessed 250207)

<http://www.nhmrc.gov.au/publications/files/e35.pdf>

Guideline for Good Clinical Practice, ICH Harmonised Tripartite Guideline E6(R1) 1996 (accessed 250207)

<http://www.ich.org/LOB/media/MEDIA482.pdf>

Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95). Annotated with TGA comments 2000 (accessed 250207)

<http://www.tga.gov.au/docs/pdf/euguide/ich/ich13595.pdf>

Definitions

Case Report Form (CRF)

A printed, optical, or electronic document designed to record all of the protocol required information to be reported to the coordinating site on each participant.

Clinical Trial/Study

Any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or pharmacodynamic effects of an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy. The terms clinical trial and clinical study are synonymous.

Clinical Trial/Study Report

A written description of a trial/study of any therapeutic, prophylactic, or diagnostic agent conducted in participants, in which clinical and statistical description, presentations, and analyses are fully integrated into a single report.

Confidentiality

Prevention of disclosure, to other than authorised individuals, of a sponsor's proprietary information or a participants identity.

Good Clinical Practice (GCP)

A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of participants are protected.

Independent Ethics Committee (IEC)/Human Research Ethics Committees (HREC)

An independent body (a review board or committee, institutional, regional, national or supranational), duly constituted of medical professionals and non-medical members, whose responsibility it is to ensure the protection of the rights, safety and well-being of participants involved in a trial and to provide public assurance of that protection by, among other things, reviewing and approving/providing favourable opinion on the trial protocol, the suitability of the investigator(s), facilities, and the methods and material to be used in obtaining and documenting informed consent of the participants.

Informed Consent

A process by which a participants voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the participants decision to participate. Informed consent is documented by means of a written, signed and dated consent form, unless otherwise dealt with in a institutional ethics approved trial protocol.

Interim Clinical Trial/Study Report

A report of intermediate results and their evaluation based on analyses performed during the course of a trial.

Investigational Product

A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorisation when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use.

Investigator

A person responsible for the conduct of a clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator. The investigator should be qualified by education, training and experience to assume responsibility for the proper conduct of the study, should be thoroughly familiar with the use of the investigational product and be aware of, and comply with, the applicable regulatory requirements. The qualifications should be appropriate to their role in the study.

Investigator/Institution

An expression meaning “the investigator and/or institution, where required by the applicable regulatory requirements”

Lead Investigator

The investigator who leads the study protocol development and takes the responsibility for the coordination of investigators at different centres participating in a multi-site trial.

Multi-centre Trial

A clinical trial conducted according to a single protocol but at more than one site, and therefore, carried out by more than one site investigator.

Participant

An individual who participates in a clinical trial, either as a recipient of the investigational product(s) or as a control.

Protocol

A document that describes the objective(s), design, methodology, statistical considerations, and organisation of a trial. The protocol usually includes the background and rationale for the trial, but these could be provided in other protocol referenced documents. Throughout the ICH GCP Guideline the term protocol refers to protocol and protocol amendments.

Protocol Amendment

A written description of a change(s) to, or a formal clarification of a protocol.

Site investigator

Any individual member of the clinical team who leads the implementation of the protocol at the individual sites. They may designate investigator responsibilities to sub-investigators.

Sub-investigator

Any individual member of the clinical trial team designated and supervised by the investigator at a trial site to perform critical trial-related procedures and/or to make specific trial-related decisions.

Well-being (of the trial participants)

The physical and mental integrity of the subjects participating in a clinical trial.

Sample Only

Procedure

Investigator's Qualifications and Agreements

The investigators should be qualified by education, training and experience to assume responsibility for the conduct of the clinical trial. The Coordinating Investigator must ensure that all participating investigators and clinical trial team members meet these requirements and that the relevant documentation is filed with the Coordinating Investigator's study documents and a copy provided to the Independent Ethics Committee as required.

The investigator must be familiar with the investigational product, the protocol, additional information sources which support the protocol and ensure the clinical trial complies with GCP.

The Coordinating Investigator may require that training and education sessions are held and resources are developed to ensure that all investigators, subinvestigators and remaining members of the clinical trial team are adequately informed to implement the protocol and maintain the protection of the rights, safety and well-being of human subjects.

The Coordinating Investigator may delegate key tasks and responsibilities to other study personnel based on their skill level, qualifications and the tasks required. The key tasks for most clinical studies likely to be conducted by PaCCSC are outlined in the Signature sheet for delegation of responsibilities. This should be completed at each site and held in the files for that site. New personnel or new delegation of tasks should be updated on this sheet as appropriate. This sheet will be checked as part of site monitoring visits.

Adequate Resources

The investigator should be able to demonstrate the potential of the centre for recruiting the subjects in line with protocol requirements, have sufficient time to conduct and complete the trial, and have access to sufficient staff to conduct and complete the trial.

Communication with the Independent Ethics Committee (IEC)

Before commencement of a trial, written approval from the relevant IEC on the application to implement the protocol must have been received. Any documentation modified during the course of the trial must be submitted to the IEC.

Compliance with Protocol

The investigator/institution should conduct the trial in line with the protocol approved by the IEC. Any deviations from the protocol must be documented by the Coordinating Investigator and approved by the relevant IECs.

Investigational Product(s)

The investigator/institution is accountable for the investigational product(s) at individual trial sites. The requirements for accountability and storage for the investigational product(s) will be addressed in a trial specific SOP for each trial, which may vary slightly between individual sites. The investigator should ensure that the investigational products are used in accordance with the protocol.

Informed Consent of Trial Participants

Prior to commencement of the trial, the investigator will have written approval from the IEC for the use of the participant consent form and any participant information sheets to be provided. Where possible the same information sheet and consent forms will be used at all sites and only modified where required by the local IEC's.

Participant information sheets and consent forms should be written and presented in a format understandable to persons of a Year 7 reading level (12 years of age) and include the following information:

- Clear identification of the institution convening the trial, the project title, the coordinating investigator and other investigators (including contact details)
- Clear purpose of the study and/or benefits to the participant
- That involvement in the project by the participant is voluntary and that participants are free to withdraw consent at any time, and to withdraw permission for use of any unprocessed data previously supplied for the trial
- Details of what participant involvement in the trial will require such as interviews, completion of questionnaires, use of any medications, surgery, investigations, or review of patient case notes, and estimated time commitment
- Explanation about randomisation, blinding and placebo use if appropriate
- Details about the financial and time burden involved in participating, such as out of pocket expenses and extra clinical appointments
- An explanation of all the risks and adverse events (nature and probability) to the participant
- A clear statement that involvement in the trial, or withdrawal from the trial will not affect ongoing clinical care nor service involvement
- Advice as to arrangements to be made to protect confidentiality of data, including that confidentiality of information provided is subject to legal limitations and duration of storage of data
- Details of the IEC that approved the trial protocol
- Details of proposed dissemination of results including access to results by participants as they become available. Each

protocol provides specific information about access to results for participants following the study closure

- Name and contact details of a site trial team member and the Coordinating Investigator who can answer questions regarding participant involvement
- Name and contact details of IEC person who can independently answer questions regarding the trial
- Documents any payments or reimbursements received by the investigators as a result of the participant consenting to the trial

Participant information sheets should be provided to the participant or participant's legally acceptable representative or proxy (dependant on individual State or Territory requirements) for consideration and/or discussion with a representative of the trial, prior to reviewing and completing a signed and dated participant consent form.

When obtaining informed consent in persons highly dependent on medical care including palliative care patients, the participant consent forms and information sheets must also comply with the additional requirements for obtaining informed consent in special cases as outlined in the *NHMRC National Statement on Ethical Conduct in Research Involving Humans – persons highly dependent on medical care (section 6)*. Specifically, there is a need to acknowledge in the informed consent processes that:

- the giving of free and informed consent can be compromised by the effect of the medical condition on the person's capacity to determine their own participation or to communicate their concerns or wishes
- the person may be reluctant to refuse consent in fear that it may compromise their ongoing medical treatment
- the prospect of benefit from research participation is neither exaggerated nor used to justify a higher risk than that involved in the patient's current treatment
- the needs and wishes of participants to spend time as they choose, particularly with family members

The Site Investigator must retain a copy of all signed consent forms within their Essential Documents.

Records and Reports

Each investigator is responsible for the data on the CRFs to be accurately and legibly recorded in line with ICH GCP requirements, maintained in line with the PaCCSC SOPs for *Essential Documents, CRF Completion, Data*

Management and Archiving of Research/Project Materials and destroyed in line with the *Record Destruction SOP*.

The Principal Investigator at individual sites is responsible for the provision of interim and final written reports to the site IEC in consultation with the Coordinating Investigator. Copies will be maintained by the coordinating and principal investigator, and the National Manager.

Safety Reporting

The reporting of all adverse and serious adverse events of studies will be in line with the *PaCCSC Adverse Event Reporting SOP*.

All serious adverse events should be reported immediately, within 24 hours by phone and fax, of becoming aware of the event, (adverse events less than 7 days) and to the PaCCSC coordinating agency except for those serious adverse events that the study protocol identifies as not needing immediate reporting. The immediate and follow-up reports should be followed promptly by a detailed written report.

The investigator should also provide any additional material requested by the PaCCSC Coordinating agency or the HREC such as autopsy or medical reports.

Premature Termination or Suspension of a Trial

If a trial is terminated or suspended prematurely, the investigator/institution will immediately inform all trial participants of reasons and future medical management. Each IEC will also be immediately informed and followed up with a written explanation of the termination or suspension.

Progress reporting

The investigator is to ensure that all contractual obligations are met including;

- Initiation and monitoring visit compliance
- Budget and finance accounting
- IEC progress and annual reporting, with copies to the PaCCSC Coordinating agency
- Progress reports as requested by the PaCCSC Coordinating agency

PaCCSC Staff Signature Sheet

Study Code	Site Code	Protocol Number	INVESTIGATOR NAME	Approval numbers

Print Full Name & Title	Signature	Initials	*Study Role	**Key Delegated Study Task(s) See list below	Duration		Investigator's Authorisation of delegated tasks
					From	To	
			Chief Investigator	1, 2, 3, 7, 8, 9, 10, 14, 19			
			Sub Investigator	1, 2, 3, 7, 8, 9, 10, 14, 19			
			Site Coordinator	21, 16, 18, 20, 21,			
			Study Nurse	1, 4, 5, 6, 11, 12, 13, 17,			
			Pharmacist	22, 23			
			Coordinating Site	15, 16, 18, 20, 21,			

*Identification of study role includes but is not limited to subinvestigators, study nurses, pharmacist (when appropriate) and data recorders. List individuals delegated significant study-related tasks (ICH GCP 4.1.5). Signature/Initials required for all persons authorised to make entries and/or corrections to Case Report Forms (ICH GCP 8.3.24)

** Identify key study tasks when delegated by the investigator. Examples of key study tasks include:

1	Informed Consent collection	7	Review of blood samples, MDRD.	13	CRF Completion	19	Study conclusion signature
2	Medical History review	8	Review of incl./exclusion criteria	14	CRF Signature	20	Archive functions
3	Con. Meds review	9	Safety assessments	15	Data query initiation	21	Monitoring
4	Measure of vital signs	10	Authorisation to randomise	16	Data Query Completion	22	Randomisation
5	Collection of blood samples	11	Product dispensing	17	Product delivery	23	Handling, manufacture, storage of investigational product
6	Handling of blood samples	12	Product Accountability	18	Communications		