



Standard Operating Procedures

6.12 Ethical Approval, Review and Reporting ©2007

History			
Version	Date	Author	Reason
1.1	10 th Jan 2006	Contributing authors	New procedure
1.2	25 th Feb 2007	S Whicker	Administrative update
1.3	18 th July 2007	B Fazekas	Update prior to MAB review
1.4	16 th October 2007	B Fazekas	Update after David Currow review

Approval				
Version	Author	Signature	Approval Name	Approval Signature
1.4	B Fazekas	<i>B. Fazekas</i>	D Currow (CI)	<i>David Currow</i>

Scheduled review

Date August 2009

Responsible person PaCCSC National Manager

6.12 Ethical Approval, Review and Reporting

Purpose

To ensure that clinical trial/study investigators are aware of their responsibilities to Independent Ethics Committee (IEC) / Human Research Ethics Committee (HREC) requirements through all stages of the trial which should ensure that a clinical trial is properly conducted and that human subjects are adequately protected.

Other related SOPs

Archiving of Research/Project Materials
Adverse Event Reporting
Electronic Data Handling
Investigator Roles and Responsibilities
Protocol Development
Version Tracking

Attachments

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 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>

ISRCTN International Standard Randomised Controlled Trial Number Register (accessed 250207) http://www.controlled-trials.com/mrct/submit_trials.asp

Definitions

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

An independent body (a review board or committee, institutional, regional, national or supranational), duly constituted of medical professionals and non-medical members as outlined by the National Health and Medical Research Council, 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 trial subjects.

Informed consent

A process by which a participant 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 specifically approved by the IEC/HREC.

Protocol

A document that describes the objective(s), design, methodology, statistical considerations, and organisation of a trial. The protocol usually also gives 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.

Subject/Trial

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

Well-being of the trial subjects

The physical and mental integrity of the participants participating in a clinical trial. In addition, the study protocol should specify the requirements of the IEC/HREC that participants have had the benefit and burden of participation clearly identified and dealt with in a way that complies with the National Statement.

Procedure

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

Each trial protocol and Investigator Brochure will be developed in line with the PaCCSC *Protocol Development and Investigator Roles and Responsibilities* SOPs. Each completed PaCCSC trial protocol will be registered with the agreed trial registry and obtain a Randomised Controlled Trial Number Register. All PaCCSC trial protocols will be submitted to an ethics committee constituted and operating in accordance with the *NHMRC National Statement on Ethical Conduct in Research Involving Humans*. Ethics approval will be sought at each participating PaCCSC site by the principal investigator at that site.

To expedite the approval process the protocol will be submitted to all IEC/HREC's and all comments and responses will be merged. Subsequent applications will incorporate modifications to documentation in line with recommendations made by the ethics committee, copies of any outcomes of Scientific Assessment Reviews and Declaration of Prior Review forms completed.

Documentation

Documentation submitted to individual ethics committees for approval will include:

- institutional application form, and payment for industry sponsored trials
- protocol and any protocol amendments
- investigator's brochure
- CRFs
- informed consent forms and subject information sheets
- any other supporting documentation to be considered eg Scientific Assessment Reviews and Declaration of Prior Review form
- Indemnity certification from the appropriate authority for that site
- Completed CTN forms where applicable

After approval of the protocol, any protocol amendment which requires a change in research activity will be submitted to the individual IECs at each site unless there is a mutual recognition clause. Administrative amendments will be addressed in the submission of a revised protocol at the completion of the trial. Identification of the protocol and amendments will be in line with the *Version Tracking* SOP.

Each site will file documentation that lists the constitution of the organisational IEC/HREC, and confirms the committee's compliance with the national requirements.

Records and Reports

All participating sites must provide a copy of the ethics approval to the coordinating site

The site investigator in consultation with the lead investigator will provide interim and/or annual reports and a final written report to the site IEC/HREC. Copies will be maintained in the investigator files in accordance with the PaCCSC *File and Data Management* and *Archiving of Research/Project Materials* SOPs.

In addition, each IEC/HREC will require renewal of ethical approval every 3 years. Notification for this will come from the coordinating site in order for the site investigator to submit.

Communication with the IEC/HREC

Before commencement of a trial, written approval from the relevant IEC/HREC 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/HREC.

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

If a trial is terminated or suspended prematurely, the IEC/HREC will also be immediately informed and followed up with a written explanation of the termination or suspension.