



PaCCSC
Palliative Care Clinical Studies Collaborative

Standard Operating Procedures

6.5.1 Study Recruitment ©2008

History			
Version	Date	Author	Reason
1.1	18 th July 2007	B Fazekas	New procedure
1.2	21 st January 2008	B Fazekas	Update after MAB review
1.3	19 th February 2008	B Fazekas	Update after review by D Currow

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

Scheduled review

Date August 2009

Responsible person PaCCSC Project Officer

6.5.1 Study Recruitment

Purpose

The recruitment of people is crucial to the success of any clinical trial. It is so important that planning of recruitment and the development of strategies to maximise recruitment takes an important place prior to study initiation.

If not done properly, a poor or non-existent recruitment strategy will result in poor levels of referrals to the study in the first place, in addition to referral of people who are unlikely to meet the entry criteria, or not complete the study protocol. Maximising referrals and recruitment to clinical trials, particularly in palliative care, is not a passive process but requires intensive effort to overcome issues of clinician and family gatekeeping, competing clinician responsibilities, and the potential vulnerability of the population, all of which make recruitment problematic.

This SOP will outline basic principles of recruitment to clinical trials conducted by PaCCSC. In addition, each site is expected to develop individual recruitment strategies (in discussion with the National Project Officer) to maximise recruitment potential at that site.

Other related SOPs

5.23.1 KPI compliance

5.5.5 Allocation of Participant ID numbers

5.23.2 CRF completion

Attachments

Study referral fax example

Pre-Screen Form

References

Work Instructions for PaCCSC studies.

IUPUI Standard Operating Procedures, Recruitment of Human Participants. V07/07.

([http://www.iupui.edu/%7Eeresgrad/human-sop/SOP%20-%20Recruitment%20of%20Human%20Participants%20\(07.07\).pdf](http://www.iupui.edu/%7Eeresgrad/human-sop/SOP%20-%20Recruitment%20of%20Human%20Participants%20(07.07).pdf))

Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95). Annotated with TGA comments 2000 (accessed 25/02/07)

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

Acknowledgments

Trans-Tasman Radiation Oncology Group (TROG), for generous access to the Policy and Procedure Manual – the Red Book.

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 sponsor on each trial subject. All events described within the study protocol should be captured the CRF.

Inclusion criteria

A list of requirements, that individuals must meet, in order to be eligible to participate in the study.

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

Informed Consent

A process by which a person 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 participant's decision to participate. Informed consent is documented by means of a written, signed and dated consent form, unless otherwise dealt with in an institutional ethics approved trial protocol.

Exclusion criteria

A list of requirements, any of which will exclude the person from participating in the study.

Prescreening

The evaluation of generalised characteristics prior to screening to initially determine eligibility. These characteristics enable an assessment to be made concerning contact and screening of the person for the study. The characteristics may be determined from the clinical notes (by the referring clinical team), the referring clinician or other sources as appropriate to the study, but not via any intervention or procedures.

Recruitment

The process where people are identified, screened and contacted for the study, or identified, screened and determined not to be eligible.

Screen Failure

Where the person has provided consent after being fully informed of the study, and has been found ineligible, either because the inclusion criteria have not been met, or an exclusion criteria was met.

Screening

Screening involves collection of information that is in addition to clinical care, it is collected for the reason of assessing eligibility for the study. These assessments may be testing for cognition, level of function, taking blood samples, requesting medication history, etc. As such this information is always collected after consent has been obtained.

Sample Only

Procedure

Recruitment

Recruitment of people cannot begin until the following has been met;

- The study, including the protocol, study documents, advertising materials and Patient Information Sheet and Consent Form has received final approval from the HREC
- The trial has been registered on a publicly accessible clinical trial registry
- The site has been added as a trial site with the TGA under the CTN scheme (if applicable)
- A site initiation visit has been conducted.

Referral

All people are to be referred by the clinical service to the PaCCSC studies (rather than through advertising or general invites for participants). Referrals will be via a number of site specific strategies all of which are aimed at;

- Increasing clinical knowledge and understanding of the study
- Ensuring that all people with specific characteristics are referred to the study team for further assessment
- Making individuals fully aware that they have been referred to a research study team, and may be contacted as a result

Referral can be through a number of different avenues: telephone, written referral letter, fax of study referral and are described within the study protocol.

All people referred to each study

- Are entered onto the study Patient Master Index maintained at each site (see 5.5.1 Electronic Data Handling) to enable tracking of KPIs.
- Have a notation made within the clinical file concerning referral

A Pre-Screen Form is completed for each person, and this is entered onto the study on-line database.

Pre-screening

Once the referral has been received a Pre-screen form is to be completed. This records the eligibility characteristics required for entry into the study. If the characteristics are not met, the person does not proceed to screening but a pre-screen form is still completed. A pre-screen form does not get completed if;

- The person does not want to be contacted
- The person dies or their condition deteriorates between the time of referral and the time of contact
- Other circumstances where the referral was not acted on. (This means that a identification number has been allocated, but no data has been entered into the study data base). It is anticipated that these occurrences will be low in number. Large numbers of referrals without action are a poor Key Performance Indicator.

The Pre-screen form can be completed from information obtained from a number of sources, including;

- referral letter
- discussion with clinical staff
- during the initial telephone contact with the person referred to the study.

- case note review (after seeking permission from the person during the telephone conversation)

Pre-screening information does not involve collection of information outside of usual clinical care. Pre-screening information can be obtained from sources without intervention of any description.

Screening and consent

Screening for eligibility takes place after the broad entry characteristics have been met as part of the Pre-screening. It is at this point that the study is fully explained, using the approved information sheet and consent form, consent is obtained according to the study protocol, and the eligibility assessments are undertaken.

Screening involves collection of information that is in addition to clinical care, it is collected for the reason of assessing eligibility for the study. As such this information is always collected after consent has been obtained.

As a result of screening, people either proceed to randomisation, or do not meet the criteria, and are a screen failure. This is recorded in the patient master index at each site, and is to be reported as part of the Key Performance Indicators for that site.

The consent and screening procedures will vary slightly between studies, and are described within the study protocols. These procedures are to be followed in order to comply with GCP requirements.