



Standard Operating Procedures

6.5.1 Study Recruitment

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Introduction / Background

The recruitment of participants is crucial to the success of a clinical study. Planning for recruitment and the development of strategies to maximise recruitment is an important activity prior to study commencement.

Poor planning for recruitment can result in poor referral rates to the study and potentially the referral of people who are unlikely to meet the inclusion criteria or not complete the study protocol. Optimising referrals and recruitment to clinical studies, particularly in palliative care, requires intensive effort to overcome barriers such as clinician and family gate keeping, competing clinician responsibilities, and the potential vulnerability of the population, all of which make recruitment problematic.

Objective

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

Scope

This SOP applies to all staff involved in clinical studies conducted by PaCCSC irrespective of individual organisational employment, role or position.

Ownership and Responsibility

Responsibilities of 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)

- To develop appropriate recruitment strategies specific for each study
- To pre-screen potential participants following referral
- To complete Pre-Screen Forms where appropriate
- To maintain the Master Patient Index
- To undertake screening for eligibility
- To ensure Participant Information and Consent Forms are signed by each participant (or proxy)

Responsibilities of the PaCCSC Coordinating Centre

- To assist sites in the development of their recruitment strategies
- To distribute recruitment tools to sites so as to facilitate recruitment of potential participants



Procedure

1. Prior to Recruitment

Recruitment of participants only commences when the following have been completed:

- The study, including the protocol, study documents, advertising materials and Patient Information and Consent Form have received final approval from the Human Research Ethics Committee (HREC)
- The study has been registered on a publicly accessible clinical study registry
- The site has been added as a study site with the Therapeutic Goods Administration (TGA) under the Clinical Trials Notification (CTN) scheme (if applicable)
- A site initiation visit
- Clearance has been given to commence the study by the PaCCSC Coordinating Centre

2. Tools to aid recruitment

The PaCCSC Coordinating Centre, in conjunction with the Lead Investigator and study team, has developed a number of tools to assist with recruitment. These tools are regularly revised and updated. Tools can include:

- Frequently asked questions
- Work instructions
- Workshop materials
- Prompt sheets and study lanyards
- Advertising materials

3. Referral

All potential participants are referred by the local clinical service to the PaCCSC studies (rather than through advertising or general invites for participants). Referrals are made via a number of site specific strategies 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

Referrals can be made via several media (described within the study protocol):

- Telephone
- Written referral letter
- Fax of study referral
- Email request



All people referred to each study:

- Are entered onto the study Patient Master Index maintained at each site (*refer* SOP 5.5.1 Electronic Data Handling) to enable tracking of Key Performance Indicators (KPIs)
- Have a notation made within the clinical file concerning referral
- Have a Pre-Screen Form completed and entered onto the study on-line database

4. Pre-screening

Following receipt of referral, a Pre-Screen Form is completed. Eligibility characteristics required for entry into the study are recorded on the form. If the characteristics are not met, and the person does not proceed to screening, a Pre-Screen Form is still completed.

A Pre-Screen Form is **not** completed under the following circumstances:

- 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 upon (an identification number has not been allocated, and no data has been entered into the study database)

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 potential participant)

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

Pre-screening serves a number of purposes to assist with recruitment:

- Referrals and prompt follow-up of referrals is encouraged and facilitated
- The use of broad eligibility characteristics encourages appropriate referrals
- Pre-screen data can be used to identify potential recruitment strategies
- Data can be used to review the study inclusion and exclusion criteria if recruitment is slower than expected

5. Screening and consent

Screening for eligibility takes place after the broad entry characteristics are met as part of Pre-screening. The study is fully explained to the potential participant, using the approved Participant Information and Consent Form. Consent is obtained according to the protocol, and the eligibility assessments (screening) are undertaken.

Screening involves collection of information that is in addition to clinical care in order to assess eligibility for the study.



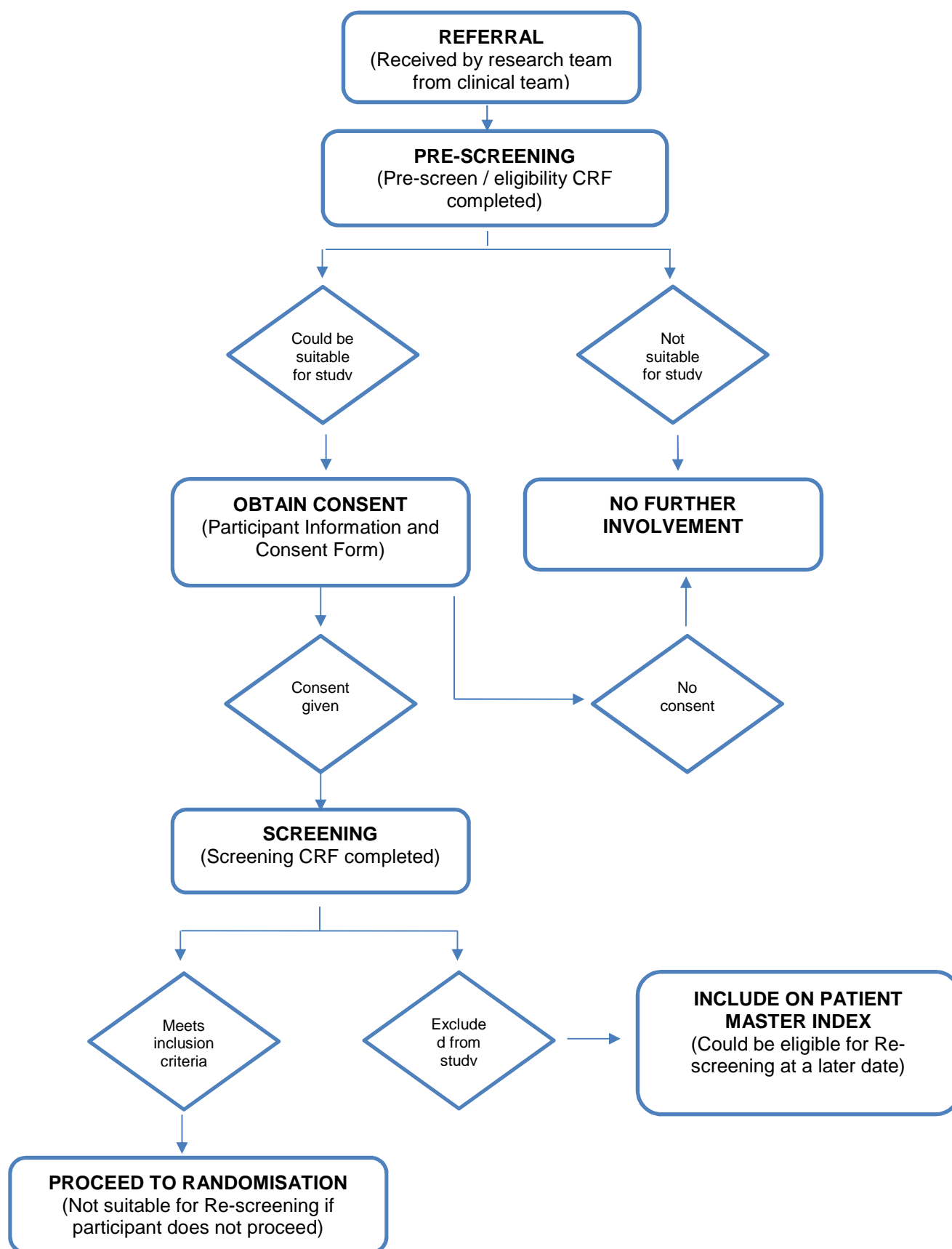
Following screening, participants either proceed to randomisation or are removed from the study if they do not meet the criteria. This is known as a Screening Failure. All screened participants are recorded in the Patient Master Index at each site. Screening numbers (including participants who proceed to randomisation and those who do not proceed) are reported as part of the KPIs for each site.

The consent and screening procedures vary between studies, and are described within the study protocols. These procedures are followed in order to comply with Good Clinical Practice (GCP) requirements.

Figure 1 details the Participant Recruitment Algorithm for PaCCSC clinical studies.



Figure 1 Participant Recruitment Algorithm





Other related SOPs

4.2.4 Delegation of Duties
5.5.1 Electronic Data Handling
5.5.5 Allocation of Participant ID Numbers
5.23.2 CRF Completion
6.5.2 Re-Screening

Other related documents

Template 36: Study Recruitment Plan
Template 37: Recruitment Review
Template 38: Recruitment Phone Calls Topics/Questions
Guidance 15: Recruitment Matrix

References

IUPUI Standard Operating Procedures, Recruitment of Human Participants. V08/2017.
<http://researchcompliance.iu.edu/hso/hsdocs/IU%20SOPs%20for%20Research%20Involving%20Human%20Subjects%2008.2017.pdf>

Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95). Annotated with TGA comments 2000 (accessed 17/10/2017)
<https://www.tga.gov.au/sites/default/files/ich13595an.pdf>

Work Instructions for PaCCSC studies

Acknowledgements

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



History			
Version	Date	Author	Reason
1.1	18/07/2007	B Fazekas	New procedure
1.2	21/01/2008	B Fazekas	Update following MAB review
1.3	19/02/2008	B Fazekas	Update after David Currow review
1.4	2/09/2010	B Fazekas, T Shelby-James	Periodic review, ratified by MAB
2.0	1/02/2011	B Fazekas	New version will all updates
2.1	2/06/2015	C Hope	Periodic review
2.2	28/02/2018	B Fazekas, S Kochovska	Periodic review Publication of the ICH GCP E6 (R2)

Approval		
Version	Approval Name	Approval Signature
2.2	David Currow	