UTS IMPACCT Trials Coordination Centre

Standard Operating Procedure

6.5.1 Study Recruitment

Version	V2.4
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Approved	M Agar
Effective date	01/04/2022
Review date	01/04/2024

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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.

Inclusion of recruitment planning within the study protocol is an important risk mitigation strategy.

Objective

This SOP describes the basic principles of recruitment to clinical studies conducted by the IMPACCT Trials Coordination Centre (ITCC), including Palliative Care Clinical Studies Collaborative (PaCCSC) and Cancer Symptom Trials (CST). In addition, each site is expected to develop individual recruitment strategies (in discussion with the PaCCSC/CST National Manager/ ITCC National Project Officer) to maximise recruitment potential at that site.

Scope

This SOP applies to all staff involved in clinical studies conducted by the ITCC, 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 ITCC

- To assist sites in the development of individual site recruitment strategies
- To coordinate the approval of recruitment materials designed for patient areas
- To distribute recruitment tools to sites so as to facilitate and maximise 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, recruitment and retention 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 has been performed and all required study training completed and system access (if applicable) granted
- Approval has been given to commence the recruitment to the study by the ITCC (*refer* SOP 5.7. Site Initiation)

2. Tools to aid recruitment

The ITCC, in conjunction with the Coordinating Principal Investigator (CPI) and study team, has developed a number of tools to assist with recruitment. These tools are regularly revised and updated. Tools can include but are not limited to:

- Informed consent script, including wording around specific identified issues such as;
    - Fear or morphine addiction
    - Commencing a preventative medication
    - Very end of life discussions
- Workshop materials
- Prompt sheets and study lanyards
- Advertising materials (posters, brochures, flyers, cards, radio/newspaper/web advertisements)
- Social media posts (Facebook, twitter, Instagram, LinkedIn)
- Posting in the clintrial refer app
- Newsletters
- Doctor to doctor letter
- Referral template
- Study PowerPoint presentation

A recruitment plan (Template 36) is detailed within the study protocol, and drafted for each study, if complex, during the study start-up phase, prior to site activation and recruitment initiation. The plan outlines the specific recruitment activities tailored to the individual study.

Periodic recruitment reviews (Template 37) and phone calls (Template 38) may be conducted by the ITCC to monitor each site's recruitment progress and activities at strategic time points during each study, particularly if there are site specific recruitment difficulties.

3. Referral

All potential participants are predominantly referred by the local clinical service to PaCCSC/CST/ITCC 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, and
- 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), including:

- telephone
- written referral letter
- fax of study referral
- email request
- periodic multidisciplinary team meetings

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),
- have a notation made within the clinical file concerning referral, and
- have a Pre-Screen Form completed and entered onto the study research data management system

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)
- Where the participant proceeds directly to screening, and the pre-screen form would be superfluous

The Pre-Screen Form can be completed from information obtained from several 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 several 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
- Prevents multiple approaches to the same patient
- Data can be used to identify recruitment barriers and 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 first, and the eligibility assessments (screening) are then undertaken.

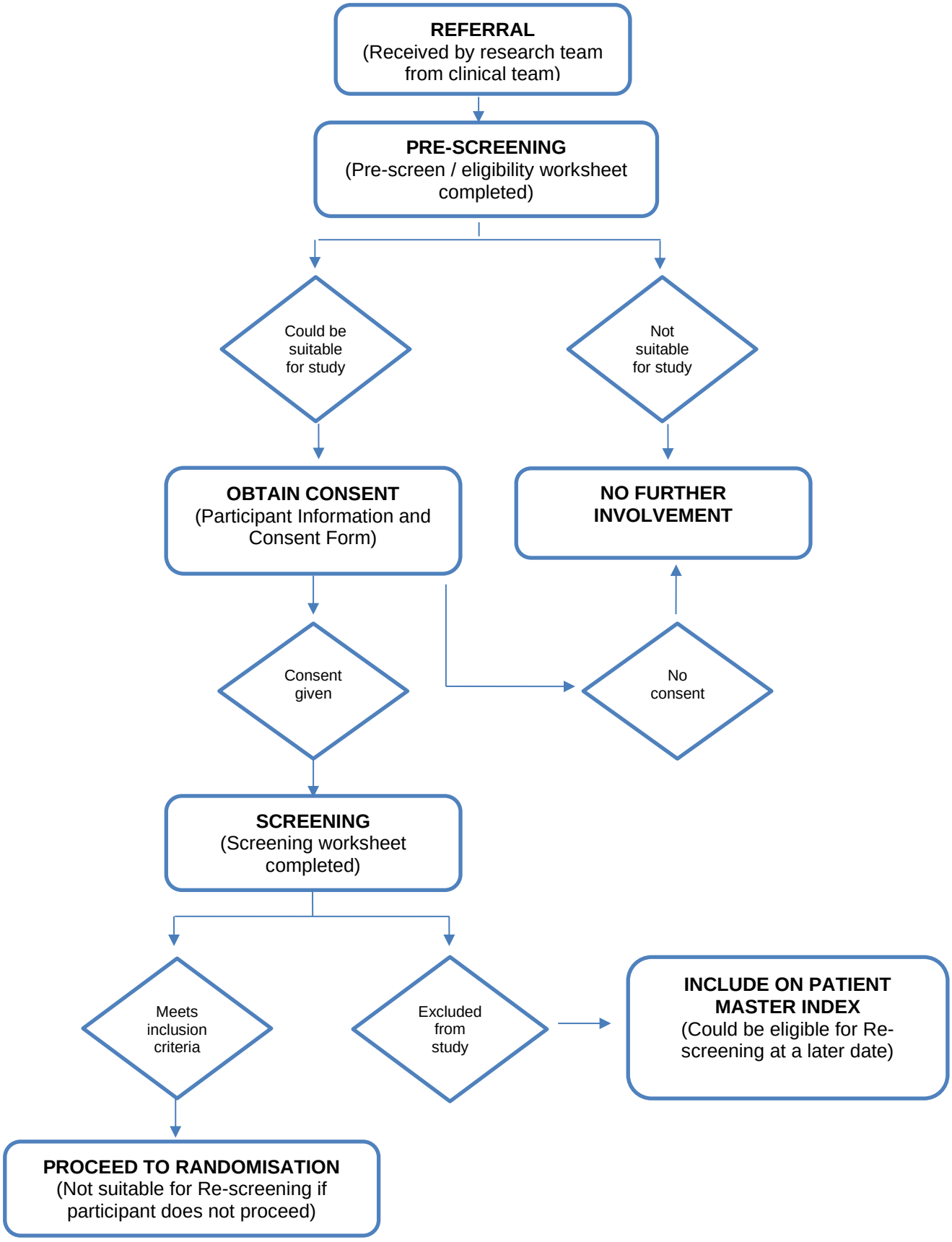
Screening involves collection of information that is in addition to clinical care in order to assess eligibility for the study.

Following screening, participants either proceed to randomisation or are removed from the study if they do not meet the criteria. The latter is known as a Screening Failure. All screened participants are recorded in the sites Patient Master Index. Screening numbers (including participants who proceed to randomisation and those who do not proceed) are reported as part of the sites Key Performance Indicators (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/CST/ITCC conducted clinical studies.

Figure 1 Participant Recruitment Algorithm



Related SOPs

4.2.4 Delegation of Duties

5.5.1 Electronic Data Handling

5.5.5 Allocation of Participant ID Numbers

5.7 Site Initiation

5.23.2 Data Collection Worksheet Completion

6.5.2 Re-Screening

Related documents

Template 36: Study Recruitment Plan

Template 37: Recruitment Review

Template 38: Recruitment Phone Calls

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

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)
2.3	16/03/2020	C Strauss	Periodic review
2.4	17/01/2022	B Fazekas, L Brown	Periodic review

Approval		
Version	Approval Name	Approval Signature
2.4	Meera Agar