Standard Operating Procedure

6.5.2 Re-Screening

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Author/s	C Strauss
Approved	M Agar
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Introduction / Background

People potentially eligible for the IMPACCT Trials Coordination Centre (ITCC) clinical studies are screened in accordance with protocol specific procedures. This process ensures that participants (and potential participants) are fully screened and enter studies after having met all the inclusion criteria. The screening procedure detailed in SOP 6.5.1 Study Recruitment is followed. However, there are some circumstances where people can be re-screened at a later date for a study, after having already been screened without proceeding.

Objective

This SOP describes the circumstances when re-screening is appropriate and how this is to be recorded.

Scope

This SOP applies to all staff involved in clinical studies conducted by the ITCC, including Palliative Care Clinical Studies Collaborative (PaCCSC) and Cancer Symptom Trials (CST), 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 identify potential participants eligible for re-screening
- To screen participants who have been identified as eligible for re-screening
- To ensure data collection worksheets and electronic Case Report Forms (eCRFs) are completed for each participant following re-screening
- To ensure Participant Information and Consent Forms are signed by each participant (or proxy) prior to re-screening, if necessary

Procedure

1. Screening

- Screening for eligibility to participate in a clinical trial takes place after the broad entry characteristics have been met as part of the Pre-screening process (*refer* SOP 6.5.1 Study Recruitment).
- 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.
- 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 (*refer* SOP 5.5.5 Allocation of Participant ID Numbers). Screening numbers (including participants who proceed to randomisation and those who do not proceed) are reported as part of the Key Performance Indicators (KPIs) for each site.
- The consent and screening procedures vary between studies and are described within the protocols. These procedures are followed in order to comply with Good Clinical Practice (GCP) requirements.

2. Re-Screening

Re-screening of participants can occur in certain circumstances and **provided the participant has not been randomised in the study already**.

Examples of circumstances when a participant can be re-screened:

- If a person consents to participate and meets the eligibility criteria but there is a delay in starting due to a change in situation (for e.g., family issues, individual request for attending private matter, etc.)
- If the person previously failed screening due to an acute event that has now resolved/reversed
- Prescribed medications have stabilised
- Reversible causes of screen failure have been adequately treated (for e.g., someone who had anaemia at the original screening that precluded involvement, and this has since been corrected/resolved by a blood transfusion)

Re-screening always occurs if the screening data has previously been entered into the RDMS, but the participant has not been randomised for that study. This is true even if nothing has seemingly changed between the initial screening and re-screening time points.

It is not appropriate to re-screen a person if they have previously failed to meet the eligibility criteria and there have been no further changes or treatments that would now indicate that the person may be suitable.

It is not appropriate to re-screen a person if they have previously been randomised to the study and did not proceed to study intervention. Such course of action may potentially delay

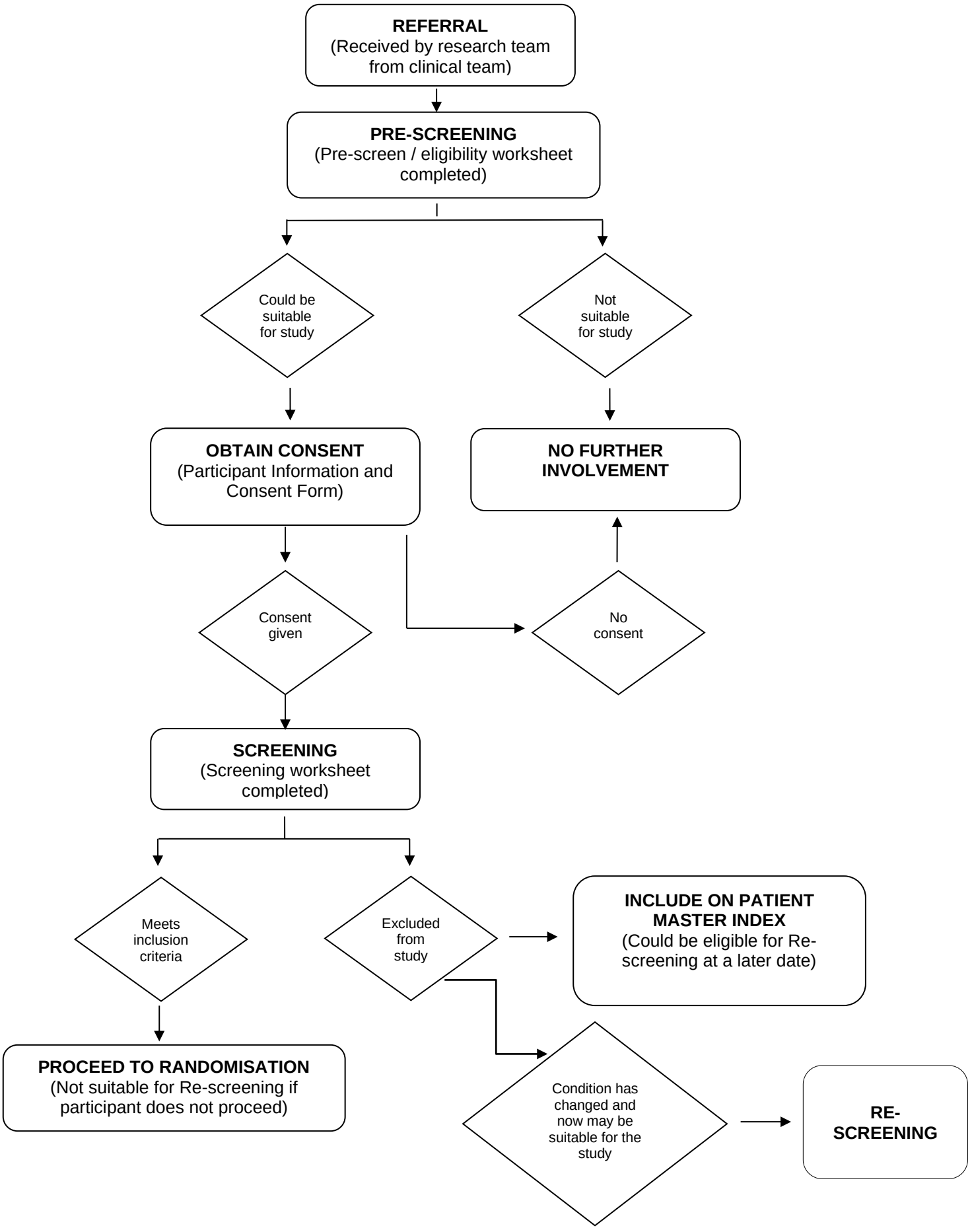
the commencement of the study. In this situation, the eligibility data is to be reviewed for currency and the data amended accordingly, the timeframe is determined by the Principal Investigator and a file note is completed. Re-screening is not undertaken at this point.

3. Re-Screening Procedure

- If screening data has been entered into the electronic case report form (eCRF) (RDMS-REDCap)
    - A new eligibility data collection worksheet is used (*refer* SOP 5.23.2 Data Collection Worksheet Completion)
    - A new identification number is assigned to the person (the 3-digit patient number). See SOP 5.5.5 Allocation of Participant ID Numbers.
    - The person is identified as having been re-screened on the data collection worksheet, eCRF and the Patient Master Index.
    - The new eligibility data collection worksheet is completed. Data is not copied from the previous eligibility worksheet to the next but completed using the current clinical situation as documented within the patient clinical notes and any other source documents.
    - Eligibility data for the re-screened participant is entered in the eCRF under the new participant identification number.
    - The person may need to sign a new Participant Information and Consent Form as part of the screening procedure (as per the individual study protocol and requirements of Human Research Ethics Committees).
- If screening data has not been entered into the eCRF (RDMS- REDCap)
    - The previous eligibility data collection worksheet can be reviewed and updated (*refer* SOP 5.23.2 Data Collection Worksheet Completion)
    - A new eligibility data collection is completed. Data is not copied from the previous eligibility CRF to the next but completed using the current clinical situation as documented within the patient clinical notes and any other source documents.
    - Eligibility data for the re-screened participant is entered in the eCRF under the new participant identification number.

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

Figure 1 Participant Recruitment Algorithm



Related SOPs

4.2.4 Delegation of Duties

5.5.5 Allocation of Participant ID Numbers

5.23.2 Data Collection Worksheet Completion

6.5.1 Study Recruitment

Related documents

N/A

References

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	8/01/2008	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
2.0	3/02/2011	B Fazekas	Changes ratified by MAB
2.1	3/06/2015	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	30/12/2021	B Fazekas	Periodic review

Approval		
Version	Approval Name	Approval Signature
2.4	Meera Agar