**[Study name] Recruitment Plan**

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| --- | --- |
| **Purpose**   * This study recruitment plan has been developed to tailor the recruitment activities of the generic ITCC SOP 6.5.1 Study Recruitment as they apply to the [insert name] study. * This is to ensure the recruitment for the [insert name] study meets all the requirements for a pre-registration study, and that the recruitment is adaptive, comprehensive and focusses on review, training and mentorship. | |
| **Full title:** | ***Specify full title for the study*** |
| **Abbreviated title:** | ***Specify abbreviated title for the study*** |
| **Trial registration** | *Specify trial registration number* |
| **Coordinating  Principal Investigator** | *Name*  *Position*  *Organisation*  *Address*  *Phone*  *Fax*  *Email* |
| **Study sponsor** | *IMPACCT Trials Coordination Centre (ITCC), University of Technology Sydney*  *235 Jones Street*  *Ultimo NSW 2007*  *Australia*  *Email: itcc@uts.edu.au* |

**NOTE TO INVESTIGATORS**

* ***This study recruitment plan template contains instructions and sample text in italics. Investigators should carefully consider the suggested text under each section, and then modify, remove or replace as appropriate to their study.***
* ***This instruction page should be removed once the study recruitment plan is completed.***

1. **Measures**

*Each study should consider the recruitment measures appropriate to the study, and to each site, and can include the following:*

1. ***Direct site support***
2. *To support all* ***site investigators*** *locally and through monthly Trial Investigator Meetings (TIM) to maximise recruitment at their site.*
3. *To support all* ***site coordinators*** *through monthly teleconferences (opposite fortnight to the TIM in 1. above) and individually through one-on-one support provided by the ITCC.*
4. *Through direct* ***one on one*** *contact with sites at strategic time points, and can include consideration of the any of the following:*
   1. *By phone 2 weeks from study commencement where there has been no pre-screen activity*
   2. *By phone 4 weeks from study commencement where no recruitment has occurred*
   3. *By phone 8 weeks from study commencement where no screening has occurred; or at 8 weeks from the most recent recruitment*

*Use of Template 37 Recruitment review can guide this conversation*

* 1. *By phone 12 weeks from study commencement where no recruitment has occurred; or at 12 weeks from the most recent recruitment*
  2. *In person 16 weeks from study commencement where no recruitment has occurred; or at 16 weeks from the most recent recruitment; for a telephone review of the sites potential to recruit to the study and to review ongoing involvement*

*Use of Template 38 Recruitment Phone calls can be helpful to guide this discussion*

* 1. *By phone 20 weeks from study commencement where no recruitment has occurred; or at 20 weeks from the most recent recruitment*
  2. *By phone 24 weeks from study commencement where no recruitment has occurred; or at 24 weeks from the most recent recruitment; to determine if the site remains a viable and continuing proposition.*

*Use of Template 38 Recruitment Phone calls can be helpful to guide this discussion with focus on items 4 and 5 to review ongoing support or site capacity*

* 1. *By phone on reaching primary endpoint of the first participant*
  2. *By on site visit on completion of the first 2 study participants for monitoring and for review of procedures and protocol review*

*Apply the SOP 5.18 Monitoring, and associated Guidance and Template documents to assist with initial monitoring.*

1. ***Centralised support***
2. *Activities* ***conducted by the IMPACCT Trials Coordination Centre (ITCC)*** *to the benefit of all participating sites:*
   1. *Direct access to the ITCC to discuss the study* 
      1. *Monthly site meeting between all site coordinators and ITCC staff, standing agenda;* 
         1. *Ethics/RGO*
         2. *Screening undertaken*
         3. *Recruitment update and issues*
         4. *Data entry/REDCap issues*
         5. *Protocol issues*
         6. *Amendments (as/if needed)*
         7. *Central monitoring items*
         8. *Other items*
      2. *Monthly Investigator Meetings (TIM) to review progress with the above agenda*
      3. *Quarterly Protocol investigator meetings to review progress, and problem solve*
   2. *Standard Operating Procedure for Study Recruitment (refer SOP 5.6.1 Site Selection; SOP 6.5.1 Study Recruitment)*
   3. *Recruitment resources for all sites:*
      1. *Recruiting in palliative care: Guidelines for research teams*
      2. *Consent script as a living document, update as sites provide feedback on questions asked by potential participants, their families or clinicians*
      3. *Advertising posters (for waiting rooms and staffing areas)*
      4. *Clinic recruitment cards (for waiting rooms)*
      5. *Letter to GP’s*
      6. *Referral template (for other departments)*
      7. *PaCCSC/CST generic brochure*
      8. *Study PowerPoint*
      9. *ITCC team presentations*
   4. *Fortnightly emailed recruitment updates*
   5. *Literature searches*
   6. *Recorded interviews with top performing sites*
   7. *External advertising and promotion activities*

***Table 1 below forms the basis of the study recruitment plan. Table 1 is to be completed for each study, where all risks have been considered and addressed.***

**Table 1: Measures to support recruitment**

| **Measures** | **Information** | **Dates/Time periods** |
| --- | --- | --- |
| **Direct Site Support** | | |
| ***Protocol Investigators*** | *At the highest level the protocol investigators meet quarterly via teleconference to discuss progress, review recruitment, protocol issues, safety reporting and site performance* |  |
| ***Site Investigators as a Group*** | *Principal Investigators and Site Coordinators are members of the Trial Meetings and meet on a monthly basis to bring together each site investigator to discuss a set agenda which includes recruitment items of best and poorest performing studies and recruitment strategies employed. Sharing of local practices to engage with and promote study recruitment is encouraged.* |  |
| ***One-on-One meetings*** *– Individual sites through one-on-one contact with the ITCC team* | *These calls will be implemented at strategic time points for each participating site and dependent on recruitment performance. No recruitment at a site for 4 weeks will trigger a phone call and will be ongoing for up to 16 weeks, at which point a site visit will occur. Phone calls will be made by the National Manager (NM) and National Project Officer (NPO) to review the sites recruitment efforts and pre-screening information at weeks 4, 8 and 12. Should a site reach 16 weeks without recruitment then a site visit will be conducted for a formal site performance visit. If there remains no recruitment at the site for a following 8 weeks a further phone contact will be made where the discussion will centre on the sites ability to remain viable, and a decision made as to whether the site should be closed and exit from the study.*  *This item is expanded on later in the document.* |  |
| ***Centralised Support*** | | |
| *Direct access to ITCC team* | *Any site staff can, and are encouraged to, make contact directly with the NM or NPO as and when required for any study related matter including recruitment.* |  |
| *SOP for Study Recruitment* | *The ITCC as the Sponsor organisation has a SOP for study recruitment (refer SOP 6.5.1 Study Recruitment).* |  |
| *ITCC recruitment resources* | *Included resources that may be tailored for use by sites includes:*   * *Consent script* * *Posters x 2 (for waiting rooms and staff rooms)* * *Clinic recruitment cards (for waiting rooms)* * *Template letter to GPs* * *Referral template (for other departments within a health care service to refer)* * *PaCCSC/CST generic brochure* * *[name] study PowerPoint* * *Other relevant ITCC team presentations* |  |
| *Regular emailed recruitment updates/ Leader board* | *Each fortnight, or on a regular basis pending recruitment, the ITCC collates the previous week’s results into a tabulated form and circulates to all sites. Graphical representation of this information may also be provided from time to time.* |  |
| *Literature searches* | *Literature searches are undertaken on an ad hoc basis on recruitment in clinical trials related to strategies and motivating factors. This information will be shared across the participating recruiting sites.* |  |
| *Advertising* | *Advertising of the study through national bodies, health network newsletters, media requests, other specific campaigns.* |  |

1. **Assessment of Measures**

*Recruitment phone calls (week 2 if there has been no pre-screening activity, then monthly where no recruitment has taken place). Topics to be covered (Template 38):*

1. *Recruitment activities conducted locally; discussion of what local activities have been conducted to influence recruitment; review of past study performance and comparison.*
2. *Pre-screens reviewed: how many; where are referrals coming from?; what are the major reasons for screen failure?*
3. *Networking: what avenues are open to the site that haven’t yet been explored?*
4. *Site difficulties: are there events at the site that have reduced their capacity to recruit?*
5. **Outcome**

*Where there has been no recruitment despite the actions in place resulting from the telephone calls, the decision to continue as a site should be discussed jointly between the site and ITCC. This ensures that resources, capacity, and funding are preserved.*