Standard Operating Procedure

5.6.1 Site Selection

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Approved	M Agar
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Introduction/Background

There are several factors that influence the capacity of a site to undertake research, successfully recruit participants and meet the state, national and international regulations of clinical trials conduct.

Sites participating in or wishing to participate in clinical studies conducted by the Palliative Care Clinical Studies Collaborative (PaCCSC) or Cancer Symptom Trials (CST), supported by the IMPACCT Trials Coordination Centre (ITCC) must undergo site feasibility/study feasibility/risk assessment prior to the start of a clinical trial to establish their capacity and resource capabilities to undertake research (including, but not limited to, their clinical expertise, access to specialities, patient population, and capacity and training of Principal Investigators).

Objective

This SOP provides guidance on the selection of new sites to participate in each ITCC clinical trial and details the site feasibility/study feasibility/risk assessment of sites prior to their selection to recruit participants to a clinical trial.

Scope

This SOP applies to all sites that have either expressed interest or been approached to take part in clinical studies conducted by the ITCC.

Ownership and Responsibility

Responsibilities of the Principal Investigator (of the new study site)

- To notify the PaCCSC/CST National Manager of their intention to become a new site

Responsibilities of the PaCCSC/CST National Manager

- To provide the Principal Investigator of the potential new site with:
  - a summary of the specific study under enquiry,
  - a confidentiality agreement form, and
  - general information about PaCCSC/CST/ITCC and the contractual and agreement documents required

Responsibilities of the ITCC National Project Officer

- To follow up with the new site
- To provide contact information about the new site
- To review, amend and provide the site feasibility and study feasibility checklists
- To provide any further information to the site
- To commence study initiation procedures as appropriate

Procedure

When a new site approaches the ITCC/PaCCSC/CST or vice versa:

- The PaCCSC/CST National Manager contacts the potential Principal Investigator at the new site via email and provides the Site Feasibility Checklist to enable the parties to assess their capacity to conduct a clinical trial.

- The new site Principal Investigator determines if the site would like to progress and informs PaCCSC/CST National Manager.

- The ITCC conducts a full evaluation of all sites and their capability to become a recruiting site for each ITCC sponsored study, using the Site Feasibility Checklist (Template 5), Study Feasibility Checklist (Template 21) and Site Risk Assessment Toolkit (Template 6).
    - These checklists are reviewed and updated to be specific to a study, if appropriate, prior to sending to the new site, and consideration is given to:
        - Availability of study nurse/project officers appropriate to the study
        - Expertise and availability of the clinical trials pharmacy
        - Other resources that may impact on the new sites capacity to conduct any specific clinical trial
    - The ITCC then sends the Site and Study Feasibility Checklists to the Principal Investigator.
- The Principal Investigator completes the Site Feasibility Checklist and Study Feasibility Checklist based on the current clinical and administrative context at the site (not prospective context). The ITCC can assist with any specific queries regarding the checklists.

- The Principal Investigator sends the completed Site Feasibility Checklist and Study Feasibility Checklist to the ITCC (a copy of the checklists is kept by the ITCC for future reference).

- The ITCC uses the Site Feasibility Checklist to complete the Site Risk Assessment Toolkit (Template 6) and works with the site to address any issues identified in the Site and Study Feasibility Checklists and Site Risk Assessment Toolkit.

- The Coordinating Principal Investigator determines (in consultation with the PaCCSC/CST National Manager/ ITCC National Project Officer) when a new site is ready to be initiated into the study. At this point, any specific training, increased monitoring, or amended funding arrangements are put in place.

- The decision to initiate a new site is emailed to the Principal Investigator of the new site. Site and study initiation are often conducted at the same time and are tailored according to the feasibility assessments.

- The initiation of a new site is communicated (by email, meeting minutes, or telephone) to all other sites participating in the study and relevant trial management committees.

For each trial, a structured risk assessment is undertaken by the Sponsor to identify potential patient, study, or organisational hazards.

Related SOPs

N/A

Related documents

Template 5: Site Feasibility Checklist

Template 6: Site Risk Assessment Toolkit

Template 21: Study Feasibility Checklist

References

Australian Code for the Responsible Conduct of Research 2007 (accessed 20/10/2017) https://www.nhmrc.gov.au/guidelines-publications/r39

COSA Standard Operating Procedures for Investigational Sites. March 2006. A publication of the Centre for Clinical Research Practice, Inc.

International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2). November 2016 (accessed 23/10/2017)

https://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R2__Step_4.pdf

National Statement on Ethical Conduct in Human Research (2007) - Updated March 2014 - (accessed 19/10/2017) http://www.nhmrc.gov.au/guidelines-publications/e72

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

Praxis Australia

History			
Version	Date	Author	Reason
1.1	7/03/2014	B Fazekas	New procedure
1.2	14/07/2015	C Hope	Periodic review
1.3	28/02/2018	B Fazekas, S Kochovska	Periodic review Publication of the ICH GCP E6 (R2)
1.4	18/02/2019	B Fazekas, S Kochovska	Periodic review
1.5	18/01/2022	B Fazekas, L Brown	Periodic review

Approval		
Version	Approval Name	Approval Signature
1.5	Meera Agar