PoCoG Site Feasibility and Selection for Psycho-oncology Research Guidelines

Overview

The Psycho-Oncology Cooperative Research Group (PoGoG) has developed a program of quality assurance for Psycho-Oncology Research. This guidance document **Site Feasibility and Selection for Psycho-oncology Research** provides a standard template for assessing potential study sites to maximise success of psycho-oncology research.

Purpose

This document provides a clearly defined pathway for researchers to evaluate site feasibility for their research. The purpose is to guide researchers to identify sites with the capacity to undertake psycho-oncology research.
This guidance describes the steps for (1) identifying the sites resources and broad interest in a potential new study, and (2) the steps for fulfilling the regulatory and ethical requirements for assessing the feasibility of implementing a protocol.

Scope

This resource is designed as a guide to assessing site feasibility/risk assessment prior to the start of a study. This resource applies to the activities involved in assessing a site's capacity to participate in the proposed study, based on available resources and ability to make a valuable contribution to recruitment

Site Selection and Feasibility

Many clinical trials are delayed or fail to meet their goals with significant scientific, ethical and financial consequences (Huang et al., 2018). Selecting sites that match the specificities of the protocol has a direct impact on the quality of data collected, study timelines, and overall project finances. Part of a major risk mitigation strategy to avoid this is selecting enough clinical sites that fit the unique needs of the study. This assessment is particularly important for complex interventions such as those required in psycho-oncology research in order to reduce publication bias and investigational resource waste (van Lankveld, et al., 2018).

An assessment of site feasibility is key to the success of any research project. It involves the process of evaluating the possibility of conducting clinical research at a particular site, with the overall objective of optimum research completion in terms of meeting the timelines, participant targets and cost. Conducting a feasibility assessment will assist in identifying potential obstacles to study conduct and design, enabling investigators to proactively develop processes and practices that mitigate risk, and to select appropriate sites to support study completion.

Steps to optimal site selection

Step 1: Define Site Requirements and Selection Criteria

The first step to selecting appropriate sites for a study is to develop an ideal site profile by identifying the **key site criteria** from the study design. For psycho-oncology protocols this involves the careful consideration of the site's services, resources, and capacity to undertake the research protocol. This data provides the fundamentals that will guide site selection. As part of the selection of recruitment sites, you should only commence a study if there are:

- Adequate resources to complete the study
- Sufficient participants to meet the study objectives
- Qualified and experienced study personnel to deliver the study and/or intervention

Important criteria to consider include:

1. ***Population Profile and Access to the Study Population***: eligible participants' availability, condition incidence, ongoing trials recruiting similar patients, and recruitment capabilities of staff.
2. ***Psycho-oncology Intervention Feasibility:*** consider the characteristics of the intervention - what is done to whom and how.
3. ***Investigator and Staffing Feasibility:*** staff availability, specialty, credentials, experience in clinical research and the studied indication.
4. ***Site Capacity /Capability***: What are the current care pathways and resources? Will the site be able to accommodate the procedure in the study protocol?
5. ***Institutional/Site Resources and Profile:*** site type (e.g., hospitals or clinics, academic centres, non-profit, government, and private sites), site's Human Research Ethics Committee (HREC) meeting timeframe, and typical timeline for contract negotiation.
6. ***Past Performance***: research experience including research studies with similar enrolment timelines, enrolment target, and complexity, and past enrolment rates.
7. ***Competition***: concurrent research in the same indication or targeting the same population that are ongoing or scheduled to start during study conduct.

Clearly defining **evaluation criteria** before the process starts will not only help identify sites that are suitable for the study, but also supports an objective comparison between eligible sites to select the best ones for a specific trial. It is also important to prioritize and define the non-negotiable items, as some criteria are absolute must-haves while others may be flexible. As data are collected, they may be added to a scoring system such as a simple spreadsheet for data analysis. (see Site Evaluation Record Template_Version 1.0_20190211)

Step 2: Identify Sites, Gather EOIs and Initial Information

Sites can be identified through tools such as:

- Internal databases of previously utilised sites
- Online and offline directories
- Publications of recent clinical trials in the studied indication
- Clinical trial registry postings (e.g. http://www.anzctr.org.au/)
- Word-of-mouth and references (e.g. snowballing)

Once a potential site is identified, the first step is to send the identified local contact an expression of interest (EOI) request for participation which includes a study synopsis to assess initial interest and site feasibility suitability data. (see Appendix A & Appendix B)

If the site is potentially interested the next step is to conduct a full site feasibility (see PoCoG Site Feasibility and Selection Template_Version 1.0_20190213) that includes specific questions addressing each of the pre-defined criteria (from Step 1).

Step 3: Evaluate and Select the Sites

After all the information is gathered, reviewed, and evaluated, an objective comparison and decisions can be made. This is also an opportunity to identify any areas of additional research support that may be considered for sites with otherwise adequate qualifications. The final sites are notified of their selection for the trial. Site initiation and set-up can then commence.

Records management

Keeping a contact log that includes the contact information of the point person at the site, an indication about the last time a site was contacted, and notes about pending items or questions, helps staying on top of the progress made and follow ups needed. (See Site Contact Record Template_Version 1.0_20190211)

References

Bird V, Le Boutillier C, Leamy M, Williams J, Bradstreet S, Slade M (2014) Evaluating the feasibility of complex interventions in mental health services: standardised measure and reporting guidelines, British Journal of Psychiatry, 204, 316-321.

Canadian Association of Psychosocial Oncology. Standards of Psychosocial Health Services for Persons with Cancer and their Families. Canadian Association of Psychosocial Oncology. 2010.

Clinical Trials Transformation Initiative. CTTI recommendations for planning for successful trial recruitment. Published May 2016, updated July 2018. https://www.ctti-clinicaltrials.org/projects/recruitment

Grant D. Huang, Jonca Bull, Kelly Johnston McKee, Elizabeth Mahon, Beth Harper, Jamie N. Roberts, Clinical trials recruitment planning: A proposed framework from the Clinical Trials Transformation Initiative, Contemporary Clinical Trials, Volume 66, 2018, Pages 74-79, ISSN 1551-7144, https://doi.org/10.1016/j.cct.2018.01.003

NHMRC Good Practice Process for Site Assessment and Authorisation Phases of Clinical Trial Research Governance v2.3 (September 2016) https://nhmrc.gov.au/sites/default/files/documents/good-practice-process.pdf

NHMRC Competencies for Australian Academic Clinical Trialists, Canberra: National Health and Medical Research Council (2018)

NHMRC National Statement on Ethical Conduct in Human Research 2007 (Updated 2018). The National Health and Medical Research Council, the Australian Research Council and Universities Australia. Commonwealth of Australia, Canberra https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018

Rajadhyaksha, V. (2010). Conducting Feasibilities in Clinical Trials: An Investment to Ensure a Good Study. Perspectives in Clinical Research, 1(3), 106–109.

Silva, A. (2018). Selecting Study-Appropriate Clinical Sites in 3 Steps. Applied Clinical Trials, Apr 12, 2018; http://www.appliedclinicaltrialsonline.com/selecting-study-appropriate-clinical-sites-3-steps

van Lankveld JJDM, Fleer J, Schroevers MJ, Sanderman R, den Oudsten BL, Dekker J. Recruitment problems in psychosocial oncology research. Psycho-Oncology. 2018;1–3. https://doi.org/10.1002/pon.4792

APPENDICES

APPENDIX A - Expression of Interest Letter Template

<<Date>>

<<Site Principal Investigator>>
<<Department>>
<<Address>>
<<State Postcode Country>>

RE: <<study title>>

Dear <<Site Principal Investigator>>

We would like to invite your expression of interest to participate in a new collaborative study being undertaken by <<insert study sponsors/collaborators (e.g. the Psycho-Oncology Co-operative Research Group (PoCoG))>> entitled *'*<<insert study title>>*'*.

Background and Aims
<<insert a brief summary of the back ground to the research and the aims/objectives it is aiming to achieve>>

What is involved?
<<list details of the level of involvement required by the site investigator. This may include screening, recruitment, consent, etc.>>

Trial Funding and Site Payments (if applicable)
<<Detail how this study will be funded and any site payment/reimbursement that will be provided.>>

Expression of Interest (EOI)
We are now contacting investigators who <<detail how potential investigators were identified>>
In order to determine the needs and suitability of your hospital or institution an expression of interest (EOI) form <<see Appendix B>> has been attached. We would be grateful if this form was completed and emailed to <<contact details including name, email and phone no.>>.

Further Information
Should you require more information about this study please contact <<contact details including name, email and phone no.>>

We look forward to receiving your completed EOI and will be back in contact with you about your site's participation <<give an appropriate timeframe e.g. in the next two months>>.

Kind Regards,

<<CIA, CIB, etc..>>

APPENDIX B - Expression of Interest Form Template

Expression of Interest (EOI) Form

Protocol ID: <<Insert the protocol identification number. For PoCoG administered studies e.g. PoCoG-207-01; supported studies e.g. PoCoG-2019-05>>
<<insert study title>>

Site Details:

Site Name	
Institution Type	<<e.g. public, private, hospital-based, community-based>>
Local Health District/Health Service	
HREC/Ethic Review Board	

Investigator Details:

First Name	**Surname:**
Qualifications	
Street Address	
Suburb	
State	**Postcode:**
Email	
Contact No.	

Study Specific Questions:

Patient Population and Recruitment

	Number of Patients	Source:
How many patients treated for <<insert cancer type or other indication of interest>> **has your centre seen in the past 12 months?**		☐ **Hospital Records/Databases** ☐ **Best Estimate**
How many patients treated for <<insert cancer type or other indication of interest>> **do you see per month?**		☐ **Hospital Records/Databases** ☐ **Best Estimate**

Of the above patients, how many patients would be eligible (based on the eligibility criteria below) to participation in the proposed study? <<Define eligibility criteria here>>	☐ **Hospital Records/Databases** ☐ **Best Estimate**
Have you participated in studies of this patient population previously?	
If yes, were you able to meet recruitment targets?	☐ **No** ☐ **Yes. Please provide details below.**

Resources and Management

Is your site/hospital/clinic currently involved or intending to be involved, in any competing studies with the same patient population?	☐ **No** ☐ **Yes. Please provide details below.**
Do you foresee any difficulties or have any concerns regarding identification of patients and consenting of these patients to take part in this study?	☐ **No** ☐ **Yes. Please specify below.**

Study Logistics

Are you potentially interested in participating in this study?	☐ **No** ☐ **Yes** ☐ **Undecided, please provide further information**

When would you be ready to commence?	☐ **<3 months** ☐ **3-6 months** ☐ **6-9 months** ☐ **9-12 months**
Do you have any colleagues that would be interested in being involved in recruiting for this study?	☐ **No** ☐ **Yes. Please provide their details below.**

Additional comments:

Signed: **Date:**

PoCoG
Psycho-oncology Co-operative Research Group

Site Feasibility Checklist

<Instructions: This checklist has been designed to be completed by PIs at each potential study site in order to assess the capacity of their site, to successfully complete the psycho-oncology research protocol and ensure study feasibility. The CI should first ensure that the checklist is adapted to contain only the **relevant items** for their study and **reword** any questions accordingly. The most current protocol should be provided to the PI with this checklist to assist them with completion of this checklist>

Study ID:	
Study title	<insert study title>
Planned commencement	<insert the date the study will commence at this site>
Anticipated duration	<insert how long this study will be open at this site>
Site	<insert the study site>
Local Health District/Health Service	<insert the LHD the site is located in>
Principal Investigator (Site)	<insert the name of the PI at this site>
HREC	<insert the name of the HREC for this site>

PoCoG
Psycho-oncology Co-operative Research Group

Site Feasibility Checklist (<study ID>)		Response	Please provide comments/details
Access to study population	How many patients (<or other participant group as appropriate> that meet study eligibility criteria (<insert eligibility criteria>) do you typically see per month?		
	What percentage of eligible participants are likely to enrol in the study at your site? Please explain your answer. Interventional studies usually recruit at approximately 30-50% of all eligible patients. Consider if there are factors that make refusal more likely (e.g. more visits than normal care, additional interventional procedures required etc.)?	%	
	Is the **number** of patients (<insert site recruitment target>) to be enrolled realistic for this site? If no, how many patients could you enrol?	☐ Yes ☐ No →	No. that could be enrolled:
	Is the enrolment **period** (<insert site recruitment period in months>) realistic for this site? If "No", why not?	☐ Yes ☐ No →	Why not?
	Will you be able to identify eligible participants using existing databases?	☐ Yes ☐ No	
	Will you need to identify participants from other sources? If "Yes", please explain how this will occur (i.e. is this feasible).	☐ Yes → ☐ No	
	Are there any cultural or local/region-specific issues that need to be considered (i.e. anything that will motivate or deter patients from enrolling in the trial)? If "Yes", please detail.	☐ Yes → ☐ No	Cultural/Regional issues:
Psycho-oncology Intervention Feasibility	Is the intervention applicable to the sample population of interest (i.e. <insert the target population>) seen at your site? Consider the characteristics of patients seen at your site (e.g. gender, ethnicity, age). If no, please explain why not.	☐ Yes ☐ No	

PoCoG
Psycho-oncology Co-operative Research Group

Site Feasibility Checklist (<study ID>)		Response	Please provide comments/details
	Does the psycho-oncology intervention outlined in the protocol differ to standard care at your site? If "Yes", please detail.	☐ Yes → ☐ No	Current standard of care:
Investigator and Staffing Feasibility	Do you (the PI) have adequate time to devote to the project? <insert any details on the role of the PI> If "No", please explain what aspects of the protocol would not be feasible for you to complete.	☐ Yes ☐ No →	
	Does the psycho-oncology team have **capacity** to deliver the intervention? Is the workload required for providing the intervention feasible to maintain? Consider how much time it requires per client per week for the intervention and any administrative tasks related to the protocol. <insert any details on the time required to administer the intervention>	☐ Yes ☐ No	
	Who will be responsible for the intervention? <insert any details on the role of psycho-oncology staff in administering the intervention> If "No", why not?	☐ Yes ☐ No →	Why not?
	Will current staffing levels of other required staff members at your site be adequate for completion of the study protocol? <insert any details on the role of other staff members in completion of the protocol> If "No", why not?	☐ Yes ☐ No →	Why not? <optional>**Please complete the list (APPENDIX A) detailing staffing at your site.**
	Will staff require any specific training to deliver the psycho-oncology intervention? If "Yes, please provide details of what training is needed.	☐ Yes → ☐ No	Training needs:

Site Feasibility Checklist (<study ID>)		Response	Please provide comments/details
	<Optional: Include this item if the protocol includes/requires ongoing support and supervision for staff> Is adequate access to support/supervision for intervention staff available at your site? If "No", why not?	☐ Yes ☐ No →	Why not?
Site Capacity /Capability	How is screening for <insert indication e.g. anxiety/depression> carried out at your site (e.g. by who, when etc…)?		
	Is there a triage/referral pathway to psycho-oncology following screening for <insert indication e.g. anxiety/depression>? Please describe in the comments how patients currently access treatment/therapy at your site.	☐ Yes ☐ No	Current Referral Pathway:
	Do the procedures outlined in the protocol differ to standard care at your site? If “Yes”, provide details.	☐ Yes → ☐ No	Current procedures:
	Are all procedures/clinical assessments feasible to carry out at your site? If "No", why not?	☐ Yes ☐ No →	Why not?
	Will staff time be available to monitor participant recruitment and compliance at your site? If "No", why not?	☐ Yes ☐ No →	Why not?
	Are you able to ensure completion of the case report forms (CRFs) as specified in the study protocol? If "No", why not?	☐ Yes ☐ No →	Why not?
	<If electronic CRFs or databases are required by the protocol> Are you able to complete the electronic or web-based CRFs? If "No", why not?	☐ Yes ☐ No →	Why not?

PoCoG
Psycho-oncology Co-operative Research Group

Site Feasibility Checklist (<study ID>)		Response	Please provide comments/details
Infrastructure	What was the number of referrals to psycho-oncology, made from your site in the previous financial year?	**Number per annum:**	
	Please explain how this information was obtained. (e.g. are screening scores and referral activity available in the eMR)?		
Institutional Resources	Does the preliminary budget <insert the budget details> appear adequate to cover estimated costs associated with **setting up** the intervention at your site? If "No", please detail.	☐ Yes ☐ No →	
	Does the preliminary budget <insert the budget details> appear adequate to cover estimated costs associated with **running** the intervention at your site? If "No", please detail.	☐ Yes ☐ No →	
	What are the timelines for ethics submission to ethics approval at your site?	**The HREC meets (e.g. monthly, bimonthly):** **Approximate time for approval from submission:** **weeks**	
	Will there be any potential challenges meeting the ethics approval timelines as detailed in the protocol? <insert the timeline dates for ethics approval> If "Yes", please explain what challenges may arise.	☐ Yes → ☐ No	Potential challenges:
Protocol Feasibility	Do you think the study design is appropriate for your site? If "No", why not?	☐ Yes ☐ No →	Why not?

PoCoG
Psycho-oncology Co-operative Research Group

Site Feasibility Checklist

Statement of Principal Investigator

Do you have capacity and are you willing to participate in the above study?

- ☐ Yes
- ☐ No, because:
  - ☐ Lack of access to psycho-oncology services to fulfil the study protocol
  - ☐ Insufficient patients who meet eligibility criteria
  - ☐ Protocol procedure(s) are too difficult
  - ☐ Ongoing competing study in my Institution
  - ☐ Other (please specify below):

_____
_____
_____
_____

ADDITIONAL COMMENTS:

Completed by

_____ _____ ___ / ___ / _____

Name **Signature** **Date**

Appendix A

<Instructions: This section of the checklist is an optional component that can be adapted to the needs of the study if it is required or the researchers think it will be useful for assessing site feasibility. Delete or insert from the list below, as required by your study protocol.>

Staff Composition		
	Head Count	**Full-time Equivalent**
Medical staff		
Cancer Care Coordinators/CNCs		
Clinical Psychologists		
Clinical Trials Staff (Total nurses and manager)		
Data Managers		
Psychiatrists		
Psychologists		
Registered Nurses		
Social Workers		
Other, please specify:		