PoCoG
Psycho-oncology Co-operative Research Group

National Ethics Application Form (NEAF) – FAQs and sample responses

It is essential that a thorough study protocol is developed prior to starting the ethics application. Ethics committees are likely to review the protocol to develop an understanding of the study and to determine risk of harm to both participants and the research team. Also, many of the questions in the NEAF can be populated from the protocol. This will also ensure consistency across documents. Keep in mind while completing the ethics application that the aim of this process is to ensure that the research team have considered the risk of harm, implemented mechanisms to minimize this risk, and weighed this risk against the potential benefits of the research.

This FAQ document is designed to assist with responses to questions in the NEAF. Study specific questions (e.g. contact details, or study descriptions) have been omitted. A full list of NEAF questions can be found on the website (https://www.neaf.gov.au) along with a reference map of the sections that make up the NEAF. While sample responses have been provided for some questions, it is important that each ***application is personalised and that the sample responses are not simply directly copied***.
Please note that the details below are correct at the time of writing. For the most up-to-date details please check the website.

SECTION 1 – TITLE AND SUMMARY OF PROJECT

Provide the title and a description of the project in clear, succinct language.

SECTION 2 - RESEARCHERS / INVESTIGATORS

Who is the Chief researcher/ investigator (Q1)?

The Chief Researcher is generally the Principal Investigator (PI) who responsible for the co-ordination of other Investigators (Chief Investigators [CIs] and Associate Investigators [AIs]) in a multicentre study). Often this person is also Chief Investigator A (CIA) on grant.

Who should be listed as the Principal Researchers (Q2)?

The Principal Researchers are all the Chief Investigators (CIs) involved in the overall study (these are usually the investigators listed on the grant application). The form asks for the expertise, responsibilities, and role of each investigator.

An example response for the PoCoG Biostatistician Dr Melanie Bell:

Expertise: Dr Bell is a biostatistician specialising in longitudinal analysis. She has worked as a statistician for over 10 years and has published over 30 papers in peer reviewed journals. Dr Bell has extensive research and teaching experience in biostatistics, including studies focused on cancer, pain, cardiovascular disease and nutrition. She has expertise in the measurement, analysis, interpretation and application of a range of patient reported measures, including health status and quality of life, and the design and analysis of longitudinal intervention studies.
Responsibilities: Dr Bell is jointly responsible for overseeing study operations across all sites. Along with her fellow PIs, she will ensure that the AIs in charge of each participating site implement HREC recommendations and submit progress and safety reports
Role: Dr Bell will advise on patient reported outcome measures, including psychological distress, quality of life, and unmet needs. She is also responsible for guiding the statistical analysis plan for data obtained in this study and primary data analysis.

If a student is involved in this research and will be using the data for part of his/ her degree, the following information should be included in response to Q2
Student name, degree enrolled in, faculty, and university, Supervisors name, qualifications and expertise.

Who should be listed as the Associate Researchers (Q3)?

The Associate Researchers or Associate Investigators (AIs) are those located at the study recruitment sites. You do *not* need to obtain signatures on the NEAF from Associate Investigators at sites – they will be collected on the Site Specific Assessment (SSA) Form. Contact details, qualifications, roles and expertise are also required for the Associate Investigators.

Who should be listed as 'other personnel relevant to the research project' (Q5)?

This would include people who will have some role in the project. Individuals do not need to be named – the professional category will suffice (e.g. Pharmacist, Neuropsychologist, Nuclear Medicine Radiographer, Research Assistants or other support staff who will be working on the study). In the case of PoCoG administered studies, the PoCoG Research Program Manager and Executive Director should be included, and their role can be described as follows:

> The Psycho-oncology Cooperative Research Group Research Program Manager (Dr Michelle Peate) and Executive Director (Dr Melanie Price) will have access to the study data for monitoring and auditing purposes. Both Dr Peate and Dr Price have extensive experience in psycho-oncology research and are familiar with the methodological and ethical issues associated with research.

Describing the training of researchers (Q7)

It is likely that the study will require some training of site investigators and site research personnel (e.g. in recruitment procedure). Two examples are listed below:

> ***Example of a study that recruits participants from sites and conducts the study centrally:***
>
> *What is this training?*
> Prior to study start-up, site investigators and research personnel will be trained to ensure they are able to commence their role in the study protocol. At a minimum, this will include being familiar with the background and aims of the study, the study materials, protocol and processes, and include rehearsal of new or unfamiliar procedures. Training will be undertaken by the study PI or study co-ordinator, and will continue with ongoing feedback and support as required.
>
> *How and by whom will the training be provided?*
> The training will be provided by the PI and/or CIs and study co-ordinator and delivered in person and/or via teleconference.
>
> *How will the outcome of the training be evaluated?*
> The training will be evaluated on an individual basis by the study co-ordinator and individual or group site meetings, as well as by regular auditing of study data for validity and completeness.

> ***Example of a study where an intervention is being delivered at sites:***
>
> *What is this training?*
> Clinicians and personnel involved in delivering an intervention will complete background reading requirements, before attending a one day training course, focused on review of both intervention manuals and practice of the intervention techniques with feedback from the senior psychologists providing the training. The training course is based on a previous workshop provided for clinicians involved in the pilot study of the intervention. In post-training questionnaires, clinicians will be evaluated for their increased knowledge about, and confidence in, managing fear of recurrence, and indicated the training was informative, relevant, interesting and length of time.
>
> *How and by whom will the training be provided?*
> The training will be provided by principal and associate investigators with extensive clinical experience and who were involved in the delivery of the previous pilot training workshop and/or pilot intervention delivery. We expect that two training courses will be run, one in Melbourne lead

by A/Prof Reed Richards and Ms Susan Storm, and another in Sydney led by Dr Johnny Storm and Prof Ben Grimm.

How will the outcome of the training be evaluated?
At the completion of the training, clinicians will be asked to complete a brief Training Evaluation Survey (TES). The written self report TES will include items surveying: basic demographic features, professional qualifications and experience, confidence in dealing with FCR pre and post training, and satisfaction with the intervention training content and delivery using purposively designed Likert scales. A proportion of the intervention sessions will be audio-recorded and evaluated by the trainers for concordance with the protocol. Additional training sessions will be conducted as required.

SECTION 3 - RESOURCES

How the study is to be funded (Q1)

In this section of the NEAF you will need to indicate how the research is being funded. This includes details of any grants that have been awarded or requested. Funding types can fall under four categories:

External Competitive Grant	This type of funding involves submitting a grant application to a body that is external to your organisation that undergoes a competitive vetting process (e.g. NHMRC, Cancer Australia, Cancer Council NSW, Cancer Institute NSW, *beyondblue* etc).
Internal Competitive Grant	This type of grant is submitted within your organisation and undergoes a competitive vetting process.
Sponsor	Funding obtained from a sponsor, which is may or may not be competitively obtained.
By Researchers, Departments or Organisation	Funding received from researchers, departments or organisations that are not competitively obtained.

If funding has been sought, or received, details will need to be entered. This will include the name of grant/ sponsor, details of in kind support and the extent of alignment between scope of the grant and HREC application (that is the funding will support the whole study as outlined in the HREC application or only part 1 of the study and further funding will be sought for part 2 of the study).

- You may wish to indicate that in-kind support, such as office space, computers, secure storage, provision of study intervention or equipment, administrative and technical assistance will be provided by the granting body or another partner organisation (in addition to the funding).

Managing a funding shortfall (Q2)

There are a number of response options for this item:

- Not applicable. The grant received will cover the entire cost of the project.
- The host organisation/ investigators have funds to cover the shortfall.
- The investigators will continue to apply for funds to cover the shortfall.
- Only Part 1 of the protocol will be undertaken until funding is secured for Part 2.

Other ways the study might be supported (Q3)

You may wish to indicate that in kind support, such as office space, computers, secure storage, administrative and technical assistance will be provided by the your sponsor/ institution (e.g. PoCoG, The University of Sydney).

Disclosure of payments (Q4)

It is preferred that participants are made aware of capitation payments (i.e. payment in money or incentives of any kind), where applicable. For this question provide information about the type of capitation and the mechanism that patients will be informed (often a statement in the participant information sheet). For example:

> Therapists' employers will be reimbursed for time spent delivering the intervention that is otherwise away from their regular employment. Participants will be made aware of this in the participant information sheet.

Commercialisation or intellectual property implications of the funding/ support arrangement (Q5-9)

Consider the implications for commercialisation (i.e. can money be made from this in the future) and intellectual property (i.e. who owns the rights to the information derived from this research). In most cases, the rights will be owned by the institution in which the research was conducted. The response used here should be checked against the funding agreement and the "National Principles of Intellectual Property Management for Publically Funded Research" (http://www.nhmrc.gov.au/grants/policy/intellectual-property-management).

An example response for a study conducted at the University of Sydney:

> The ownership of any intellectual property that arises from the study will belong to the University of Sydney and study investigators. The University will also comply with the principles outlined in the National Principles of Intellectual Property Management for Publically Funded Research ('National Principles"), University of Sydney (Intellectual Property) Rule 2002, and the funding agreement. The University will grant to the funding body a permanent, irrevocable, free, world-wide, non-exclusive licence (including a right to sub-licence) to use, reproduce, communicate, modify, and adapt study-related intellectual property.

Restrictions on the publication of result from this research (Q9)

Ideally there should be ***NO*** restrictions on the publication of results from research, and as a general rule universities, such as The University of Sydney, will not sign-off any research agreements that place unrealistic restrictions on publishing data. However, for research undertaken as part of a tender or consultancy contract, these documents should be checked for any restrictions agreed to in the contract.

SECTION 4 – PRIOR REVIEWS

The reviewing Australian HRECs (Q6)

For multi-site studies, all the Australian HRECS that will be requested to review the study should be listed.

"Have you previously submitted an application..." (Q8)?

The answer to this question is usually 'No' – particularly under the single ethical review process of multi-centre research. The answer may be yes if the study is being expanded to a multi-site study, or if this is a new submission of the study to the same HREC that has previously declined approval or for a submission of a study previously approved but that did not go ahead or the approval lapsed for another reason.

Research conducted overseas (Q10)

If the research is to also be conducted overseas, you will need to consider the local requirements and legislation, and how they will be met. For example:

> Each site in New Zealand has local requirements for the conduct of the study. These will be coordinated by the lead investigator in New Zealand, Dr Michaela Quinn in collaboration with the study management team at the Psycho-oncology Co-operative Research Group (PoCoG) in Australia.

Peer review (Q11)

Any peer review a study has undergone (or is undergoing), such as granting body review process, the PoCoG scientific endorsement process, or a review by any other scientific advisory committee should be indicated here. For PoCoG endorsed studies, the endorsement letter which describes what this process involves can be attached to the ethics application and/or quoted in the application.
For studies that have undergone peer review as part of the funding process the following sentence could be used:

> The research proposal has been peer reviewed and funded by NHMRC in the 2015 funding round (APP007007).

SECTION 5 - PROJECT

Expected benefits to the wider community (Q7)

Benefits that may apply include:

- Improved patient outcomes which in turn reduce health costs to the community
- Improved best practice
- Improved knowledge and understanding
- Have implications for service delivery and/ or policy
- Outcomes may be applicable to other health conditions

Example responses:

This intervention has the potential to reduce fear of cancer recurrence (FCR) to improve patient quality of life, and reduce health care costs. Should the intervention be found to be effective, the goal will be to inform and train clinicians to implement the intervention into clinical practice. The intervention may be an additional option for improving psychosocial outcomes of cancer survivors and have service and policy implications in terms of implementing 'best practice' recommendations. It is possible that the same techniques may be effectively applied to health anxiety not related to cancer, in transient FCR, or associated conditions.
If this decision-aid is effective, this approach to improving patient knowledge and understanding about clinical trials may result in enhanced decision-making, increased recruitment and retention rates in clinical research. If effective, the utilisation of decision-aids may also provide a mechanism to reduce the time required to effectively recruit into clinical trials, thus decreasing the time to ascertain effectiveness of treatments and abandoning less effective treatments, valuable for health researchers and patients worldwide.

Expected benefits to participants (Q8)

The extent of benefit to participants can vary:

	Example response
Little benefit	Participants are not expected to directly benefit from participation in this study, but may gain satisfaction from knowing that their experiences may contribute to scientific knowledge and helping future patients faced with similar symptoms/ decisions.
Moderate benefit	Participants may directly benefit from participating in the study as a result of a better understanding of the rationale of clinical trials, and by being assisted in making a more informed decision.
Direct benefit	Participants may directly benefit from the intervention, through a reduction in fear of cancer recurrence and the associated anxious, depressive and ruminative symptoms. Therapists will receive further training and experience in a structured therapy plan for fear of cancer recurrence.

Justifying risk of harm or discomfort (Q10)

Ultimately, it is important to justify any harm or discomfort participants may experience (as the responsibility of participant safety falls on HREC as well as researchers). Things to consider when addressing this question include:

- A cancer population is likely to be experiencing distress – so the norms for the study sample may be different to healthy participants. Where possible find a reference for population specific norms.
- Health care providers can be skilled in identifying and managing distress and in some clinics distress screening is a part of usual care so the usual care pathway may address the issue.
- In the situation where a participant has clinical levels of distress, regardless of whether or not the distress is a result of the study, the recommended process is to contact the participant and encourage them to contact their own health care provider, or their GP. Alternatively, the

participant's may prefer assistance in identifying a local psychologist or mental health professional. In the situation of a participant suspected of being at immediate risk of self-harm or of harming others, implementation of standard mental health protocols apply including consultation with the local area mental health team.

	Example responses:
No (very low) risk	There are no foreseeable risks to clinicians participating in this study. During piloting, clinicians indicated that decision aids assist them in comprehensively assessing patient needs. Thus it is anticipated that clinicians involved in the study will have greater confidence in the information provision for the RAVES clinical trial with the decision aid.
Low risk	It is possible that participants may find some of the material contained in the decision aid or questionnaires unsettling, or that it raises new issues. However previous decision aid studies indicate that patients are not distressed and value the information provided. If a participant does find the information provided anxiety provoking, they will be encouraged to contact the researchers, or their clinician, and if warranted, referred for psychosocial support as detailed in the study protocol.
Moderate risk	While it is anticipated that the intervention will benefit most participants, it is possible that some participants may become or remain distressed during study participation, including those in the control arm. Procedures are detailed in the study protocol to ensure participants who meet pre-defined thresholds of additional psychological morbidity will receive appropriate care according to the severity. In cases of mild psychological co-morbidities, the therapists will continue the intervention as per protocol, and provide treatment for co-morbidities once final study assessment has been completed. In cases of moderate psychological co-morbidities the therapist will continue the intervention as per protocol and provide treatment for co-morbidities, once the intervention has been completed, while noting the delivery of additional psychological treatment during the assessment period. In cases of severe psychological co-morbidities the therapist will interrupt the intervention to provide treatment for those co-morbidities, and then continue the intervention and assessments once these issues have been resolved while noting the deviation from the intervention protocol. Participants displaying significant psychological co-morbidity before the intervention commences will have the option of addressing their issues with the therapist or being referred for additional support.
High risk	This study is investigating the impact of a psychological therapy in suicidal patients. Although the theoretical basis of this intervention has the potential to offer significant benefit to these patients there is a risk that the intervention may increase distress and consequently increase suicide ideation. Careful efforts will be made to ensure that consent is informed – with patients able to access the study co-ordinator for questions and clarification. After agreeing to participate, a protective study design that includes risk management protocols to address this risk will be used. For instance, at the end of each therapeutic session the treating psychologist will conduct a suicide risk assessment. If the patient is deemed high risk then the psychologist will consult with the local area mental health team. Additionally, serious adverse events monitoring processes will be put in place for suicide attempts and a Data Safety Monitoring Board (DSMB) will be recruited to ensure the safety of participants and validity and integrity of the data.

Other risks (Q11)

Any risks to people involved (other than participants) should also be considered and indicated. Ideally, there should be no risk to the research team, organisation or others.

Commercial benefit of the research for investigators and sponsors (Q12)

Any anticipation of commercial benefit arising from the research should to be described here.

Risk of harm as a result of dissemination (Q16)

Generally, as aggregate (non-identifiable) results are disseminated there is little to no risk of harm. However, in the situation where the result may have a harmful effect on participants and/ or the communities that they are a part of, this should be indicated and the benefits measured against the risks.

Mechanisms to monitor the project (Q17)

This may include:

- Regular meetings of the study investigators to monitor the conduct and progress of the study and to solve problems as they arise. This might include a review of:
  - participant recruitment rate (eligibility confirmation &review of screening logs)
  - follow−up of participants in the study (completion of study questionnaires, etc)
  - reasons for attrition
  - adverse events
  - need for interim analysis / early termination of study
  - data collection, entry and cleaning issues
- Therapists will have monthly telephone-based supervision sessions to debrief and discuss the progress of the intervention, any problems or concerns that have arisen, and to ensure that the structure and outline of the interventions are being followed across all sites.
- Testing of fidelity to treatment protocols in both arms. For example:

  Fidelity to treatment protocols in both arms will also be monitored by regular review of session checklists. The recording of therapy sessions and a review of a random 10% of recordings by the research team, with feedback given where non-fidelity is identified.

- Reporting of serious adverse events. For example:

  In the FCR study, participating therapists will be responsible for notifying the Principal Investigator (PI) and study co-ordinators of serious adverse events and other intervention related issues. Any untoward occurrence in study participants (e.g. unfavourable and unintended signs, symptoms temporally associated with the use of an intervention, whether or not related to the intervention) will be considered a serious adverse event (SAE). Any SAEs that occur after informed consent is signed will be recorded on the AE Case Report Form (CRF). The PI is responsible for reporting serious adverse events in line with HREC requirements and as outlined in the study protocol.

- Monitoring of psychological wellbeing. For example:

  The psychological wellbeing of participants will continue to be monitored during the follow-up period after intervention delivery. Post intervention assessments will be reviewed on submission. Participants identified as having significant psychological co-morbidity will be contacted by the research team within two days and offered further support or referral options as per the study protocol.

- Staff training. For example:

  The research assistants will be trained by the study co-ordinator to ensure they are able to screen, recruit and consent patients to the study following the study protocol. They will also be given grounding in ICH GCP and the National Statement on Human Research 2007, and applicable guidelines and will have access to mentors who will be able to advise them on their role and any concerns that may arise.

Data and Safety Monitoring Board (DSMB) (Q18)

A Data and Safety Monitoring Board (DSMB) is a multi-disciplinary independent group of experts who monitor patient safety and treatment efficacy data while a study is ongoing. DSBM makes recommendations to the Study Management Committee about whether the study should continue or be suspended or terminated based on both internal and external data. The use of a DSMB in Australia is not mandatory, however it is recommended that human studies that are high risk (life-threatening), have a long

duration, conducted on vulnerable populations, have a high profile, or have unknown risks may benefit from having a DSMB. The Principal Investigator is responsible for determining the need for a DSMB.

The formation of a DSMB is advised if two or more of the following criteria are met:

- This study is a large, multicentre study
- The aim of the study will be to provide definitive data about effectiveness and safety of an intervention
- Prior data suggest that the intervention has the potential to induce unacceptable toxicity
- The study evaluates mortality or another major endpoint, such that inferiority of one treatment arm has safety and effectiveness implications
- It will be ethically important for the trial to be stopped if the primary question has been definitively answered or it becomes apparent the trial will not answer the question, even if secondary questions or complete safety information are not yet fully addressed.

A DSMB may not be necessary for low to moderate risk studies, for studies with small sample sizes or very short-term endpoints. If this is the case, an explanation as to why it is not thought necessary will be required, such as:

> The likelihood of a serious adverse event occurring in the study is low and consequently there are no stopping rules. Given the short timeframe of this study (2.5 years) it is also unlikely that the issue of overwhelming benefit or futility will arise. Thus a DSMB will not be established.
>
> Study progress will be monitored by the PoCoG Scientific Advisory Committee (SAC) as part of a quality assurance process, including monitoring of adverse events. A risk management process outlined in the study protocol will be implemented, ensuring that in the unlikely event of a serious adverse event (SAE) the study management team will be convened to discuss a management process within 48 hours of the reported SAE.

High risk studies are likely to require a DSMB to monitor the safety of the study.

SECTION 6 - PARTICIPANTS

Research participants (Q1) and exclusion of specific participants or groups (Q5)

The inclusion or exclusion of specific types of research participants, with specific ethical concerns as identified by The National Statement, requires an explanation (Q1). If any particular participants or groups are excluded an explanation will also be needed (Q5). Examples include:

Research participants	*Example justifications*
People whose primary language is other than English (LOTE)	• This intervention targets people whose primary language is other than English and aim to improve the quality of care received in this population. • Participants who are not fluent in written and oral English may not meet the inclusion criteria as participation involves written questionnaires and/or interviews conducted in English only.
Women who are pregnant and the human foetus	• The intervention does not involve any physical or invasive components, and will therefore not pose a risk to women who are pregnant or risk to human foetuses.
Children and/or young people (ie. <18 years)	• This intervention is specifically designed to improve outcomes in children and young people <18 years. Parental consent will be sought for these participants. • Children and young people have also been excluded from this research as they are who most likely require very different treatment approaches to fear of cancer recurrence compared to adult cancer survivors, which are beyond the scope of this study.

People in existing dependent or unequal relationships	• Some participants may have been in a previous provider-receiver relationship with the clinician involved. However, recruitment for the study will be undertaken by the research co-ordinator rather than clinicians involved in the study. Potential participants will be clearly informed that whether they consent or decline to participate in the study, or to later withdraw from the study they may do so without impact on any provider-receiver relationship.
People highly dependent on medical care	• This intervention specifically targets patients who are highly dependent on medical care. Their care will be carefully monitored for any changes, and adverse events flagged and monitored as per the study protocol. Participants have the option to withdraw from the study at any time without impacting their usual care. • The intervention is targeted at patients who are cancer survivors and the study specifically excludes those in remission or those who are having hospital treatment as the issues around uncertainty about the future are very different for those with active disease. Whilst some participants may be continuing to receive hormonal therapies or other outpatient based cancer treatments (usually given over a number of years), it is not anticipated that any participants will require extensive medical care. Patients being actively treated for their disease, in particular those who are highly dependent on medical care do not meet the inclusion criteria for this study.
People with a cognitive impairment, an intellectual disability or a mental illness	• Participants who have an intellectual or mental impairment that precluded them from providing informed consent are excluded from this study. • People with mental health co-morbidities will not be excluded from the study, but the presence of mental health co-morbidities will be documented, as will the number of subsequent sessions (if any) to address comorbid issues. • People with clinical levels of fear of cancer recurrence and associated anxiety are the intended target of this intervention specifically developed to target these issues. • As participation in this study will involve completing a questionnaire participants who have an intellectual or mental impairment may have difficulty reading and understanding the content of the questionnaires and/or interviews.
Aboriginal and/or Torres Strait Islander peoples	• Due to the location of study centres Aboriginal and/or Torres Strait Islander peoples are unlikely to be enrolled into the study. In the event that an Aboriginal and/or Torres Strait Islander would like to participate, consent will be sought with the customs and requirements of each community considered during the process. • Aboriginal and/or Torres Strait Islander peoples may be coincidently enrolled in this study. ATSI status is not being documented in this study and the researchers will be unaware if participants' are ASTI
People who may be involved in illegal activity	• The intervention will focus on the individuals' fear of cancer recurrence, and will not seek out any information on illegal activity. Where illegal activity is disclosed, the therapists or clinician involved will proceed according to professional standards and relevant local legislation.

Where there is more than one group of participants the information in this next section will need to be provided for each group.

Lay description of participation (Q6)

It is very important that this section is written carefully. Writing a lay description is not just a matter of simplifying the language but also using language that will communicate the ideas. The key points to include are the why the participant has been included (e.g. disease type), the purpose of the study, what is involved and how long their participation will be required. Examples:

> This study looks at the affect of a physical activity (PA) program on how people with lung cancers feel. Participants will receive either a lifestyle information booklet or an 8 week physical activity program. The program is tailored to an individual's fitness level; they will have a supervised physical activity session each week, and support to help overcome any barriers to exercising. We will also provide telephone support and a device known as a pedometer that measures the number of steps taken in a day. The information will be used to track progress but more importantly, will provide patients with immediate feedback and a way to reinforce progress. Everyone will be assessed at 0, 2, 4, and 6 months using questionnaires, lung function, blood, and fitness tests. For a week before each assessment everyone will wear a device that records how much they are moving. At the end of the study we will compare how patients in both groups feel and the effect that the program had on their health and well−being.

> Patients invited to participate in the study will be told about what they would need to do if they decide to be involved and they will be asked to provide written consent before to being randomly allocated to one of two treatment groups. Participants in the intervention arm will take the recommended dose of ginkgo; participants in the control arm will take the recommended dose of placebo (i.e. a substance that has no therapeutic effect used as for comparison). All participants will come to the hospital 5 times over a 12 month period to participate in a neuropsychological assessment (investigating the relationship between the nervous system/ brain, and mental functions such as language, memory, and perception). Each assessment will take about 90 minutes to complete, it includes doing some exercises with pencil and paper, completing some questionnaires about how they have been feeling and doing some exercises on computer. They will also have some blood tests each time, some of the blood tests are part of their standard care and others are specifically for the study. All participants will receive 6 monthly updates on the study progress. They will be contacted by the research assistant or research study co-ordinator to arrange a convenient time for their follow−up visits and to see how they are doing overall.

Specifying the nature of any existing relationships or ones likely to arise between the potential participants and research team (Q7)

Relationships may exist where the treating clinician is also a member of the research team. It should be clearly stated that potential participants should be clearly informed and the decision to participate in the study will not influence their relationship with any of the investigators or staff involved in their medical care. For example:

> Some potential participants may have a past or current relationship with a health care professional who is also an investigator. Potential participants will be clearly informed that their relationship with any of the investigators or staff involved in their medical care will not be influenced by their choice to participate (or not participate).

Steps taken to ensure that the research relationship does not impair voluntary consent and participation (Q8)

Indicate here that informed consent will include assurances that participation is voluntary and will not influence clinical care relationships. For example:

> Potential participants will be assured that the decision to participate is voluntary and will have no influence on their relationship with medical staff or the setting in which they receive the intervention, any members of the research team, or the organisations involved in the study.

Steps taken to ensure that decisions about participation in the research will not impair any existing or foreseeable future relationships (Q10)

Indicate that potential participants will be assured that participation is voluntary and will not influence current or future clinical care relationships. For example:

> Potential participants will be assured that the decision to participate is voluntary and that they can withdraw from the study at any time without any repercussions. Specifically, any decision at any time point (about participation) will not affect the current or future care of the patient nor the relationship with medical staff, therapists, research team, or the organisations involved. This will be clearly stated in the Participant Information Sheet and Consent Form.

The impact of the research on the relationship between participants and the researcher (Q11)

The answer to this question is usually 'No'. If this is not the case an explanation is required. For example,

> Some potential participants will be in a doctor-patient relationship with one or more of the researchers. However that researcher will only be involved in mentioning the study to the potential participant, who will be referred to the research assistant for a fuller explanation of the study and to gain informed consent. They will be assured that participation or not is entirely their decision and will not affect their relationship with any member of their health team in any way.

Male to female ratios (Q16)

The response to this section will depend on your sample, which ideally should reflect the distribution of the disease, issue or condition within the general community. Example responses are:

> It is expected that more women than men will be recruited into the study as anxiety and depression is more prevalent in women in the general population.

> Clinicians participating in the study will be equitably invited to participate regardless of gender. It is expected that the male to female ratio will reflect that existing in practice. There is no available information from which to base an estimation of this ratio.

> Prostate cancer is a malignancy of the male genital tract and therefore the sample will be male.

Advertisements of the study (Q17)

Attach any examples of planned advertising. This may include providing details of the text/ script used. For example:

> The research assistant will discuss the study with participants by telephone. The following script will be used:
>
> "Hello, I am <research assistant name> from <hospital>. <Dr name> suggested that I contact you about a research study, did <Dr name> mention the study when you last saw them?
>
> Is this is a convenient time to tell you a little more about what the study involves?
>
> Our study aims to find out if an <describe intervention> helps people, like you, with <disease type> to <outcomes>. The study involves doing <describe involvement – what and how often and the time commitment>."

If it became known that a person was recruited to, participated in, or was excluded from the research, would that knowledge expose the person to any disadvantage or risk (Q18)?

The answer to this question is usually 'No'. If this is not the case an explanation is required. For example, if a participant was 'known' as being involved in a study investigating the psychological impact of genetic testing for a breast cancer susceptibility mutation, it is possible that this information may negatively impact on the cost or coverage of their health insurance.

Seeking consent from participants (Q19)

Usually potential participants will have the capacity to give informed consent. Occasionally, investigations of vulnerable populations who do not have the capacity to give informed consent will be undertaken. These populations include children and young adults or those who are mentally incapacitated. Mechanisms to determine the participant's capacity to decide whether or not to participate include:

- The nature of the study population (e.g. children aged <14 years are likely to require guardian consent and children assent, those aged 14-15 are likely to require both guardian and child consent);
- Clinicians' judgement on the patients capacity to given informed consent;
- Informal assessment by the research team at the point of first contact (phone call) to confirm whether patients are eligible, explain the study in further detail, and answer any questions.

The NEAF asks for a description of the consent process for both those who have the capacity to provide it and those who do not. Key points to consider in your response are:

- How are potential participants identified?
- When and how potential participants will be screened for eligibility, and by whom?
- Who will be inviting the potential participants to the study and have they been trained?
- What information is provided and when will this be given?
- What obligations will potential participants and/ or their legal guardians be informed about?
- When will potential participants and/ or their legal guardians be advised that participation is voluntary and they can with draw at any point without impacting on their relationship with their care team?
- Who will obtain consent and in what form (verbal or written)?
- When will participant information be forwarded to the research team?
- Will the research team contact the participant and/ or their legal guardians and for what reason?
- If consent forms are not received by the research team, what are the planned actions?

The NEAF requests information about whether individual participants are identifiable by other members of their group and the consequent risks. A risk might be being embarrassed or ostracised (For example, participants recruited from their place of work such as doctors or other health professionals have the potential to be affected if their results were known to their employer).

Reiterate that participants will be advised that participation is voluntary and will not impact the participants' relationship with the research team, setting in which they work, or other services. Also reiterate that the decision to decline or withdraw from participating in the study will not affect their future care or their relationship with medical staff at the clinic/ hospital.

In the event that there are consequences to withdrawal, clearly state them. Example responses:

> As outlined previously, participation is entirely voluntary. Prior to entry into the study, prospective participants (both patients and therapists) will be informed of their ability to withdraw at any time, without giving a reason but the intervention and resources being tested in the study will no longer be available to withdrawn participants. The Patient Information Sheet clearly explains that withdrawal from the study will impact on the accessibility to the intervention which is only available at this time through the study.

Any payment to be made to participants must be described. The main consideration is that payment is not to be used as an incentive. Reimbursement for time spent by staff on a study or study-associated costs is acceptable where the payment is made to the department (not the individual). It is also acceptable for the reimbursement of costs accrued as a result of participation. For example:

The payments to the workplace will be the equivalent hourly rate for a senior psychologist employed within NSW Health Department (6 hours/patient @ $75.00/hour based on $62.23+20% as of 7/07/2010). Participating therapists will be reimbursed for travel expenses incurred attending the training workshop and their workplace will be reimbursed for the time spent treating patients on the study.

Example responses for why this payment will not impair the voluntary nature of the consent:

Reimbursed travel expenses will be those that are reasonably incurred, that is, a train or bus ticket from the participant's suburb of residence to the hospital and will be paid upon receipt of the ticket/ invoice. This payment is not disproportionate to the expense incurred and therefore should not influence the voluntary decision to consent.
Reimbursement for the time spent on the study will be made to the employer, not the individual therapists, at an equivalent rate to the hourly cost of a senior psychologist employed within NSW Health Department (6 hours/patient @ $75.00/hour based on $62.23+20% as of 7/07/2010).

It is also recommended that consent to use stored data for future research will be sought at this stage even if this is for an unspecified future study. For example:

Specific written consent has been sought from participants for their data to be stored and utilised for future research studies, with the understanding that consent for the specific project will be sought from participants at that future time.

SECTION 7 – PARTICIPANT SPECIFIC

The requirements of this section will vary depending on answers for previous questions. The questions listed below are a selection:

Question	Example response
Describe the dependent relationship between the participants and the researcher, members of the research team, and/or any person involved in the recruitment/consent process	Participants in this study will all be treated by a clinician for their diagnosis of thoracic cancer. Their clinician will introduce the study and the Research Assistant will contact potential participants to provide more information and obtain consent. The participant will not be in a dependent relationship with members of the research team or anyone involved in the consent process.
How will the process of obtaining consent enable persons in dependent relationships to give voluntary consent?	The Research Assistants are independent of the relationship between the participant and their treating clinician. They will discuss the study with patients, ensuring that patients understand the decision to participate is their own.
Will there be any specific risks to participants in this research project as a result of the dependent relationship?	No
If a participant chooses to withdraw from the research, how will the ongoing dependant relationship with the participant be maintained?	If the participant chooses to withdraw from research, their ongoing medical care will continue uninterrupted by the treatment team. The treatment team will only be informed of the patient's withdrawal from the study if it is likely to require a change in their ongoing management.

SECTION 8 – CONFIDENTIALITY/ PRIVACY

Privacy guidelines (Q1)

For this question the source and type of information being collected needs to be described. Select one of the following types of information and justify why this has been chosen:

Type of information	*Definition*	*Example responses*
Individually identifiable	Data that allow the identification of a specific individual. Examples of identifiers may include the individual's name, image, date of birth or address, Medicare number, etc.	Data linkage will be used in this study. Linkage of Cancer Registry data, Medicare data and hospital records data requires participant identifying information. Following linkage, identifying data will be stored separately from the study database. Participants will be asked to provide written consent to the collection of their identifying data.
Re-identifiable	Data that may have had identifiers removed and replaced by a code. It is possible to use the code to re-identify the person to whom the data relate (de-identification is reversible).	All research documentation will be labelled with a unique person number as an identifier and stripped of any potentially identifiable information. This data needs to be re-identifiable in order to link with follow-up data and medical information accessed from cancer registries. The intervention is conducted in the clinical setting, and clinicians will record and store data according to standard professional guidelines and confidentiality practices.
Non-identifiable	Data where the identifiers have been removed permanently, or may never have identifiable information (anonymous information). Also can be called: de-identified.	No identifiable data is necessary for this study of oncology social work practice and involves completing a one-time (cross-sectional) survey. Consent is assumed by completion of the online survey.

The way information collected about participants will be used (Q2).

The NEAF asks for a description of the way in which collected data is used. For example:

> Participants' responses on written questionnaires will be numerically coded and analysed as group data. Telephone interviews will be audio–taped, transcribed and coded for themes using a grounded theory approach.

Will the information used by the research team be in identified or re-identifiable form (Q3)?

The answer to this question is usually 'Yes' for longitudinal studies. This will require the selection of one out of four options for the use of data. It is recommended the response that allows for the data to be "used for another purpose for which ethical approval will be sought" be selected. This is a good opportunity to check for specific data requirements the study sponsors and/or collaborators, or other organisations (including PoCoG) may have for the data, including reporting, establishing databases/ registers or the third party use.

Personnel with access to the data (Q4).

List the investigators and research staff specifically working on this study and describe the type of information and nature of use or access. (For studies administered by PoCoG, the Research Program Manager and Executive Director should be listed as having access to data). An example response:

> Access to the data will be provided to:
> - The Investigators named in this application - to monitor process of the study and for analysis purposes.

- The Executive Director (Dr Melanie Price) and Research Program Manager (Dr Michelle Peate) of the Psycho-Oncology Cooperative Research Group (PoCoG) - for monitoring of the study and auditing of data.
- The study co-ordinators (Gene Kelly and Fred Astaire) - monitoring of participation status and administrative purposes such as mail out of questionnaires and data entry.
- Research Assistants - data entry of de-identified data.

Format of stored of information (Q5).
The format of the information collected will determine the appropriate form of secure storage, thus describing the format of information will enable the HREC to understand how the information can be secured. For example:

During the research project, information collected will be stored in paper form (paper questionnaires), computer files (e.g. web–based questionnaires stored on a computer server in databases) and computerised audio files (of interviews conducted in qualitative phase of the study, and study sessions for treatment fidelity and adherence checks).

Security of stored information from misuse, loss or unauthorised access (Q6).
It is important that information is stored appropriately and securely. Generally information can be securely stored using the mechanisms described below:

- paper documents – stored in locked filing cabinets in locked offices
- electronic data – on secure password-protected computer network systems with regular backups

Example response for this question:

Safeguards will be in place to protect confidentiality and anonymity of study participants. Only the study CIs, AIs, study staff and PoCoG Executive Director and Research Project Manager will have access to completed questionnaire data and other research documents. Any written documents will use ID numbers and computer databases will be password protected. Principles of confidentiality in the therapist-patient relationship stand for all participants in the study throughout the intervention.

All material will be kept in a locked filing cabinet, in a locked office, in a secure University building. All electronic data will be stored on a computer network system maintained at the Psycho-Oncology Cooperative Research Group, School of Psychology, the University of Sydney. The system is secured by user names and passwords and protected from external access via a firewall, which is administered by the University of Sydney. Each computer 'locks' after a nonoperational period of 15 minutes to ensure security of information stored. User passwords are changed regularly.

An example when using data management software:

A REDCap (Research Electronic Data Capture) database will be used to enable secure and confidential collection, storage and maintenance of the research data for this study. REDCap is a secure, web-based application designed exclusively to support data capture for research studies and is secured according to The University of Sydney's security protocols which conform to electronic data standards. It provides: 1) an intuitive interface for data entry (with data validation); 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages (SPSS, SAS, Stata, R); and 4) procedures for importing data from external sources.

The REDCap application was chosen as it enables multisite users to contribute via the internet to a secure database and allows the PoCoG-based study co-ordinator to overseeing all data entries. This online method of collection data can ensure the confidentiality of research data by eliminating the need for the transmission of data from sites to PoCoG by other methods (e.g., post or fax). Access to a REDCap database is restricted and password protected. The study co-ordinator will assign different

> levels of access to the REDCap database to ensure confidentiality of all sources of data. The study co-ordinator will have full access to all data using independent password codes. Site investigators and site staff will have access to their site specific data only, enabling local data entry and reporting specific to their site. The independent access codes for the different parts of the REDCap database ensure that individuals involved in the research project only have access to the data they have consent to access. Participants will only have access to enter their own data, and not to view any other data. This process ensures confidentiality and secure storage of all the research data.

How will information be stored at the completion of the project (Q9)?
In response to this question, indicate how the data will be archived and whether the information will be stored in individually identifiable, re-identifiable, or non-identifiable format at the completion of the project.

Length of time that the information will be stored at the completion of the project (Q10)?
Refer to the Data Management SOP, NHMRC requirements, and national legislation for more information about storing data after the study is completed. For example:

> All materials will be kept for at least 15 years from the publication of results, as per national requirements, and then disposed of by secure destruction methods such as shredding of paper data and erasure of computer–generated data.

What are the arrangements for the storage of information should the principal investigator ceases to work at the current organisation (Q11).
To address this item refer to your organisational policy as each institution is likely to have recommendations. For example, the data from PoCoG administered studies will remain with PoCoG:

> Storage of the information collected for, used in, or generated by this project will remain the property of the Psycho-Oncology Cooperative Research Group (PoCoG), The University of Sydney, and as such will remain secured on the premises.

Ownership of information (Q13).
To address this item refer to organisational policy, funding agreement and any research agreements for the study. For example:

> The Chief Investigators jointly own the information resulting from the research along with the Psycho-Oncology Cooperative Research Group (PoCoG), The University of Sydney.

Limitations on the dissemination of results (Q14).
To address this item refer to your organisational policy. The University of Sydney usually recommends that there should be **NO** rights to impose limitations or conditions on the publication of results. However, in some cases there may be intellectual property rights to consider in regards to the timing of publications. In such cases, where limitations may be required, discussion with the University's research office and/ or legal department is advised.

Disposal of information (Q15).
It is likely that an institution or organisation will have a policy relating to information disposal. There are also requirements set out by funding bodies and national guidelines. The Australian Code for the Responsible Conduct of Research states that generally the minimum recommended period for retention of information is five years from the date of publication. However, there are particular cases which different time spans are to be considered. These include:

- Short-term research for assessment purposes only may only require a retention period of 12 months after the completion of the project.
- Most clinical trials and medical research studies should retain information for at least 15 years after publication of results.
- Studies that involve psychological testing or interventions with children should be kept for 25 years after the birth of participants.
- Some data may be considered for permanent retention in special circumstances; such as gene therapy research or work that has community or heritage value.

The University of Sydney and Local Area health Services recommends retaining information for a minimum seven years after the publication of results for non-pharmacological studies.

A plan for the destruction of research data is an important part of research data management. Destruction must be carried out securely using an irreversible method that renders the data unreadable. There are two types of information to consider:

- Digital information may be destroyed by digital file shredding, erasure via degaussing (i.e. using a magnetic field), physical destruction of storage media, or reformatting (only if guaranteed to be non-reversible). Deleting digital data does NOT mean that it is destroyed. All back-ups are to also be destroyed.
- Non-digital information may be destroyed by shredding, pulping, burning, chemical recycling (microform or x-ray), or dissolving in acid (video or audio tapes)

An example response:

> Yes, data will be destroyed.
>
> *At what stage will the information be disposed?*
> The data may be destroyed fifteen years after the completion of the study.
>
> *How will information, in all forms, be disposed?*
> All information collected for, used in, or generated by this project will be disposed by secure destruction methods. Non-digital information (e.g. paper files) will be shredded and digital information (computer files) will be deleted through a process of repeated over-writing of the documents and deletion from the server, ensuring that the contents cannot be recovered. Back-up tapes are periodically kept for two years, according to University policy and then are rewritten.

Reporting results to participants. (Q16).

The specifics whether the results will be reported to participants and the form in which this will be done are to be described. This is often in the form of a study newsletter and/ or summary. For example:

> At the completion of the study interested participants will be sent a lay summary of the results, and future directions of the research via a newsletter. This report will contain aggregated data which will not identify individual participants and their responses.
>
> *How will the results be communicated to participants?*
> The newsletter will be mailed or emailed by the research team to the participants who indicated their interest in receiving a copy of the results at the time of providing informed consent.
>
> *Who will be responsible for communicating the project results to participants?*
> The research team will be responsible for communicating the project results to participants.

Is the research likely to produce information of personal significance to individual participants (Q17)?

The answer to this question is usually 'No'. If this is not the case an explanation is required. For example, in a study where genetic testing is involved, the patient might be told that any genetic findings of possible significant to them will be disclosed confidentially through a letter.

Will individual participant's results be recorded with their personal records (Q18)?

The answer to this question is usually 'No' unless the results will impact on future care.

Is it intended that results that relate to a specific participant be reported to anyone other than that participant (Q19)?

The answer to this question is usually 'No'. It should be noted that in some cases, it is possible that information arising from this study may be of clinical importance and be communicated to the treating clinician. For example, in a situation where a participant's welfare or life may be at risk (e.g. from self-harm) the treating clinician is to be notified. For studies where results are reported to anyone other than the participant details should be provided.

Is the research likely to reveal a significant risk to the health or well being of persons other than the participant (Q20)?
This question refers to anyone who may be involved with the study (e.g. research staff and investigators) or the participant (e.g. family and friends). The answer to this question should always be 'No'.

Dissemination of results (Q21-23)?
If there is a risk that the dissemination of results could cause harm of any kind to individual participants in any way (Q21), describe the potential harm that may result (physical, psychological, spiritual, emotional, social or financial wellbeing, or to their employability or professional relationships or to their communities) and why it cannot be avoided and/ or is necessary**.**

Describe the plans to disseminate the results of the research (Q22).
For example:

> Manuscripts will be submitted to peer-reviewed scientific journals and conference presentations will be prepared for both national and international conferences.

Describe how the confidentiality of participants and their data is to be protected in the dissemination of research results (Q23).
For example:

> All study results will be reported in aggregate form, no individual participants will be identified.

SECTION 9 – PROJECT SPECIFIC

This section represents additional study-specific information. Below are some example issues that may arise from previous responses in the application.

Issue	*Example response*
Method of randomisation	The study is a parallel randomised controlled trial, with equal numbers of participants randomised to the intervention and control arm. Randomisation will be performed by a statistician blinded to the identity of participants, using computer-generated random numbers
Whether the hypothesis offers a realistic possibility that the intervention is at least as effective as standard treatment	Given the lack of any evidence-based standard treatment for disease X, the strong theoretical foundation of the intervention and the promising pilot data we believe that it is highly likely that the intervention will be more effective than current standard practice.
The justification for the use of placebo or non-treatment control group, including alternative effective treatments and any risk of harm in the absence of treatment	There is currently no evidence-based standard treatment for disease X, which is why we have used an intervention Y control group. Use of a nonspecific treatment control group which controls for attention effects and overcomes care variations across centres, is now considered gold standard and superior to 'no treatment' controls, which are considered unreliable.
How variations in response will be treated	Participants who develop any psychological co-morbidities during intervention delivery and follow-up will be managed according to the severity of their symptoms. In cases of mild psychological comorbidities the therapists will continue the intervention as per protocol and provide treatment for comorbidities once final study assessment has been completed at 6 months. In cases of moderate psychological

	comorbidities the therapist will continue the intervention as per protocol and provide treatment for comorbidities once intervention has been completed, while noting the delivery of additional psychological treatment during the assessment period. In cases of severe psychological comorbidities the therapist will interrupt the intervention to provide treatment for severe co-morbidities and then continue the intervention and assessments once these issues have been resolved while noting the deviation from the intervention protocol. In cases where participants display significant psychological comorbidity before the intervention, the participant will be contacted by the research team and asked if they would like this issue followed up with the therapist. If a participant returns a questionnaire after the intervention completion with scores on the DASS21 indicating significant psychological comorbidity, the participant will be contacted by the research team and asked if they would like to discuss this further with their therapist from the intervention. Should the participant desire further consultation with their therapist, the research team will pass on the participant details to the therapist for follow-up. Scores above 21 on the depression scale, 15 on the anxiety subscale or 26 on the stress scale of the DASS21, will be followed up. Any untoward occurrence in study participants (e.g. unfavourable and unintended signs, symptoms temporally associated with the use of an intervention, whether or not related to the intervention) will be considered an adverse event (AE). Any AEs that occur after informed consent is signed will be recorded on the AE Case Report Form (CRF). The relevant ethics committee will be notified of any adverse events.
Endpoints	The study will close once the recruitment target is reached. There are no safety endpoints, nor criteria for early study termination, nor planned interim analyses.
Details of contingencies and management of these	The contingencies in place for managing psychological comorbidities experienced by study participants are outlined above and are detailed in the full study protocol. While the intervention and/or assessment schedule may be modified, we do not expect that patients will be withdrawn by the research team or clinican. If patients require referral to other practitioners for complementary care or unrelated morbidity, details will be recorded. Patients who withdraw from the study will be asked if they would consent to continue completing follow-up measures and for any of their existing data to be included in analysis. If consent is not given any electronic or paper records pertaining to their involvement will be erased and destroyed.
Explain the arrangements in place to ensure there is adequate compensation for participants.	Although the risk of requiring compensation in this study is low, all parties involved in this research will have be covered by appropriate and reasonably available insurance necessary to provide indemnity for any liability as a result of the study.
Use of tissue sample(s) and mechanisms to store, manage and destroy tissue.	The samples will be retained to enable assessment of future molecular markers and tests that may shed light on the mechanisms of cancer and other illnesses as they emerge. The samples will be stored at the research laboratory at the hospital of origin until being sent to central storage facility where they will be stored until used or for the

	long–term. Investigators will have access to the samples in the future. All patients will be asked to consent to use of their tissue in future research; and appropriate ethical approvals will be obtained by the laboratory team for future research. The collection of samples and clinical data will be carried out according to the study protocol. A password protected study specific database including coded clinical data and sample information (location, type of sample, date of collection, use of sample) will be retained by the study investigators. Samples will be stored long–term in a laboratory freezer with required alarms to prevent thawing in the event of a break down. Access logs will be stored in the lab. All access to the samples will have to be approved by the study investigators; they will retain details of any studies, investigators, and copies of ethics approvals of these studies, a list of the samples provided and the clinical data to match.

SECTION 10 - SIGNATURES

The PI signatures from all sites are required (AIs only need to sign SSA Forms)
Only the signature from the Head of Department from the coordinating site (which is also the site of the lead PI) is required. Heads of Department from sites will need to sign the SSA Form.
Please note: Where a researcher is also the Head of Department, the researcher cannot sign as the Head of Department. Their line manager must sign as the "Head of Department" in both the NEAF and the SSA Form.