

Locality Assessment by Locality Organisation

Refer to pages 13–15 of Guidelines for Completion of the National Application Form for Ethical Approval of a Research Project (NAFG-2009-v1).

Locality organisation sign off

Ethics committees review whether investigators have ensured their studies would meet established ethical standards if conducted at appropriate localities. Each locality organisation is asked to use the locality assessment form to check that the investigator has also made the appropriate local study arrangements.

Ethics approval for study conduct at each site is conditional on favourable locality assessment at that locality.

Please note that the locality organisation may have additional requirements to be met before a study may commence at that locality.

Part One: General

To be completed by the principal investigator for this locality.

Full project title:	Male cancer patients/survivors who need - but are not accessing – psycho-oncological services: Action research to identify sources of distress and develop intervention.
Short project title:	Action research to address the distress of men with cancer
Locality to be assessed:	MidCentral DHB*****or whichever*****

Brief
outline of
study:

Men can be reluctant to seek help for medical or psychological issues. Consequently they suffer worse cancer outcomes, are more socially isolated in dealing with their cancer-related distress, and more vulnerable to depression, alcohol and substance abuse ('self medication'), and suicide. Disadvantaged minorities suffer even more.

This research recognises that psycho-social interventions can be powerfully effective for men (2-3 times as for women) but that men can be difficult to engage in current services. We want to work towards developing a service attractive to men, which can be used by the Cancer Society. We also want to gather information relevant to producing health promotion strategies aimed at earlier diagnosis. The project involves several stages, and closely involves men with cancer in order to ensure that the end product is particularly male-friendly. Our sampling strategy targets men who live in lower SES and more rural areas of the country, because these are the men who suffer most and have most to gain from services.

The first stage of this research involves interviewing male cancer patients regarding their experience of (1) how they came to be diagnosed, (2) how they made treatment decisions, (3) what cancer-related stresses they suffered, and (4) whether they used any services to help with that stress. Interview data will be analysed by postgraduate psychology research students from Massey University.

Ethical approval is being sought from the Health and Disability Ethics Committee, and will be produced to your organisation in due course.

WHAT WE ARE ASKING OF THE LOCALITY

We need to recruit 40 participants living in the Levin-Foxton-Otaki and Whanganui-south Taranaki areas through health workers with the Palmerston North Regional Cancer Treatment Service (MidCentral Health)(medical and radio oncologists, Maori cancer co-ordinators, specialist cancer nurses e.g. colorectal and urology nurses), Central Districts division of the Cancer Society (support workers), and PHO nurses (Central, and Wanganui Regional, Te Tihi Hauora o Taranaki PHOs)

Health workers will be requested to review their case lists for patients who meet our criteria and pass an information sheet to them during a normal appointment, preferably with a brief word of recommendation. No further action is required of the health worker. Men who are interested can contact the researcher who will explain the study further and obtain written informed consent.

BENEFITS AND RISKS TO PATIENTS

There are no physical risks associated with this research.

Interviews. Talking about cancer can be distressing to some patients. It can also be valuable in helping participants process their experience and emotions, as it helps them order their thoughts and experience their feelings thereby working through them a little further. However, the topics to be covered in the interview are made clear in the information sheet so that potential participants can decline to become involved. Also, we can take our time in the interview and will not push to discuss anything that a participant is not comfortable discussing. Participants will also be advised that they can stop the interview at any time, and also withdraw permission for use of the recording at any time up until it is transcribed. That said, it is our experience that in fact many interview participants find telling their story to a keenly interested researcher an enjoyable experience, and it is also important to many that by being interviewed they are able to make a positive contribution.

Team discussions. Psychological effects should be overwhelmingly positive. The opportunity to work in a team on a constructive project in which the participants are considered expert by virtue of their experience of life and cancer is expected to be meaningful and valuable.

Psychological backup. In the event that any participant does experience such distress that he would like the assistance of professional services, we have an agreement with the Psycho-Oncology Service (POS) run by Massey University/MidCentral DHB to provide services for participants from the Horowhenua/Otaki participants, and with the counselling services of the Cancer Society to provide services for participants from Whanganui/South Taranaki. These services will be provided free of charge, and researcher Heather Heron-Speirs will remind participants of their availability if any elevated distress is observed.

Principal investigator (for this locality):

There is no 'investigator' as such for this 'locality'.

The principal investigator for the study is Dr Christine Stephens,
Associate Professor, School of Psychology, Massey University,
Palmerston North

The investigator who will be actively undertaking this research is Ms
Heather Heron-Speirs, PhD student

Contact details:

Dr Christine Stephens, Associate Professor, School of
Psychology, Massey University, Private Bag 11 222, Palmerston North,
Phone (06) 350 5799 ext.2081, C.V.Stephens@massey.ac.nz

Ms Heather Heron-Speirs, 756 Foxton Road, RD 12, Levin 5572, Phone
(06) 368 0471, haheeron@clear.net.nz

Part Two: Locality Issues

To be completed by the principal investigator for this locality and signed by the authorised locality representative. (See the Guidelines (NAFG-2009-v1) (pages 13–15) for more information and examples.) Identify any local issues and specify how these issues will be addressed.

1. Suitability of local researcher

For example, are all roles for the investigator(s) at the local site appropriate (for example, has any conflict the investigator might have between her or his local roles in research and in patient care been adequately resolved)?

☒ Yes ☐ No

2. Suitability of the local research environment

a) Are all the resources (other than funding that is conditional on ethical approval) and/or facilities that the study requires appropriate and available (for example, is staffing adequate? Is this site accessible for mobility-impaired people where necessary)?

☒ Yes ☐ No

b) Have all potentially affected managers of resources such as patient records or laboratory managers been notified?

☐ Yes ☐ No

3. Have issues such as cultural issues specific to this locality or to people being recruited at this locality been addressed?

☐ Yes ☐ No

4. Have the local investigator contact details and other important contact details been provided to the locality organisation for checking?

☐ Yes ☐ No

Part Three: Declaration by locality organisation

I am authorised to complete locality approval on behalf of this locality organisation. I understand that I may withdraw locality approval if any significant local concerns arise. I agree to advise the principal investigator and then the relevant ethics committee should this occur.

(Questions 1–4 at Part Two above must be completed prior to signing.)

I confirm the organisation has sufficient indemnity insurance to compensate participants for harm that does not qualify for compensation under the Injury Prevention, Rehabilitation and Compensation Act 2001.

Signature:

Date:

Name:

Position:

Contact details: