Appendix 5.1: Approval Certificate from the Sydney West Area Health Service Human Research Ethics Committee

SYDNEY WEST AREA HEALTH SERVICE | NSW HEALTH

HUMAN RESEARCH ETHICS COMMITTEE (Westmead Campus)
Research Office, Room 2020 Clinical Sciences
Westmead Hospital, Hawkesbury Road, Westmead NSW 2145

Telephone: 02 9845 8183
Facsimile: 02 9845 8352
Email: researchoffice@wmi.usyd.edu.au

Our Ref: ***HREC2009/3/4.5(2938) AU RED HREC09/WMEAD/32***

18 June 2009

Laureate Prof Rob Sanson-Fisher
School of Medicine & Public Health
Room 267 David Maddison Building
University of Newcastle
Callaghan NSW 2308

Dear Professor Sanson-Fisher

Project title: 'Development and psychometric evaluation of two measures of perceived need: one for young people with cancer; one for carers'

Thank you for your letter dated 28 May 2009 addressing the matters raised in the HREC's letter dated 9 April 2009 following single ethical review of the above project at its meeting held on 31 March 2009.

This HREC has been accredited by the NSW Department of Health as a lead HREC to provide the single ethical and scientific review of proposals to conduct research within the NSW public health system. This lead HREC is constituted and operates in accordance with the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research* and the *CPMP/ICH Note for Guidance on Good Clinical Practice.*

I am pleased to advise that the HREC has now granted ethical approval of this multicentre site research project to be conducted at:

- Westmead Hospital - Chief Investigator Professor Rob Sanson-Fisher, University of Newcastle (A/Prof Ian Kerridge, Westmead Hospital Principal Researcher / clinician)
- Royal North Shore Hospital – Chief Investigator Dr William Stevenson

The following documentation has been reviewed and approved by the HREC:

- Detailed Research Protocol
- First Letter of Invitation from Hospitals - Master Version 1 dated 2 March 2009
- Reminder Letter from Hospital – Master Version dated 2 March 2009
- Participant Information and Consent Form – Master Version 1 dated 2 March 2009
- Cancer Needs Survey for Young People – Version 1 dated 28 May 2009
- Cancer Needs Survey Parents and Carers - Version 1 dated 28 May 2009

Please note the following conditions of approval:

- The coordinating investigator will immediately report anything which might warrant review of ethical approval of the project in the specified format, including unforeseen events that might affect continued ethical acceptability of the project.
- Proposed amendments to the research protocol or conduct of the research which may affect the ethical acceptability of the project, are provided to the HREC to review in the specific format. A copy of all proposed changes is also provided to the relevant research governance officer.
- The HREC must be notified, giving reasons, if the project is discontinued at a site before the expected date of completion.
- The coordinating investigator must provide an annual report to the HREC and a final report at completion of the study, in the specified format. HREC approval is valid for 12 months from the date of final approval and continuation of the HREC approval beyond the initial 12 month approval period is contingent upon submission of an annual report each year. A copy of the Annual / Final Research Report Form is attached and can be obtained electronically from the Research Office on request.
- It should be noted that compliance with the ethical guidelines is entirely the responsibility of the researcher.

You are reminded that this letter constitutes *ethical approval only*. You must not commence this research project at a site until separate authorisation from the Chief Executive or delegate of that site has been obtained. A copy of this letter and the approved Master Participant Information and Consent Forms, Letters of Invitation and Survey must be forwarded to all site investigators for submission to the relevant Research Governance Officer.

A summary of the HREC Standard Operating Procedures is attached for your reference. Should you have any queries about the HREC's Terms of Reference, Standard Operating Procedures or membership, please contact the HREC Executive Officer through the Research Office on 9845 8183 or emailing researchoffice@wmi.usyd.edu.au.

In all future correspondence concerning this study, please quote your approval number ***HREC2009/3/4.5(2938) AU RED HREC09/WMEAD/32.***

The HREC wishes you every success in your research.

Yours sincerely

Ms Tina Goodenough
HREC Executive Officer
SWAHS Human Research Ethics Committee (Westmead Campus)

Appendix 5.2: Approval Certificate from The Alfred Hospital Human Research Ethics Committee

TheAlfred

ETHICS COMMITTEE CERTIFICATE OF APPROVAL

This is to certify that

Project No: 84/09

Project Title: Development and psychometric evaluation of two measures of perceived need: one for young people with cancer; one for carers.

Principal Researcher: Professor Rob Sanson-Fisher

Detailed Research Plan: 84/09

Participant Information and Consent Form version 2 **dated:** 13-Mar-2009

was considered by the Ethics Committee on ***26-Mar-2009*** *and* ***APPROVED*** *on* **02-Apr-2009**

It is the Principal Researcher's responsibility to ensure that all researchers associated with this project are aware of the conditions of approval and which documents have been approved.

The Principal Researcher is required to notify the Secretary of the Ethics Committee, via amendment or progress report, of

- Any significant change to the project and the reason for that change, including an indication of ethical implications (if any);
- Serious adverse effects on participants and the action taken to address those effects;
- Any other unforeseen events or unexpected developments that merit notification;
- The inability of the Principal Researcher to continue in that role, or any other change in research personnel involved in the project;
- Any expiry of the insurance coverage provided with respect to sponsored clinical trials and proof of re-insurance;
- A delay of more than 12 months in the commencement of the project; and,
- Termination or closure of the project.

Additionally, the Principal Researcher is required to submit

- A Progress Report on the anniversary of approval and on completion of the project *(forms to be provided)*;

The Ethics Committee may conduct an audit at any time.

All research subject to the Alfred Hospital Ethics Committee review must be conducted in accordance with the National Statement on Ethical Conduct in Human Research (2007).

The Alfred Hospital Ethics Committee is a properly constituted Human Research Ethics Committee in accordance with the National Statement on Ethical Conduct in Human Research (2007).

SPECIAL CONDITIONS

None

SIGNED: _____
Chair, Ethics Committee (or delegate)

Please quote Project No and Title in all correspondence

R. FREW
SECRETARY
ETHICS COMMITTEE

Appendix 5.3: Approval Certificate from the Peter MacCallum Cancer Centre Human Research Ethics Committee

ETHICS COMMITTEE CERTIFICATE OF APPROVAL

This is to certify that

Project No:09/08

Project Title: Development and psychometric evaluation of two measures of perceived need: one for young people with cancer; one for carers.

Principal Researcher: Ms K Thompson

has been considered by the Ethics Committee and is ***APPROVED.***

Approval date: 27th July 2009 **Expiry date: 27th July 2014**

It is the Principal Researcher's responsibility to ensure that all researchers associated with this project are aware of the conditions of approval and which documents have been approved.

The Principal Researcher is required to notify the Secretary of the Ethics Committee, via amendment or progress report, of

- Any significant change to the project and the reason for that change, including an indication of ethical implications (if any);
- Serious adverse effects on participants and the action taken to address those effects;
- Any other unforseen events or unexpected developments that merit notification;
- Any change in Principal Researcher;
- Any expiry of the insurance coverage provided with respect to sponsored clinical trials and proof of re-insurance;
- A delay of more than 12 months in the commencement of the project; and,
- Termination or closure of the project.

Additionally, the Principal Researcher is required to submit

- Evidence of the registration of the project with an approved clinical trials registry prior to enrolment of the first participant to the trial *(applicable only to clinical trials)*;
- An Annual Report every 12 months for the duration of the project *(forms to be provided)*;
- A Request for Extension of the project prior to the expiry date, if applicable; and,
- A detailed Final Report at the conclusion of the project.

The Ethics Committee may conduct an audit at any time.

All research subject to Peter MacCallum Cancer Centre Ethics Committee review must be conducted in accordance with the National Statement on Ethical Conduct in Human Research (2007).

SPECIAL CONDITIONS

SIGNED: _____ **DATE:** _____
Jeremy Kenner (Ethics Coordinator)

Please quote Project No and Title in all correspondence

Appendix 5.4: Approval Certificate from the Princess Alexandra Hospital Human Research Ethics Committee

Princess Alexandra Hospital
Health Service District

Queensland Government

Queensland **Health**

Office of the Human Research Ethics Committee

Enquiries to: Ethics Manager
Phone: (07) 3240 7672
Fax: (07) 3240 7667
Our Ref: 2009/084
E-mail PAH_Ethics_Research@health.qld.gov.au
Date 12 May 2009

A/Prof Paula Marlton
Department of Haematology
Princess Alexandra Hospital
Woolloongabba 4102

APPROVAL LETTER – PRINCESS ALEXANDRA HOSPITAL

Dear A/Prof Marlton

Research Protocol: 2009/084

Development and psychometric evaluation of two measures of perceived need: one for young people with cancer; one for carers	
NEAF:	**Version 2.0, dated 20 March 2009**
Participant Information and Consent Form: **Research Project Information Sheet:**	**Version 1, dated 20 March 2009** **Version 1 dated 19 March 2009**
Detailed Research Plan	
Questionnaire: **Cancer Needs Survey – Young People** **Cancer Needs Survey – Parents and Carers**	

At a meeting of the Princess Alexandra Hospital Human Research Ethics Committee (PAH HREC) held on 7/04/2009, the Committee reviewed the above research Protocol. The Princess Alexandra Hospital Human Research Ethics Committee is duly constituted, operates in accordance and complies with the current National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research 2007*.

On the recommendation of the Human Research Ethics Committee approval is granted for your project to proceed. This approval is subject to researcher(s) compliance throughout the duration of the research with certain requirements as outlined in the *National Statement on Ethical Conduct in Human Research 2007 and Australian Research Code for the Responsible Conduct of Research.*

The following links have been provided for your convenience:
http://www.nhmrc.gov.au/publications/synopses/_files/e72.pdf
http://www.nhmrc.gov.au/publications/synopses/_files/r39.pdf

Some requirements are briefly outlined below. Please ensure that you communicate with the PAH HREC on the following:

- ***Protocol Changes:*** Substantial changes made to the protocol require HREC approval.

- ***Problems and SAEs:*** The HREC must be informed of any problems that arise during the course of the study which may have ethical implications. Serious adverse events must be notified to the HREC as soon as possible.
- ***Lapsed Approval***: If the study has not commenced within twelve months approval will lapse requiring resubmission of the study to the HREC.
- ***Annual Reviews:*** All studies are required by the NHMRC to be reviewed annually. To assist with reporting obligations an Annual Report template is available on the PAH HREC website. This form is required to be completed and returned to the HREC within the 12 month reviewing period.

As this research involves the recruitment of patients from the Princess Alexandra Hospital Health Service District (PAHHSD), it is my responsibility to remind you of your ongoing duty of care for all people recruited into projects or clinical trials whilst public patients. All conditions and requirements regarding confidentiality of public information and patient privacy apply. You are required to comply at all times with any application requirements of Australian Law including the Health Services Act, the Privacy Act and other relevant legislation, ethics obligations and guidelines which may be applicable to the PAHHSD from time to time including, without limitation, any requirement in respect of the maintenance, preservation or destruction of patient records.

When the study involves patient contact, it is your responsibility as the principal investigator to notify the relevant consultant and request their approval.

Should you have any problems, please liaise directly with the Chair of the HREC early in the program.

A copy of this letter should be presented when required as official confirmation of the approval of the Princess Alexandra Hospital Human Research Ethics Committee.

We wish you every success in undertaking this research.

Yours sincerely

Dr David Theile Snr
DISTRICT CHIEF EXECUTIVE OFFICER
METRO SOUTH DISTRICT

Office	Postal	Phone	Fax
Princess Alexandra Hospital Health Service District	Ipswich Road Woolloongabba Q 4102	61 7 3240 7672	61 7 3240 7667

Appendix 5.5: Approval Certificate from the Royal Adelaide Hospital Human Research Ethics Committee

Government of South Australia
SA Health

Royal Adelaide Hospital
North Terrace
Adelaide SA 5000
Tel +61 8 8222 4000
Fax +61 8 8222 5939
ABN 80 230 154 545
www.health.sa.gov.au

Research Ethics Committee
Level 3, Hanson Institute
Tel (08) 8222 4139
Fax (08) 8222 3035
Email:
Heather.O'Dea@health.sa.gov.au

10 June 2009.

Dr Michael Osborn
Haematology Senior Registrar
Division of Haematology
IMVS / SA PATHOLOGY

Dear Dr Osborn,

Re: "Development and psychometric evaluation of two measures of perceived need: one for young people with cancer; one for carers."
Research Plan, Version 1 (26 May 2009).
Participant Information Sheet & Consent Form, Version 1 (26 May 2009).

RAH PROTOCOL NO: 090604.

I am pleased to advise that Research Ethics Committee EXPEDITED APPROVAL has been given to the above project. Please quote the RAH Protocol Number allocated to your study on all future correspondence.

The following documents have also been reviewed and approved:

- **Invitation letter to participants, Version 2 (10 June 2009)**
- **Reminder Invitation letter to participants, Version 2 (10 June 2009)**
- **Sample email to patient's treating clinician, Version 1 (26 May 2009)**

The REC acknowledges receipt of the following documents which have been reviewed:

- **Cancer needs survey – Parents and Carers**
- **Cancer needs survey – Young People**
- **Test-Retest Letter from Research Team**
- **NEAF Application**

Research Ethics Committee deliberations are guided by the NHMRC National Statement on Ethical Conduct in Human Research 2007.

The general conditions of approval follow:

- For all clinical trials, the study must be registered in a publicly accessible trials registry prior to enrolment of the first participant.
- Adequate record-keeping is important. If the project involves signed consent, you should retain the completed consent forms which relate to this project and a list of all those participating in the project, to enable contact with them in the future if necessary. The duration of record retention for all clinical research data is 15 years.
- You must notify the Research Ethics Committee of any events which might warrant review of the approval or which warrant new information being presented to research participants, including:
  (a) serious or unexpected adverse events which warrant protocol change or notification to research participants,
  (b) changes to the protocol,
  (c) premature termination of the study,
  (d) a study completion report within 3 months of the project completion.
- The Committee must be notified within 72 hours of any serious adverse event occurring at this site.
- Approval is ongoing, subject to satisfactory annual review. Investigators are responsible for providing an annual review to the RAH REC Executive Officer each year using the Annual Review Form available at: http://www.rah.sa.gov.au/rec/index.php

Yours sincerely,

Dr A Thornton
CHAIRMAN
RESEARCH ETHICS COMMITTEE

Appendix 5.6: Approval Certificate from the Royal Perth Hospital Human Research Ethics Committee

Department of Health
Government of Western Australia
South Metropolitan Area Health Service

Royal Perth Hospital

ETHICS COMMITTEE

Prof F M van Bockxmeer PhD MHGSA, ARCPA, FAHA
PathWest Laboratory Medicine
Tel: 9224 2322 Fax: 9224 2491
Email Frank.VB@health.wa.gov.au

Room 5105, Colonial House
Tel: 9224 2292

Ref: EC 2009/094
(This number must be quoted on all correspondence)

5th November 2009

Dr Julian Cooney
Haematology Department
Royal Perth Hospital

Dear Julian

EC 2009/094 Development and psychometric evaluation of two measures of perceived need: one for young people with cancer; one for carers

Thank you for your responses to the queries raised by the Ethics Committee. I am pleased to advise that the above study is now **APPROVED.**

The following general conditions apply to all approvals by this Committee, and starting a trial or research project following the issue of ethics approval will be deemed to be an acceptance of them by all investigators:

1. The submission of an application for Ethics Committee approval will be deemed to indicate that the investigator and any sponsor recognises the Committee as a registered (with AHEC) Health Research Ethics Committee and that it complies in all respects with the National Statement on Ethical Conduct Research Involving Humans and all other national and international ethical requirements. **The Committee will not enter into further correspondence on this point.**

2. All income arising from the study must be lodged in a hospital special purposes account. Performance of a clinical trial for a sponsor is a service for tax purposes and all GST obligations must be met.

3. The investigator will report adverse events accompanied by a statement as to whether or not the trial should continue. The Committee reserves the right to not receive reports whose complexity or level of detail requires the expenditure of unreasonable time and effort. The Committee receives voluminous paperwork relating to adverse event reporting. From time to time the Committee chairman may require these reports to be summarised and approval is granted subject to the agreement of the investigator that he or she will prepare such a summary on request.

4. The Committee has decided that, as the responsibility for the conduct of trials lies with the investigator, all correspondence should be signed by the investigator.

5. All trial drugs must be dispensed by the Pharmacy Department. A fee is levied for this service and investigators must regard this fee as an item requiring a budget allocation. Alternatively, if a sponsor agrees, separate direct funding of pharmacy services may be undertaken. There are provisions for this fee to be waived for locally-inspired unfunded studies not having an external sponsor.

6. Though state institutions are outside the jurisdiction of the Privacy Act and related legislation, the Committee will assume that the privacy provisions of that Act will be

the minimum standards applying during the conduct of a trial at Royal Perth Hospital. Traditional standards of patient confidentiality will apply.

7. The Committee will not acknowledge trial communications as a matter of course, unless they relate to a matter requiring Committee approval. Evidence of dispatch of a letter will be deemed to be evidence of receipt. This rule may be waived at the Committee's discretion on provision of a *pro forma* receipt by the investigator for the Chairman's signature and return. However, trivial correspondence (as judged by the Committee) will not be acknowledged even if a *pro forma* receipt is provided. Where an investigator requests written approval or written record of a matter for special purposes (say at the request of a sponsor), the investigator should prepare the required letter for the chairman's signature rather than expect the Committee secretary to prepare it. This mechanism increases the probability that the trial details in the letter are correct.

8. The Committee will provide the names and representative affiliation of members on request, but will not provide personal details or voting records.

9. A brief annual report on each project approved will be required at the end of each fiscal year, in default of which approval for the study may be suspended. Ethics approvals at RPH do not carry an expiry date so the annual report is an important part of Ethics Committee procedure.

10. The Committee has the authority to audit the conduct of any trial without notice. Exercise of this authority will only be considered if there are grounds to believe that some irregularity has occurred or if a complaint is received from a third party, or the Committee wishes to undertake an audit for QA purposes.

11. Complaints relating to the conduct of a clinical trial should be directed to the Chairman and will be promptly investigated. Complaints about the Ethics Committee decisions or policies that cannot be resolved by discussion with the Chairman or about any actions of a particular member including the Chairman, should be directed to the Director of Clinical Services. Only written complaints (not e-mail) will be accepted for investigation.

Investigators of sponsored studies are advised to draw the above conditions to the attention of the sponsor. Investigators are reminded that records of consent or authorisation for participation in special studies (including clinical trials) form part of the Acute Hospital Patient Record and should be stored with that record in accordance with the WA *Health Patient Information Retention and Disposal Schedule (Version 2) 2000.* A copy of the 'Patient Information Sheet' should also be included in the medical records as part of informed consent documentation.

Yours sincerely

Prof Frank M van Bockxmeer
Chairman, Royal Perth Hospital Ethics Committee

The Royal Perth Hospital Ethics Committee is constituted and operates in accordance with NH&MRC Guidelines.

Copy: David Miotti (Business Manager);

Appendix 5.7: Approval Certificate from the University of Newcastle Human Research Ethics Committee

HUMAN RESEARCH ETHICS COMMITTEE
Certificate of Approval

THE UNIVERSITY OF NEWCASTLE AUSTRALIA

Applicant: (first named in application)	Dr Anthony Shakeshaft
Co-Investigators / Research Students:	Ms Kate Thompson Associate Professor Paula Marlton Dr Julian Cooney Dr Michael Osborn Conjoint Professor Afaf Girgis Laureate Professor Robert Sanson-Fisher Ms Tara McHarg Associate Professor Ian Kerridge Dr Andrew Wei Doctor Mariko Carey Dr William Stevenson
Protocol:	Development and psychometric evaluation of 2 measures of perceived needs: 1 for young persons with cancer; 1 for parents

In approving this protocol, the Human Research Ethics Committee (HREC) is of the opinion that the project complies with the provisions contained in the *National Statement on Ethical Conduct in Human Research, 2007*, and the requirements within this University relating to human research.

Note: Approval is granted subject to the requirements set out in the accompanying document ***Approval to Conduct Human Research***, and any additional comments or conditions noted below.

Details of Approval

HREC Approval No: H-842-0604	**Date of Initial Approval:** 16-Jun-2004

Approved to: 01-Sep-2010

Approval is granted to this date or until the project is completed, whichever occurs first. If the approval of an External HREC has been "noted" the approval period is as determined by that HREC.

Progress reports due: Annually.

If the approval of an External HREC has been "noted", the reporting period is as determined by that HREC.

Approval Details

Initial Application

Approved

17.03.04
Conditional approval.
The Committee considered this to be a very worthwhile study.
[a] The Committee agreed that it would not approve direct contact with young people aged 14 and 15. For these ages, the study invitation was to be sent to the parents initially, asking them to discuss it with their son/daughter. The Committee appreciated the rights of these young people to express their views and needs, however weighed against that was the potential to cause distress to parents in by-passing them when parental consent would generally be required for young people of that age. While young people could access medical care independently from 14 years, this did not extend to other areas, particularly

contractual arrangements.
[b] It was proposed to follow up non-respondents to the initial letter with a reminder sent by the Cancer Registry, and up to three follow-up phone calls at two-weekly intervals. The Committee sought an assurance that there would be a maximum of one mail follow-up and one telephone follow-up that made contact.
[c] If children and/or parents were to be contacted at intervals greater than 6months, then an additional check should be made to ensure the ongoing suitability of their participation in the project.
[d] The application signalled the intent to cross-link data. It was not clear whether this was for triangulation and hence supplied as aggregated, de-identified data or otherwise. Specific consent to cross-link data was to be obtained from both the child and the child's parents if this was identifiable, personal, or sensitive data. If the researchers did not think this was feasible then they should justify why consent was not to be obtained.
[e] The Committee recommended that the information letters, surveys etc be developed for a reading age much younger than the proposed 11 - 12 years to adequately cater for the range of literacy skills and in recognition of the disruption to schooling that might have resulted from the young person having cancer. Reading age for the needs assessment measure for parents should not be much higher for the same reason. In their present form they were complex documents.
[f] Once the surveys had been developed, they would need to be submitted to the HREC prior to their implementation.
[g] Page 10 of the application stated that the researchers Shakeshaft, Sanson-Fisher and Girgis "will coordinate the appropriate involvement of co-investigators." Any additions to the research team were to be notified to the HREC by way of an Application for Variation, and participants were to be advised likewise.
[h] Cover letter to young people from NSW Cancer Council and Information Sheet.
These were complex and carried a demanding, heavy tone. They referred to "young persons" throughout which was quite stilted - could use "young people" or "teenagers". They used complex words like "facilitator", "statutory requirement", "random", "privacy protection procedures" and "identify strategies to improve health care". The Committee requested that the advice and input of people who worked with young people with cancer, eg CanTeen, be sought in revising all letters and information involving the young people.
[i] Amendments to Attachments 3 to 6 - Research Team's letters to Young Persons and Parents
(i) As per item [h] above, simplify the language used throughout.
(ii) Use section headings to make it easier for them to read as set out in the Guidelines to the application form.
(iii) List what was involved in dot point format.
[j] Amendments to Attachment 7 - Letter to treating clinicians.
The application stated that they would be asked whether the cancer patient was physically and psychological able to receive an approach. There were to be specific statements to that effect in the letter and the response form. As the approach to 14 - 15 year olds was to be via the parents, this was to be explained to clinicians and they were to be asked if in their opinion the parents would be able to cope with such an approach.

21.04.04
Nothing to report

19.05.04
Conditional approval.
The Committee ratified the decision of the Acting Chair to continue conditional approval pending justification from the researcher for the decision to exclude teenagers aged 14 and 15. This decision had been made in response to the following comment from the Committee (02/04 meeting):
The Committee agreed that it would not approve direct contact with young people aged 14 and 15. For these ages, the study invitation was to be sent to the parents initially, asking them to discuss it with their son/daughter. The Committee appreciated the rights of these young people to express their views and needs, however weighed against that was the potential to cause distress to parents in by-passing them when parental consent would generally be required for young people of that age. While young people could access medical care independently from 14 years, this did not extend to other areas, particularly contractual arrangements.
Subsequent advice from the researcher was that the matter had been reconsidered in consultation with CanTeen and young people in this age group would be invited via initial contact with their parents as requested by the Committee.

16.06.04
Approved with comments.
The Committee ratified the approval granted by the Acting Chair on 28 May 2004, which was subject to amendments to the study documents and clarification of recruitment method for the cross-sectional survey.

07.07.04
Approval confirmed with the comment that the cross-sectional questionnaire will be submitted to the HREC for approval when developed.

19.09.07
Approval renewed for a further three-year period.

Progress Report / Renewal

Approved

Variation

19-Aug-2009

Variation to:

1. Increase the eligible age range of participants from 14 - 19 to 14 - 25 years of age, at the time of their cancer diagnosis.

2. In addition to the NSW Cancer Registry, expand the sources of recruitment to include: Westmead Hospital NSW; Royal North Shore Hospital NSW; Peter MacCallum Cancer Centre VIC; The Alfred Hospital VIC; Princess Alexandra Hospital QLD; and the Royal Adelaide Hospital.

3. Add the following people to the research team: Dr Mariko Carey (University of Newcastle); Ms Kate Thompson (Peter MacCallum Cancer Centre); Assoc Prof Ian Kerridge (Westmead Hospital); Dr Andrew Wei (The Alfred Hospital); Dr William Stevenson (Royal North Shore Hospital); Assoc Prof Paula Marlton (Princess Alexandra Hospital); and Dr Michael Osborn (Royal Adelaide Hospital).

4. Amend the recruitment method to allow participating hospitals to make initial contact with eligible potential participants and their families identified from patient databases at each site. Survival status of young people to be confirmed by cross-checking with either the death registry or current medical record. Clinician consent required prior to hospital issuing information pack with consent to contact form (or in VIC a 'do not contact' form').

5. Amend the method of issuing information packs and completing questionnaires to either paper-based (as currently used) OR online. Potential participants will be randomly allocated to either method with comparison of the two data collection modes to be undertaken.

6. Amend/introduce the following participant documents accordingly:
a. Initial Letter, Reminder Letter and Participant Information/Consent (Westmead Hospital);
b. Initial Letter, Reminder Letter and Participant Information/Consent (Royal North Shore Hospital);
c. Initial Letter, Reminder Letter and Participant Information/Consent (Royal Adelaide Hospital);
d. Initial Letter, Reminder Letter and Participant Information/Consent (Princess Alexandra Hospital);
e. Initial Letter and Information/Consent (The
Alfred Hospital);
f. Initial Letter and Information/Consent (Peter MacCallum Cancer Centre);
a. First Letter of Invitation from Research Team (v2, dated 07/05/2009);
b. Reminder Letter of Invitation from Research Team (v2, dated 07/05/2009);
c. Project Information Sheet from Research Team (v2, dated 07/05/2009); and
d. Test-Retest Letter from Research Team (v2, dated 07/05/2009).

Approved

The Committee ratified the approval granted by the Chair on 30 July 2009 under the provisions for expedited review.

Variation

21-Apr-2010

Variation to:

1. Add Dr Julian Cooney to the research team. Dr Cooney will coordinate recruitment at the Royal Perth Hospital site.

2. Increase the eligible age range for young people recruited via the Princess Alexandra Hospital (PAH) from 14-25 years to 14-30 years at the time of their cancer diagnosis.

3. Add the Royal Perth Hospital (RPH) as an additional recruitment site.

4. Expand data collection by including de-identified grouped demographic data on non-consenters, to enable identification of any sample bias.

5. Modify the eligibility criteria for potential participants recruited via the Peter McCallum Cancer Centre (PMCC) to include those "aged 14-25 years at the time of their first inpatient visit...or their first referral to OnTrac@PeterMac."

6. Amend the final question of the test-retest survey to indicate that with permission, future contact will occur in 12 months time.

7. Amend/submit the following study documents to reflect the above:
a. Invitation Letter from PAH (v2, dated 21/08/2009);
b. Reminder Letter from PAH (v2, dated 21/08/2009);
c. Information Statement - University of Newcastle for PAH (v2, dated 21/08/2009);
d. Invitation Letter from RPH (v1, dated 22/07/2009);
e. Reminder Letter from RPH (v1, dated 23/07/2009);
f. Participant Information and Consent Form specific to RPH (v1, dated 22/07/2009);
g. Invitation Letter from PMCC (v2, dated 28/09/2009);
h. Participant Information and Consent Form specific to PMCC (v3, dated 20/01/2010);
i. Information Statement - University of Newcastle for PMCC (v2, dated 28/09/2009);
j. Cancer Needs Survey - Young People
k. Cancer Needs Survey - Parents and Carers

Approved

The Committee ratified the approval granted by the Chair on 12/03/10 under provisions for expedited review.

Authorised Certificate held in Research Services

Professor Alison Ferguson
Chair, Human Research Ethics Committee

Appendix 5.8: Invitation letter, project information sheet, consent form and reminder letter from Westmead Hospital

SYDNEY WEST
Area Health Service

Department of Haematology

Westmead Hospital
Hawkesbury Road
Westmead NSW 2145
Ph 61 2 9845 7073
Facsimile 61 2 9689 2331
kerridge@med.usyd.edu.au

FirstName LastName
Address 1
Suburb State Postcode

Cancer in Young Adulthood – Identifying Needs
Version 1 – 02/03/2009

Dear FirstName and Family,

I am writing to see if you would be willing to take part in a research study on the needs of young people diagnosed with cancer and the needs of their carers. Researchers at the University of Newcastle have developed a questionnaire to assess these needs.

Records at Westmead Hospital indicate that FirstName LastName was diagnosed with cancer between the ages of 14 and 25 years. **Would you be willing for Westmead Hospital to pass on your contact details to the research team so that they can write to you and invite you to participate in this study?**

If you decide to participate your contribution will assist researchers to identify the specific needs of young people with cancer and their carers. Gathering this information will allow clinicians and researchers to design interventions and inform health services in order to more effectively meet these needs. I have enclosed an information sheet (blue) prepared by the researchers describing the study and what you would be asked to do if you take part.

Please read through the information sheet together and discuss it. Then, if you are **willing to be contacted** please complete and sign the attached consent form (yellow) as soon as possible. There is one consent form for FirstName LastName and one consent form for your parent/s or partner. Signing this form does **NOT** mean you are agreeing to take part in the study, it means you will allow the researchers to mail you some more specific information. If we have not heard from you in two weeks we will contact you again to find out what you would like to do. A copy of the consent form is printed on the reverse side of this letter for you to keep.

To find out more details about this request please call Tara Clinton-McHarg at the University of Newcastle on 02 4913 187 or email tara.clinton-mcharg@newcastle.edu.au.

If receiving this letter has raised any questions or concerns about cancer and you would like to speak to a professional counsellor please call the Cancer Helpline on Free Call 13 11 20.

Thank you for considering this request. We look forward to hearing from you soon.

Yours sincerely

Associate Professor Ian Kerridge BA BMed(Hons) MPhil FRACP FRCPA
Provider No: 0600425L
Staff Specialist

PARTICIPANT INFORMATION SHEET AND CONSENT FORM

Study Title: Cancer in Young People – Identifying Needs

Principal Investigator: Dr Ian Kerridge
Department: Haematology

Invitation
You are invited to participate in a research study into the needs of young people with cancer, and the needs of their parents, partners and carers.

The study is being conducted by:
Prof Rob Sanson-Fisher, Professor of Health Behaviour, University of Newcastle
Dr Ian Kerridge, Staff Haematologist and BMT Physician, Westmead Hospital
Ms Tara Clinton-McHarg, PhD Candidate, University of Newcastle

The study is part of a national collaborative study coordinated by Australian researchers.

Before you decide whether or not you wish to participate in this study, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the following information carefully and discuss it with others if you wish.

What is the purpose of the study?
In order to improve the care provided to young people who have been diagnosed with cancer, it is important to ask them what they see as their main areas of need and to find out which of those needs they would most like help with. Since parents, partners and carers of these young people are also affected, it is important to ask them what their needs are too. Two questionnaires have been developed: one for young people who have experienced cancer and the other for parents and carers of young people who have experienced cancer. These questionnaires will be sent to a large number of young people and parents and carers so that we can identify the most common needs.

Who will be invited to enter the study?
Young people aged between 14-30 years who have been diagnosed with cancer in the past five years, and their parents, partners, and carers.

Do you have a choice?
Participation in this study is voluntary. It is completely up to you whether or not you participate. If you decide not to participate, it will not affect the treatment you receive now or in the future. Whatever your decision, it will not affect your relationship with the staff caring for you. If you wish to withdraw from the study once it has started, you can do so at any time without having to give a reason.

What will happen on the study?
If you agree to participate in this study, you will be asked to sign the Participant

Consent Form. You will then be contacted by the researchers and invited to complete a questionnaire. The questionnaire will take approximately 20 minutes to complete and asks about needs related to your daily life, emotions, relationships, information, treatment, work, and study. The questionnaire also includes items which assess its acceptability to young people with cancer and their parents and carers. One group of participants will be sent a pen and paper version of the questionnaire and the other group will be emailed an online version of the questionnaire. A computer will allocate each participant into a group randomly, like the flip of a coin. Neither the researchers nor the participant can decide which version of the questionnaire the participant receives. In order to evaluate the test-retest reliability of the questionnaire, approximately half of the participants will be asked to complete the same survey again one week later.

Are there any risks?
If you are distressed by anything presented in this information sheet or when completing the questionnaire, the researchers encourage you to call the following people who can support you:

- → Your local GP
- → The Cancer Council Helpline – Free Call 131 120
- → CanTeen – Free Call 1800 226 833

Are there any benefits?
If we knew more about the physical, emotional and social needs faced by young people who have experienced cancer, along with the problems they face from treatment, it may be possible to identify ways to improve health care for them and their parents, partners and carers.

We cannot promise you any personal benefits from taking part. However, 94% of cancer patients who took part in another cancer needs study indicated they appreciated the opportunity to comment on their cancer experience.

Confidentiality / Privacy
Of the people treating you, only the researchers named above will know whether or not you are participating in this study. Any identifiable information that is collected about you in connection with this study will remain confidential and will be disclosed only with your permission, or except as required by law. Only the researchers named above will have access to your details and results that will be held securely at the University of Newcastle.

What happens with the results?
Results of the study will be reported to the Human Research Ethics Committees for monitoring purposes, published in peer-reviewed journals, and presented at conferences and other professional forums. Results will also form part of Ms Tara Clinton-McHarg's PhD thesis. Results will only be reported in such a way that you cannot be identified.

PARTICIPANT INFORMATION SHEET AND CONSENT FORM

Study Title: Cancer in Young People – Identifying Needs

Complaints
This study has been approved by the Human Research Ethics Committee's of Sydney West Area Health Service and the University of Newcastle. If you have any concerns about the conduct of the study, or your rights as a study participant, you may contact the Westmead Hospital Patient Representative, Ms Jillian Gwynne Lewis, Telephone 02 9845 7014 or email jillian.lewis@swahs.health.nsw.gov.au. You should quote HREC Number *HREC2009/3/4.5(2938) AU RED HREC09/WMEAD/32.*

Contact details
When you have read this information, the researcher Ms Tara Clinton-McHarg can discuss it with you and answer any queries you may have. If you would like to know more at any stage, please do not hesitate to contact her on 02 4913 8187 or email tara.clinton-mcharg@newcastle.edu.au. If you have any problems while on the study, please contact

Dr Ian Kerridge
Telephone – 02 98457073

Thank you for taking the time to consider this study.

If you wish to take part in it, please sign the attached consent form.
This information sheet is for you to keep.

PARTICIPANT INFORMATION SHEET AND CONSENT FORM

Study Title: Cancer in Young People – Identifying Needs

CONSENT TO PARTICIPATE IN RESEARCH – Young Person

Name of Researchers: Prof Rob Sanson-Fisher, Dr Ian Kerridge, and Ms Tara Clinton-McHarg

1. I understand that the researchers will conduct this study in a manner conforming to ethical and scientific principles set out by the National Health and Medical Research Council of Australia and the Good Clinical Research Practice Guidelines of the Therapeutic Goods Administration.

2. I acknowledge that I have read, or have had read to me the Participant Information Sheet relating to this study. I acknowledge that I understand the Participant Information Sheet. I acknowledge that the general purposes, methods, demands and possible risks and inconveniences which may occur to me during the study have been explained to me by the researchers and I, being over the age of 16 years or over the age of 14 years but under the age of 16 years (*delete as applicable*), acknowledge that I understand the general purposes, methods, demands and possible risks and inconveniences which may occur during the study.

3. I acknowledge that I have been given time to consider the information and to seek other advice.

4. I acknowledge that refusal to take part in this study will not affect the usual treatment of my condition.

5. I acknowledge that I am volunteering to take part in this study and I may withdraw at any time.

6. I acknowledge that this research has been approved by the Sydney West Area Health Service Human Research Ethics Committee and the University of Newcastle Human Research Ethics Committee

7. I acknowledge that I have received a copy of this form and the Participant Information Sheet, which I have signed.

8. I acknowledge that any regulatory authorities may have access to my medical records to monitor the research in which I am agreeing to participate. However, I understand my identity will not be disclosed to anyone else or in publications or presentations.

Before signing, please read 'IMPORTANT NOTE' following.
IMPORTANT NOTE
This consent should only be signed as follows:
1. *Where a participant is between the age of 14 and 16 years, it should be signed by the participant and by a parent or person responsible.*
2. *Where a participant is over the age of 16 years, then by the participant personally.*

PARTICIPANT INFORMATION SHEET AND CONSENT FORM

Study Title: Cancer in Young People – Identifying Needs

CONSENT TO PARTICIPATE IN RESEARCH – Young Person

(Please tick)

☐ I am a young person who has been diagnosed with cancer

To be completed by all participants aged 14 years and over

Name of participant _____ Date of Birth _____

Address of participant _____

Email address of participant _____

Signature of participant _____ **Date:** _____

For participants between the ages of 14 and 16 years only

Name of parent or person responsible_____

Signature of person responsible_____**Date:** _____

26 July 2010

FirstName LastName
Address 1
Suburb State Postcode

Cancer in Young Adulthood – Identifying Needs

Dear FirstName and Family,

You may recall me writing to you a few weeks ago to see if you would be willing to take part in a research study on the needs of young people diagnosed with cancer and the needs of their carers. As I have not yet received a reply from you, I am writing to you again.

Records at Westmead Hospital indicate that FirstName LastName was diagnosed with cancer between the ages of 14 and 25 years. **Would you be willing for Westmead Hospital to pass on your contact details to the research team so that they can write to you and invite you to participate in this study?**

If you decide to participate your contribution will assist with the validation of two measures to assess the specific needs of young people with cancer and their carers. Having this information will allow clinicians and researchers to design interventions and inform health services in order to more effectively meet these needs. I have enclosed an information sheet (blue) prepared by the researchers describing the study and what you would be asked to do if you take part.

Please read through the information sheet together and discuss it. Then, if you are **willing to be contacted** please complete and sign the attached consent form (yellow) as soon as possible. There is one consent form for FirstName LastName and one consent form for their parent/s or partner. Signing this form does **NOT** mean you are agreeing to take part in the study, it means you will allow the researchers to mail you some more specific information. If we have not heard from you in two weeks we will contact you again to find out what you would like to do. A copy of the consent form is printed on the reverse side of this letter for you to keep.

The Human Research Ethics Committees of Sydney West Area Health Service and the University of Newcastle have approved this study. The information published from this research will not contain your name or identify you in any way.

To find out more details about this request please call Tara Clinton-McHarg at the University of Newcastle on 02 4913 8187 or email tara.clinton-mcharg@newcastle.edu.au.

If receiving this letter has raised any questions or concerns about cancer and you would like to speak to a professional counsellor please call the Cancer Helpline on Free Call 13 11 20.

Thank you for considering this request.
Yours sincerely

Dr Ian Kerridge
Staff Haematologist and BMT Physician

Appendix 5.9: Invitation letter, project information sheet, consent form and reminder letter from Royal North Shore Hospital

First Letter of Invitation From Royal North Shore Hospital – Local – Version 1 – 02/03/2009

26 July 2010

FirstName LastName
Address 1
Suburb State Postcode

Cancer in Young Adulthood – Identifying Needs

Dear FirstName and Family,

I am writing to see if you would be willing to take part in a research study on the needs of young people diagnosed with cancer and the needs of their carers. Researchers at the University of Newcastle have developed a questionnaire to assess these needs.

Records at Royal North Shore Hospital indicate that FirstName LastName was diagnosed with cancer between the ages of 14 and 25 years. **Would you be willing for Royal North Shore Hospital to pass on your contact details to the research team so that they can write to you and invite you to participate in this study?**

If you decide to participate your contribution will assist researchers to identify the specific needs of young people with cancer and their carers. Gathering this information will allow clinicians and researchers to design interventions and inform health services in order to more effectively meet these needs. I have enclosed an information sheet (blue) prepared by the researchers describing the study and what you would be asked to do if you take part.

Please read through the information sheet together and discuss it. Then, if you are **willing to be contacted** please complete and sign the attached consent form (yellow) as soon as possible. There is one consent form for FirstName LastName and one consent form for their parent/s or partner. Signing this form does **NOT** mean you are agreeing to take part in the study, it means you will allow the researchers to mail you some more specific information. If we have not heard from you in two weeks we will contact you again to find out what you would like to do. A copy of the consent form is printed on the reverse side of this letter for you to keep.

To find out more details about this request please call Tara Clinton-McHarg at the University of Newcastle on 02 4913 187 or email tara.clinton-mcharg@newcastle.edu.au.

If receiving this letter has raised any questions or concerns about cancer and you would like to speak to a professional counsellor please call the Cancer Helpline on Free Call 13 11 20.

Thank you for considering this request. We look forward to hearing from you soon.

Yours sincerely

Dr William Stevenson
Staff Haematologist

PARTICIPANT INFORMATION SHEET AND CONSENT FORM

Study Title: Cancer in Young People – Identifying Needs

Principal Investigator: Dr William Stevenson
Department: Staff Haematologist

Invitation
You are invited to participate in a research study into the needs of young people with cancer, and the needs of their parents, partners and carers.

The study is being conducted by:
Prof Rob Sanson-Fisher, Professor of Health Behaviour, University of Newcastle
Dr William Stevenson, Staff Haematologist, Royal North Shore Hospital
Ms Tara Clinton-McHarg, PhD Candidate, University of Newcastle

The study is part of a national collaborative study coordinated by Australian researchers. Before you decide whether or not you wish to participate in this study, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the following information carefully and discuss it with others if you wish.

What is the purpose of the study?
In order to improve the care provided to young people who have been diagnosed with cancer, it is important to ask them what they see as their main areas of need and to find out which of those needs they would most like help with. Since parents, partners and carers of these young people are also affected, it is important to ask them what their needs are too. Two questionnaires have been developed: one for young people who have experienced cancer and the other for parents and carers of young people who have experienced cancer. These questionnaires will be sent to a large number of young people and parents and carers so that we can identify the most common needs.

Who will be invited to enter the study?
Young people aged between 14-30 years who have been diagnosed with cancer in the past five years, and their parents, partners, and carers.

Do you have a choice?
Participation in this study is voluntary. It is completely up to you whether or not you participate. If you decide not to participate, it will not affect the treatment you receive now or in the future. Whatever your decision, it will not affect your relationship with the staff caring for you. If you wish to withdraw from the study once it has started, you can do so at any time without having to give a reason.

What will happen on the study?
If you agree to participate in this study, you will be asked to sign the Participant Consent Form. You will then be contacted by the researchers and invited to complete a questionnaire. The questionnaire will take approximately 20 minutes to complete and asks about needs related to your daily life, emotions, relationships, information, treatment, work, and study. The questionnaire also includes items which assess its acceptability to young people with cancer and their parents and carers. One group of participants will be sent a pen and paper version of the questionnaire and the other group will be emailed an online

version of the questionnaire. A computer will allocate each participant into a group randomly, like the flip of a coin. Neither the researchers nor the participant can decide which version of the questionnaire the participant receives. In order to evaluate the test-retest reliability of the questionnaire, approximately half of the participants will be asked to complete the same survey again one week later.

Are there any risks?
If you are distressed by anything presented in this information sheet or when completing the questionnaire, the researchers encourage you to call the following people who can support you:

- → Your local GP
- → The Cancer Council Helpline – Free Call 131 120
- → CanTeen – Free Call 1800 226 833

Are there any benefits?
If we knew more about the physical, emotional and social needs faced by young people who have experienced cancer, along with the problems they face from treatment, it may be possible to identify ways to improve health care for them and their parents, partners and carers.

We cannot promise you any personal benefits from taking part. However, 94% of cancer patients who took part in another cancer needs study indicated they appreciated the opportunity to comment on their cancer experience.

Confidentiality / Privacy
Of the people treating you, only the researchers named above will know whether or not you are participating in this study. Any identifiable information that is collected about you in connection with this study will remain confidential and will be disclosed only with your permission, or except as required by law. Only the researchers named above will have access to your details and results that will be held securely at the University of Newcastle.

What happens with the results?
Results of the study will be reported to the Human Research Ethics Committees for monitoring purposes, published in peer-reviewed journals, and presented at conferences and other professional forums. Results will also form part of Ms Tara Clinton-McHarg's PhD thesis. Results will only be reported in such a way that you cannot be identified.

Complaints
This study has been approved by the Human Research Ethics Committee's of Sydney West Area Health Service and the University of Newcastle. If you have any concerns about the conduct of the study, or your rights as a study participant, you may contact the Royal North Shore Hospital Patient Representative, telephone 02 9926 7612. You should quote HREC Number *HREC2009/3/4.5(2938) AU RED HREC09/WMEAD/32*.

PARTICIPANT INFORMATION SHEET AND CONSENT FORM

Study Title: Cancer in Young People – Identifying Needs

Contact details
When you have read this information, the researcher Ms Tara Clinton-McHarg can discuss it with you and answer any queries you may have. If you would like to know more at any stage, please do not hesitate to contact her on 02 4913 8187 or email tara.clinton-mcharg@newcastle.edu.au. If you have any problems while on the study, please contact

Dr William Stevenson
Telephone – 02 9926 7601

Thank you for taking the time to consider this study.

If you wish to take part in it, please sign the attached consent form.
This information sheet is for you to keep.

PARTICIPANT INFORMATION SHEET AND CONSENT FORM

Study Title: Cancer in Young People – Identifying Needs

CONSENT TO PARTICIPATE IN RESEARCH – Young Person

Name of Researchers: Prof Rob Sanson-Fisher, Dr William Stevenson and Ms Tara Clinton-McHarg

1. I understand that the researchers will conduct this study in a manner conforming to ethical and scientific principles set out by the National Health and Medical Research Council of Australia and the Good Clinical Research Practice Guidelines of the Therapeutic Goods Administration.

2. I acknowledge that I have read, or have had read to me the Participant Information Sheet relating to this study. I acknowledge that I understand the Participant Information Sheet. I acknowledge that the general purposes, methods, demands and possible risks and inconveniences which may occur to me during the study have been explained to me by the researchers and I, being over the age of 16 years or over the age of 14 years but under the age of 16 years (*delete as applicable*), acknowledge that I understand the general purposes, methods, demands and possible risks and inconveniences which may occur during the study.

3. I acknowledge that I have been given time to consider the information and to seek other advice.

4. I acknowledge that refusal to take part in this study will not affect the usual treatment of my condition.

5. I acknowledge that I am volunteering to take part in this study and I may withdraw at any time.

6. I acknowledge that this research has been approved by the Sydney West Area Health Service Human Research Ethics Committee and the University of Newcastle Human Research Ethics Committee

7. I acknowledge that I have received a copy of this form and the Participant Information Sheet, which I have signed.

8. I acknowledge that any regulatory authorities may have access to my medical records to monitor the research in which I am agreeing to participate. However, I understand my identity will not be disclosed to anyone else or in publications or presentations.

Before signing, please read 'IMPORTANT NOTE' following.

IMPORTANT NOTE

This consent should only be signed as follows:

1. *Where a participant is between the age of 14 and 16 years, it should be signed by the participant and by a parent or person responsible.*
2. *Where a participant is over the age of 16 years, then by the participant personally.*

PARTICIPANT INFORMATION SHEET AND CONSENT FORM

Study Title: Cancer in Young People – Identifying Needs

CONSENT TO PARTICIPATE IN RESEARCH – Young Person

(Please tick)

☐ I am a young person who has been diagnosed with cancer

To be completed by all participants aged 14 years and over

Name of participant _____ Date of Birth _____

Address of participant _____

Email address of participant _____

Signature of participant _____ Date: _____

For participants between the ages of 14 and 16 years only

Name of parent or person responsible_____

Signature of parent or person responsible_____ Date: _____

Reminder Letter From Royal North Shore Hospital – Local – Version 1 – 02/03/2009

26 July 2010

FirstName LastName
Address 1
Suburb State Postcode

Cancer in Young Adulthood – Identifying Needs

Dear FirstName and Family,

You may recall me writing to you a few weeks ago to see if you would be willing to take part in a research study on the needs of young people diagnosed with cancer and the needs of their carers. As I have not yet received a reply from you, I am writing to you again.

Records at Royal North Shore Hospital indicate that FirstName LastName was diagnosed with cancer between the ages of 14 and 25 years. **Would you be willing for Royal North Shore Hospital to pass on your contact details to the research team so that they can write to you and invite you to participate in this study?**

If you decide to participate your contribution will assist with the validation of two measures to assess the specific needs of young people with cancer and their carers. Having this information will allow clinicians and researchers to design interventions and inform health services in order to more effectively meet these needs. I have enclosed an information sheet (blue) prepared by the researchers describing the study and what you would be asked to do if you take part.

Please read through the information sheet together and discuss it. Then, if you are **willing to be contacted** please complete and sign the attached consent form (yellow) as soon as possible. There is one consent form for FirstName LastName and one consent form for their parent/s or partner. Signing this form does **NOT** mean you are agreeing to take part in the study, it means you will allow the researchers to mail you some more specific information. If we have not heard from you in two weeks we will contact you again to find out what you would like to do. A copy of the consent form is printed on the reverse side of this letter for you to keep.

The Human Research Ethics Committees of Sydney West Area Health Service and the University of Newcastle have approved this study. The information published from this research will not contain your name or identify you in any way.

To find out more details about this request please call Tara Clinton-McHarg at the University of Newcastle on 02 4913 8187 or email tara.clinton-mcharg@newcastle.edu.au.

If receiving this letter has raised any questions or concerns about cancer and you would like to speak to a professional counsellor please call the Cancer Helpline on Free Call 13 11 20.

Thank you for considering this request.
Yours sincerely

Dr William Stevenson
Staff Haematologist

Appendix 5.10: Invitation letter, project information sheet, consent form and reminder letter from Princess Alexandra Hospital

Version 1 19/03/2009

Queensland Government
Queensland Health

26 July 2010

FirstName LastName
Address 1
Suburb State Postcode

Cancer in Young Adulthood – Identifying Needs

Dear FirstName and Family,

I am writing to see if you would be willing to take part in a research study on the needs of young people diagnosed with cancer and the needs of their carers. Researchers at the University of Newcastle have developed a questionnaire to assess these needs.

Records at Princess Alexandra Hospital indicate that FirstName LastName was diagnosed with cancer between the ages of 14 and 25 years. **Would you be willing for Princess Alexandra Hospital to pass on your contact details to the research team so that they can write to you and invite you to participate in this study?**

If you decide to participate your contribution will assist researchers to identify the specific needs of young people with cancer and their carers. Gathering this information will allow clinicians and researchers to design interventions and inform health services in order to more effectively meet these needs. I have enclosed an information sheet (blue) prepared by the researchers describing the study and what you would be asked to do if you take part.

Please read through the information sheet together and discuss it. Then, if you are **willing to be contacted** please complete and sign the attached consent form (yellow) as soon as possible. There is one consent form for FirstName LastName and one consent form for their parent/s or partner. Signing this form does **NOT** mean you are agreeing to take part in the study, it means you will allow the researchers to mail you some more specific information. If we have not heard from you in two weeks we will contact you again to find out what you would like to do. A copy of the consent form is printed on the reverse side of this letter for you to keep.

To find out more details about this request please call Tara Clinton-McHarg at the University of Newcastle on 02 49138187 or email tara.clinton-mcharg@newcastle.edu.au.

If receiving this letter has raised any questions or concerns about cancer and you would like to speak to a professional counsellor please call the Cancer Helpline on Free Call 13 11 20.

Thank you for considering this request. We look forward to hearing from you soon.

Yours sincerely

A/Prof Paula Marlton
Head of Leukaemia and Lymphoma Services

PARTICIPANT INFORMATION SHEET AND CONSENT FORM

Study Title: Cancer in Young People – Identifying Needs

Queensland Government
Queensland Health

Principal Investigator: A/Prof Paula Marlton
Department: Haematology

Invitation
You are invited to participate in a research study into the needs of young people with cancer, and the needs of their parents, partners and carers.

The study is being conducted by:
Prof Rob Sanson-Fisher, Professor of Health Behaviour, University of Newcastle
A/Prof Paula Marlton, Head of Leukaemia and Lymphoma Services, Princess Alexandra Hospital
Ms Tara Clinton-McHarg, PhD Candidate, University of Newcastle

The study is part of a national collaborative study coordinated by Australian researchers. Before you decide whether or not you wish to participate in this study, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the following information carefully and discuss it with others if you wish.

What is the purpose of the study?
In order to improve the care provided to young people who have been diagnosed with cancer, it is important to ask them what they see as their main areas of need and to find out which of those needs they would most like help with. Since parents, partners and carers of these young people are also affected, it is important to ask them what their needs are too. Two questionnaires have been developed: one for young people who have experienced cancer and the other for parents and carers of young people who have experienced cancer. These questionnaires will be sent to a large number of young people and parents and carers so that we can identify the most common needs.

Who will be invited to enter the study?
Young people aged between 14-30 years who have been diagnosed with cancer in the past five years, and their parents, partners, and carers.

Do you have a choice?
Participation in this study is voluntary. It is completely up to you whether or not you participate. If you decide not to participate, it will not affect the treatment you receive now or in the future. Whatever your decision, it will not affect your relationship with the staff caring for you. If you wish to withdraw from the study once it has started, you can do so at any time without having to give a reason.

What will happen on the study?
If you agree to participate in this study, you will be asked to sign the Participant Consent Form. You will then be contacted by the researchers and invited to complete a questionnaire. The questionnaire will take approximately 20 minutes to complete and asks about needs related to your daily life, emotions, relationships, information, treatment, work, and study. The questionnaire also includes items which assess its acceptability to young people with cancer and their parents and carers. One group of participants will be sent a

PARTICIPANT INFORMATION SHEET AND CONSENT FORM

Study Title: Cancer in Young People – Identifying Needs

pen and paper version of the questionnaire and the other group will be emailed an online version of the questionnaire. A computer will allocate each participant into a group randomly, like the flip of a coin. Neither the researchers nor the participant can decide which version of the questionnaire the participant receives. In order to evaluate the test-retest reliability of the questionnaire, approximately half of the participants will be asked to complete the same survey again one week later.

Are there any risks?
If you are distressed by anything presented in this information sheet or when completing the questionnaire, the researchers encourage you to call the following people who can support you:

- → Your local GP
- → The Cancer Council Helpline – Free Call 131 120
- → CanTeen – Free Call 1800 226 833

Are there any benefits?
If we knew more about the physical, emotional and social needs faced by young people who have experienced cancer, along with the problems they face from treatment, it may be possible to identify ways to improve health care for them and their parents, partners and carers.

We cannot promise you any personal benefits from taking part. However, 94% of cancer patients who took part in another cancer needs study indicated they appreciated the opportunity to comment on their cancer experience.

Confidentiality / Privacy
Of the people treating you, only the researchers named above will know whether or not you are participating in this study. Any identifiable information that is collected about you in connection with this study will remain confidential and will be disclosed only with your permission, or except as required by law. Only the researchers named above will have access to your details and results that will be held securely at the University of Newcastle.

What happens with the results?
Results of the study will be reported to the Human Research Ethics Committees for monitoring purposes, published in peer-reviewed journals, and presented at conferences and other professional forums. Results will also form part of Ms Tara Clinton-McHarg's PhD thesis. Results will only be reported in such a way that you cannot be identified.

Complaints
This study has been approved by the Human Research Ethics Committee's of Princess Alexandra Hospital and the University of Newcastle. If you have any concerns about the conduct of the study, or your rights as a study participant, you may contact: The Patient Liaison Officer, Clinical Governance Unit, Princess Alexandra Hospital, Ipswich Rd Woolloongabba QLD 4120. You should quote HREC # 2009/084.

PARTICIPANT INFORMATION SHEET AND CONSENT FORM

Study Title: Cancer in Young People – Identifying Needs

Contact details
When you have read this information, the researcher Ms Tara Clinton-McHarg can discuss it with you and any queries you may have. If you would like to know more at any stage, please do not hesitate to contact her on 02 4913 8187 or email tara.clinton-mcharg@newcastle.edu.au. If you have any problems while on the study, please contact

A/Prof Paula Marlton
Telephone – 07 3240 7896

Thank you for taking the time to consider this study.

If you wish to take part in it, please sign the attached consent form.
This information sheet is for you to keep.

PARTICIPANT INFORMATION SHEET AND CONSENT FORM

Study Title: Cancer in Young People – Identifying Needs

CONSENT TO PARTICIPATE IN RESEARCH – Young Person

Name of Researchers: Prof Rob Sanson-Fisher, A/Prof Paula Marlton and Ms Tara Clinton-McHarg

1. I understand that the researchers will conduct this study in a manner conforming to ethical and scientific principles set out by the National Health and Medical Research Council of Australia and the Good Clinical Research Practice Guidelines of the Therapeutic Goods Administration.

2. I acknowledge that I have read, or have had read to me the Participant Information Sheet relating to this study. I acknowledge that I understand the Participant Information Sheet. I acknowledge that the general purposes, methods, demands and possible risks and inconveniences which may occur to me during the study have been explained to me by the researchers and I, being over the age of 16 years or over the age of 14 years but under the age of 16 years (*delete as applicable*), acknowledge that I understand the general purposes, methods, demands and possible risks and inconveniences which may occur during the study.

3. I acknowledge that I have been given time to consider the information and to seek other advice.

4. I acknowledge that refusal to take part in this study will not affect the usual treatment of my condition.

5. I acknowledge that I am volunteering to take part in this study and I may withdraw at any time.

6. I acknowledge that this research has been approved by the Princess Alexandra Hospital Human Research Ethics Committee and the University of Newcastle Human Research Ethics Committee

7. I acknowledge that I have received a copy of this form and the Participant Information Sheet, which I have signed.

8. I acknowledge that any regulatory authorities may have access to my medical records to monitor the research in which I am agreeing to participate. However, I understand my identity will not be disclosed to anyone else or in publications or presentations.

Before signing, please read 'IMPORTANT NOTE' following.
IMPORTANT NOTE
This consent should only be signed as follows:
1. *Where a participant is between the age of 14 and 16 years, it should be signed by the participant and by a parent or person responsible.*
2. *Where a participant is over the age of 16 years, then by the participant personally.*

PARTICIPANT INFORMATION SHEET AND CONSENT FORM

Study Title: Cancer in Young People – Identifying Needs

CONSENT TO PARTICIPATE IN RESEARCH – Young Person

(Please tick)

☐ I am a young person who has been diagnosed with cancer

To be completed by all participants aged 14 years and over

Name of participant _____ Date of Birth _____

Address of participant _____

Email address of participant _____

Signature of participant _____ Date: _____

For participants between the ages of 14 and 16 years only

Name of parent or person responsible_____

Signature of parent or person responsible_____ Date: _____

Please return in the reply paid envelope provided.

Queensland Government
Queensland Health

26 July 2010

FirstName LastName
Address 1
Suburb State Postcode

Cancer in Young Adulthood – Identifying Needs

Dear FirstName and Family,

You may recall me writing to you a few weeks ago to see if you would be willing to take part in a research study on the needs of young people diagnosed with cancer and the needs of their carers. As I have not yet received a reply from you, I am writing to you again.

Records at Princess Alexandra Hospital indicate that FirstName LastName was diagnosed with cancer between the ages of 14 and 25 years. **Would you be willing for Princess Alexandra Hospital to pass on your contact details to the research team so that they can write to you and invite you to participate in this study?**

If you decide to participate your contribution will assist with the validation of two measures to assess the specific needs of young people with cancer and their carers. Having this information will allow clinicians and researchers to design interventions and inform health services in order to more effectively meet these needs. I have enclosed an information sheet (blue) prepared by the researchers describing the study and what you would be asked to do if you take part.

Please read through the information sheet together and discuss it. Then, if you are **willing to be contacted** please complete and sign the attached consent form (yellow) as soon as possible. There is one consent form for FirstName LastName and one consent form for their parent/s or partner. Signing this form does **NOT** mean you are agreeing to take part in the study, it means you will allow the researchers to mail you some more specific information. If we have not heard from you in two weeks we will contact you again to find out what you would like to do. A copy of the consent form is printed on the reverse side of this letter for you to keep.

The Human Research Ethics Committees of Princess Alexandra Hospital and the University of Newcastle have approved this study. The information published from this research will not contain your name or identify you in any way.

To find out more details about this request please call Tara Clinton-McHarg at the University of Newcastle on 02 49138187 or email tara.clinton-mcharg@newcastle.edu.au.

If receiving this letter has raised any questions or concerns about cancer and you would like to speak to a professional counsellor please call the Cancer Helpline on Free Call 13 11 20.

Thank you for considering this request.
Yours sincerely

A/Prof Paula Marlton
Head of Leukaemia and Lymphoma Services

Appendix 5.11: Invitation letter, project information sheet, consent form and reminder letter from Royal Adelaide Hospital

FirstName LastName
Address 1
Suburb State Postcode

Cancer in Young Adulthood – Identifying Needs

Dear FirstName and Family,

I am writing to see if you would be willing to take part in a research study on the needs of young people diagnosed with cancer and the needs of their carers. Researchers at the University of Newcastle have developed a questionnaire to assess these needs.

Records at Royal Adelaide Hospital indicate that you were diagnosed with cancer between the ages of 14 and 25 years. Your treating clinician Title ClinicianName has given his/her consent for me to contact you. **Would you be willing for Royal Adelaide Hospital to pass on your contact details to the research team in Newcastle so that they can write to you and invite you to participate in this study?**

If you decide to participate your contribution will assist researchers to identify the specific needs of young people with cancer and their carers. Gathering this information will allow clinicians and researchers to design interventions and inform health services in order to more effectively meet these needs. I have enclosed an information sheet (blue) prepared by the researchers describing the study and what you would be asked to do if you take part.

Please read through the information sheet together and discuss it. Then, if you are **willing to be contacted** please complete and sign the attached consent form (yellow) as soon as possible. There is one consent form for the young person and one consent form for their parent/s or partner. Signing this form does **NOT** mean you are agreeing to take part in the study, it means you will allow the researchers to mail you some more specific information. If we have not heard from you in two weeks we will contact you again to find out what you would like to do.

To find out more details about this request please call Tara Clinton-McHarg at the University of Newcastle on 02 49138187 or email tara.clinton-mcharg@newcastle.edu.au.

If receiving this letter has raised any questions or concerns about cancer and you would like to speak to a professional counsellor please call the Cancer Helpline on Free Call 13 11 20.

Thank you for considering this request. We look forward to hearing from you soon.

Yours sincerely

Dr Michael Osborn
Department of Haematology

RAH Letter of Invitation version 1, dated: 26th May 2009

Haematology and Bone Marrow Transplant Unit

Royal Adelaide Hospital/IMVS

Participant Information Sheet and Consent Form

PROTOCOL TITLE: Development and Psychometric Evaluation of two Measures of Perceived Need: One of Young People with Cancer; One for Carers

PRINCIPAL INVESTIGATORS:
Dr Michael Osborn (Royal Adelaide Hospital)

Prof Rob Sanson-Fisher, Professor of Health Behaviour (University of Newcastle)

Ms Tara Clinton-McHarg, PhD Candidate (University of Newcastle)

1. Introduction

You are invited to take part in this research project because our medical records indicate you are: 1) between the ages of 18-30 years; and 2) have been treated for cancer at Royal Adelaide Hospital in the last 5 years. The research project aims to identify the unmet needs of young people who have been diagnosed with cancer, and the unmet needs of their parents, partners and carers.

This Participant Information Sheet tells you about the research project. It explains what is involved to help you decide if you want to take part.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or your local health worker.

This is a voluntary research project and you do not have to be involved. If you do not wish to participate, your medical care will not be affected in any way. Also, you may withdraw from the project any time after you have commenced.

If you decide you want to take part in the research project and you are willing to be contacted by the researchers, you will be asked to complete and sign the consent form (yellow) at the end of this information sheet. There is one consent form for the patient and one consent form for their parent/s or partner. Signing this form does **NOT** mean you are agreeing to take part in the study, only that you agree to receive more information about it.

This copy of the Participant Information sheet is for you to keep.

2. What is the purpose of this research project?

The purpose of this project is to identify the unmet needs of young people with cancer, and the unmet needs of their parents, partners and carers.

In order to improve the care provided to young people who have been diagnosed with cancer, it is important to ask them what they see as their main areas of need and to find out which of those needs they would most like help with. Since parents, partners and carers of these young people are also affected, it is important to ask them what their needs are too.

Two questionnaires have been developed: one for young people who have experienced cancer and the other for parents, partners, and carers of young people who have experienced cancer. These

questionnaires will be sent to approximately 400 young people across Australia, and 400 parents, partners and carers so that we can identify the most common needs. This is a National study involving Hospitals in Victoria, New South Wales, Queensland, South Australia and Western Australia.

This research is being conducted by researchers at Royal Adelaide Hospital (Dr Michael Osborn) and the University of Newcastle (Prof Rob Sanson-Fisher and Ms Tara Clinton-McHarg). The results of this research will be used by Ms Clinton-McHarg to obtain her PhD. This research has been funded by the National Health and Medical Research Council of Australia (NHMRC).

3. What does participation in this research project involve?

If you agree to take part in this research, you will be contacted by the researchers and invited to complete a questionnaire. The questionnaire will take approximately 20 minutes to complete, and asks about needs related to your daily life, emotions, relationships, information, treatment, work, and study. The questionnaire also includes items which assess its acceptability to young people with cancer and their carers.

Participants will be allocated to one of two groups. One group of participants will be sent a pen and paper version of the questionnaire. The other group will be emailed an online, web-based version of the questionnaire. A computer will allocate each participant into a group randomly, like the flip of a coin. Neither the researchers nor the participant will decide which version of the questionnaire each participant receives. In order to evaluate the test-retest reliability of the questionnaire, approximately half of the participants will be asked to complete the same survey again one week later. In order to send you a questionnaire, the research team will ask for your mail and email contact details.

You will not be paid for your participation in this project.

4. What are the possible benefits?

We cannot guarantee or promise that you will receive any personal benefits from participating in this study. However, 94% of cancer patients who took part in another cancer needs study indicated they appreciated the opportunity to comment on their cancer experience.

Findings of this research will be used to improve health care for young people who have experienced cancer and their parents, partners and carers.

5. What are the possible risks?

There are no known risks to you from being involved in this study. If you become upset or distressed as a result of your participation in the research, the researchers encourage you to call the following people who can support you:

- → Your local GP
- → The Cancer Council Helpline – Free Call 131 120
- → CanTeen – Free Call 1800 226 833

6. Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at a later stage.

If you decide to leave the project after you have returned your questionnaire, the researchers would like to keep any data that has already been collected. This is to help them make sure that the results of the research can be measured properly. If you do not want them to do this, you must tell them before you withdraw from the research project.

Your decision whether to take part or not, or to take part and then withdraw, will not affect your relationship with the researchers or Royal Adelaide Hospital.

7. How will I be informed of the final results of this research project?

If you wish to obtain a final copy of the research report describing the results of this study, please tell the researchers and they will arrange for one to be sent to you. Results of the study will be published in professional journals, and presented at conferences and other professional forums. Results will also form part of Ms Tara Clinton-McHarg's PhD thesis.

8. What will happen to information about me?

Any information obtained in connection with this research project that can identify you will remain confidential and will only be used for the purpose of this research project. It will only be disclosed with your permission, except as required by law.

Of the people treating you, only the researchers above and their staff will know whether or not you are participating in this study. All of your personal information will be coded so that you cannot be identified by name, and only the research team will have access to the master list that will link your name with your data. All information will be stored in a locked filing cabinet and password protected files at the University of Newcastle, and will be disposed of as confidential waste after 7 years.

In any publication and/or presentation, information will be provided in such a way that you cannot be identified.

9. Can I access research information kept about me?

In accordance with relevant Australian privacy and other relevant laws, you have the right to access the information collected and stored by the researchers about you. Please contact one of the researchers named at the end of this document if you would like to access your information.

Further, in accordance with regulatory guidelines, the information collected in this research project will be kept for at least 7 years. You must be aware that the information may become de-identified at some point and access to information about you after this point will not be possible.

10. Is this research project approved?

The ethical aspects of this research project have been approved by the Research Ethics Committee of Royal Adelaide Hospital and the University of Newcastle.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)* produced by the National Health and Medical Research Council of Australia. This statement has been developed to protect the interests of people who agree to participate in human research studies.

11. Consent

If you are willing to be contacted by the researchers, please complete and sign the attached consent form (yellow) as soon as possible. There is one consent form for the patient and one consent form for their parent/s or partner. Signing this form does **NOT** mean you are agreeing to take part in the study, it means you will allow the researchers to mail you some more specific information.

12. Who can I contact?

The person you may need to contact will depend on the nature of your query. Therefore, please note the following:

If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project, you can contact:

The Principal Investigator, Dr Michael Osborn, Royal Adelaide Hospital, telephone 0430 272 334

or:

The Project Coordinator, Ms Tara Clinton-McHarg, University of Newcastle, telephone: (02) 49138187

If you wish to speak to someone not directly involved in the study about your rights as a volunteer, or about the conduct of the study, you may also contact:

The Chairman, Research Ethics Committee, Royal Adelaide Hospital, telephone (08) 82224139.

Government of South Australia
Central Northern Adelaide Health Service

Haematology and Bone Marrow Transplant Unit
Royal Adelaide Hospital/IMVS

Participant Consent Form - Young Person

PROTOCOL TITLE: Development and Psychometric Evaluation of two Measures of Perceived Need: One of Young People with Cancer; One for Carers

PRINCIPAL INVESTIGATORS:

Dr Michael Osborn (Royal Adelaide Hospital)

Prof Rob Sanson-Fisher, Professor of Health Behaviour (University of Newcastle)

Ms Tara Clinton-McHarg, PhD Candidate (University of Newcastle)

1. The nature and purpose of the research project has been explained to me. I understand it, and agree to take part.
2. I understand that I may not benefit from taking part in this study.
3. I understand that, while information gained during the study may be published, I will not be identified and my personal results will remain confidential.
4. I understand that I can withdraw from the study at any stage and that this will not affect my medical care, now or in the future.
5. I have had the opportunity to discuss taking part in this investigation with a family member or friend.

(Please tick)

☐ I am a young person who has been diagnosed with cancer

Name: _____

Date of Birth: _____

Address: _____

Email address: _____

Signed: _____ Dated: _____

Please return this form in the reply-paid envelope provided.

Approved by Royal Adelaide Hospital Research Ethics Committee on XXXXXXX

26 July 2010

FirstName LastName
Address 1
Suburb State Postcode

Cancer in Young Adulthood – Identifying Needs

Dear FirstName and Family,

You may recall me writing to you a few weeks ago to see if you would be willing to take part in a research study on the needs of young people diagnosed with cancer and the needs of their carers. As I have not yet received a reply from you, I am writing to you again.

Records at Royal Adelaide Hospital indicate that you were diagnosed with cancer between the ages of 14 and 25 years. Your treating clinician Title ClinicianName has given his/her consent for me to contact you. **Would you be willing for Royal Adelaide Hospital to pass on your contact details to the research team so that they can write to you and invite you to participate in this study?**

If you decide to participate your contribution will assist with the validation of two measures to assess the specific needs of young people with cancer and their carers. Having this information will allow clinicians and researchers to design interventions and inform health services in order to more effectively meet these needs. I have enclosed an information sheet (blue) prepared by the researchers describing the study and what you would be asked to do if you take part.

Please read through the information sheet together and discuss it. Then, if you are **willing to be contacted** please complete and sign the attached consent form (yellow) as soon as possible. There is one consent form for FirstName LastName and one consent form for their parent/s or partner. Signing this form does **NOT** mean you are agreeing to take part in the study, it means you will allow the researchers to mail you some more specific information. If we have not heard from you in two weeks we will contact you again to find out what you would like to do.

The Research Ethics Committees of Royal Adelaide Hospital and the University of Newcastle have approved this study. The information published from this research will not contain your name or identify you in any way.

To find out more details about this request please call Tara Clinton-McHarg at the University of Newcastle on 02 4913 8187 or email tara.clinton-mcharg@newcastle.edu.au.

If receiving this letter has raised any questions or concerns about cancer and you would like to speak to a professional counsellor please call the Cancer Helpline on Free Call 13 11 20.

Thank you for considering this request.
Yours sincerely

Dr Michael Osborn
Department of Haematology

Appendix 5.12: Invitation letter, project information sheet, consent form and reminder letter from Royal Perth Hospital

Appendix 1 – First Letter of Invitation from RPH – Local – Version 1 – 22/07/2009

Government of **Western Australia**
Department of **Health** South Metropolitan
Area Health Service

Royal Perth Hospital
ABN 13 993 250 709

26 July 2010

FirstName LastName
Address 1
Suburb State Postcode

Cancer in Young Adulthood – Identifying Needs

Dear FirstName and Family,

I am writing to see if you would be willing to take part in a research study on the needs of young people diagnosed with cancer and the needs of their carers. Researchers at the University of Newcastle have developed a questionnaire to assess these needs.

Records at Royal Perth Hospital indicate that FirstName LastName was diagnosed with cancer between the ages of 14 and 25 years. **Would you be willing for Royal Perth Hospital to pass on your contact details to the research team so that they can write to you and invite you to participate in this study?**

If you decide to participate your contribution will assist researchers to identify the specific needs of young people with cancer and their carers. Gathering this information will allow clinicians and researchers to design interventions and inform health services in order to more effectively meet these needs. I have enclosed an information sheet (blue) prepared by the researchers describing the study and what you would be asked to do if you take part.

Please read through the information sheet together and discuss it. Then, if you are **willing to be contacted** please complete and sign the attached consent form (yellow) as soon as possible. There is one consent form for FirstName LastName and one consent form for their parent/s or partner. Signing this form does **NOT** mean you are agreeing to take part in the study, it means you will allow the researchers to mail you some more specific information. If we have not heard from you in two weeks we will contact you again to find out what you would like to do. A copy of the consent form is enclosed with this letter for you to keep.

To find out more details about this request please call Tara Clinton-McHarg at the University of Newcastle on 02 49138187 or email tara.clinton-mcharg@newcastle.edu.au.

If receiving this letter has raised any questions or concerns about cancer and you would like to speak to a professional counsellor please call the Cancer Helpline on Free Call 13 11 20.

Thank you for considering this request. We look forward to hearing from you soon.

Yours sincerely

Dr Julian Cooney
Consultant Haematologist

ROYAL PERTH HOSPITAL
PATIENT INFORMATION SHEET
PARTICIPANT INFORMATION SHEET
Principal Investigator: Dr Julian Cooney, Haematology Department RPH

Identifying the needs of young people with cancer (EC2009/094)

You are being invited to participate in a research study into the needs of young people with cancer, and the needs of their parents, partners and carers.

The study is part of a national collaboration coordinated by Australian researchers, including:

- Prof Rob Sanson-Fisher, Professor of Health Behaviour, University of Newcastle
- Dr Julian Cooney, Consultant Haematologist, Royal Perth Hospital
- Ms Tara Clinton-McHarg, PhD Candidate, University of Newcastle

Before you decide whether or not you wish to participate in this study, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the following information carefully and discuss it with others if you wish.

What is the purpose of the study?
In order to improve the care provided to young people who have been diagnosed with cancer, it is important to ask them what they see as their main areas of need and to find out which of those needs they would most like help with. Since parents, partners and carers of these young people are also affected, it is important to ask them what their needs are too. Two questionnaires have been developed: one for young people who have experienced cancer and the other for parents and carers of young people who have experienced cancer. These questionnaires will be sent to a large number of young people and parents and carers so that we can identify the most common needs.

Who will be invited to participate?
Young people aged between 14-30 years who have been diagnosed with cancer in the past five years, and their parents, partners, and carers.

Do you have a choice?
Participation in this study is voluntary. It is completely up to you whether or not you participate. If you decide not to participate, it will not affect the treatment you receive now or in the future or your relationship with the staff caring for you. If you wish to withdraw from the study once it has started, you can do so at any time without having to give a reason.

What will happen on the study?
If you agree to participate, you will be contacted by the researchers and invited to complete a questionnaire. The questionnaire will take approximately 20 minutes to complete and asks about needs related to your daily life, emotions, relationships, information, treatment, work, and study. The questionnaire also includes items that assess its acceptability to young people with cancer and their parents and carers. One group of participants will be sent a pen and paper version of the questionnaire and the other group will be e-mailed an on-line version of the questionnaire. A computer will allocate you to a group (either pen and paper or electronic) randomly, like the flip of a coin. Neither the researchers nor the participant can decide which version of the questionnaire you will receive. Also, in order to evaluate the 'test-retest reliability' of the questionnaire - how consistently it is when used multiple times - approximately half of the participants will be asked to complete the same survey again one week later.

Are there any risks?
The only conceivable risk to participation is that answering some items on the questionnaire might cause some discomfort or make you upset. If you are distressed by anything presented in this

information sheet or when completing the questionnaire, we encourage you to call the following people who can support you:

- → Your local GP
- → The Cancer Council Helpline – Free Call 131 120
- → CanTeen – Free Call 1800 226 833

Are there any possible benefits?
If we knew more about the physical, emotional and social needs faced by young people who have experienced cancer, along with the problems they face from treatment, it may be possible to identify ways to improve health care for them and their parents, partners and carers.

We cannot promise you any personal benefits from participating in the study. However, many of the people who participated in a similar cancer needs study indicated they appreciated the opportunity to comment on their cancer experience.

Your confidentiality and privacy
Of the people treating you, only the researchers named above will know whether or not you are participating in this study. Any identifiable information that is collected about you in connection with this study will remain confidential and will be disclosed only with your permission, or except as required by law. Only the researchers named above will have access to your details and results that will be held securely at the University of Newcastle. All people who handle your information will adhere to traditional standards of confidentiality and will comply with all relevant privacy legislation. In Australia, this is in the Privacy Act 1988.

What happens with the results?
Results of the study will be reported to the Human Research Ethics Committees for monitoring purposes, published in peer-reviewed journals, and presented at conferences and other professional forums. Results will also form part of Ms Tara Clinton-McHarg's PhD thesis. Results will only be reported in such a way that you cannot be identified.

Contact details
When you have read this information, the researcher Ms Tara Clinton-McHarg can discuss it with you and answer any questions you may have. If you would like to know more at any stage, please do not hesitate to contact Tara on (02) 4913 8187 or email tara.clinton-mcharg@newcastle.edu.au.

If you have any questions or problems while involved in the study, please contact the RPH Investigator **Dr Julian Cooney on (08) 9224 1166** or Study Coordinator, Megan Margaria on 92247038.

This study has been approved by the Royal Perth Hospital Ethics Committee. If you have any concerns about the conduct of the study or your rights as a study participant, please contact the Ethics Committee Chairman, Prof Frank Van Bockxmeer on (08) 92242244. Please quote the ethics approval number EC 2009/094.

ROYAL PERTH HOSPITAL
PATIENT INFORMATION SHEET
PARTICIPANT INFORMATION SHEET
Principal Investigator: Dr Julian Cooney, Haematology Department RPH

Identifying the needs of young people with cancer

Investigators: Prof Rob Sanson-Fisher, Dr Julian Cooney and Ms Tara Clinton-McHarg

CONSENT/ASSENT FORM
(young person)

1. I understand that the researchers will conduct this study in a manner conforming to ethical and scientific principles set out by the National Health and Medical Research Council of Australia and the Good Clinical Research Practice Guidelines of the Therapeutic Goods Administration.

2. I acknowledge that I have read, or have had read to me the Participant Information Sheet relating to this study. I acknowledge that I understand the Participant Information Sheet. I acknowledge that the general purposes, methods, demands and possible risks and inconveniences which may occur to me during the study have been explained to me by the researchers and I, being over the age of 16 years or over the age of 14 years but under the age of 16 years (*delete as applicable*), acknowledge that I understand the general purposes, methods, demands and possible risks and inconveniences which may occur during the study.

3. I acknowledge that I have been given time to consider the information and to seek other advice.

4. I acknowledge that refusal to take part in this study will not affect the usual treatment of my condition.

5. I acknowledge that I am volunteering to take part in this study and I may withdraw at any time.

6. I acknowledge that this research has been approved by Royal Perth Hospital Ethics Committee and the University of Newcastle Human Research Ethics Committee

7. I acknowledge that I have received a copy of the Participant Information Sheet and I will be given a copy of this consent form once signed.

8. I acknowledge that any regulatory authorities may have access to my medical records to monitor the research in which I am agreeing to participate. However, I understand my identity will not be disclosed to anyone else or in publications or presentations.

*Before signing, please **note:***
This consent should only be signed as follows:
1. *Where a participant is under the age of 18 years, it should be signed by the participant and by a parent or person responsible.*
2. *Where a participant is over the age of 18 years, then by the participant personally.*

ROYAL PERTH HOSPITAL
PATIENT INFORMATION SHEET
PARTICIPANT INFORMATION SHEET
Principal Investigator: Dr Julian Cooney, Haematology Department RPH

To be completed by all participants aged 14 years and over

Name of participant _____ Date of Birth _____

Email address of participant _____

Signature of participant _____ Date: _____

For participants between the ages of 14 and 18 years only

Name of parent or legal guardian_____

Signature of parent or legal guardian_____ Date: _____

For all participants

Name of Investigator _____

Signature of Investigator_____ Date: _____

Appendix 2 – Reminder Letter from RPH – Local – Version 1 – 23/07/2009

Government of **Western Australia**
Department of **Health** South Metropolitan
Area Health Service

Royal Perth Hospital
ABN 13 993 250 709

26 July 2010

FirstName LastName
Address 1
Suburb State Postcode

Cancer in Young Adulthood – Identifying Needs

Dear FirstName and Family,

You may recall me writing to you a few weeks ago to see if you would be willing to take part in a research study on the needs of young people diagnosed with cancer and the needs of their carers. As I have not yet received a reply from you, I am writing to you again.

Records at Royal Perth Hospital indicate that FirstName LastName was diagnosed with cancer between the ages of 14 and 25 years. **Would you be willing for Royal Perth Hospital to pass on your contact details to the research team so that they can write to you and invite you to participate in this study?**

If you decide to participate your contribution will assist with the validation of two measures to assess the specific needs of young people with cancer and their carers. Having this information will allow clinicians and researchers to design interventions and inform health services in order to more effectively meet these needs. I have enclosed an information sheet (blue) prepared by the researchers describing the study and what you would be asked to do if you take part.

Please read through the information sheet together and discuss it. Then, if you are **willing to be contacted** please complete and sign the attached consent form (yellow) as soon as possible. There is one consent form for FirstName LastName and one consent form for their parent/s or partner. Signing this form does **NOT** mean you are agreeing to take part in the study, it means you will allow the researchers to mail you some more specific information. If we have not heard from you in two weeks we will contact you again to find out what you would like to do. A copy of the consent form is enclosed with this letter for you to keep.

The Human Research Ethics Committees of Royal Perth Hospital and the University of Newcastle have approved this study. The information published from this research will not contain your name or identify you in any way.

To find out more details about this request please call Tara Clinton-McHarg at the University of Newcastle on 02 49138187 or email tara.clinton-mcharg@newcastle.edu.au.

If receiving this letter has raised any questions or concerns about cancer and you would like to speak to a professional counsellor please call the Cancer Helpline on Free Call 13 11 20.

Thank you for considering this request.
Yours sincerely

Dr Julian Cooney
Consultant Haematologist

Appendix 5.13: Invitation letter, project information sheet and "do not contact" form from The Alfred Hospital

Version 2 13/03/2009 84/09

26 July 2010

FirstName LastName
Address 1
Suburb State Postcode

Development and psychometric evaluation of two measures of perceived need: one for young people with cancer; one for carers

Dear FirstName and Family,

I am writing to see if you would be willing to take part in a research study on the needs of young people diagnosed with cancer and the needs of their carers. Researchers at the University of Newcastle have developed a questionnaire to assess these needs.

Records at The Alfred Hospital indicate that you were diagnosed with cancer between the ages of 14 and 25 years. **Would you be willing for The Alfred Hospital to pass on your contact details to the research team so that they can write to you and invite you to participate in this study?**

If you decide to participate your contribution will assist researchers to identify the specific needs of young people with cancer and their carers. Gathering this information will allow clinicians and researchers to design interventions and inform health services in order to more effectively meet these needs. I have enclosed an information sheet (blue) prepared by the researchers describing the study and what you would be asked to do if you take part.

Please read through the information sheet together and discuss it. **If you are willing to be contacted by the researchers, you do not have to do anything.** The researchers will contact you with some more specific information about the study in four weeks time. Receiving this information does **NOT** mean you are agreeing to take part in the study.

If you do not wish to be contacted by the researchers, please complete and sign the attached 'Do not contact' form (yellow) as soon as possible. A copy of the 'Do not contact' form is printed on the reverse side of this letter for you to keep. If we have not heard from you in four weeks we will assume that you are willing to be contacted by the researchers and you will be sent some more specific information about the study. Receiving this information does **NOT** mean you are agreeing to take part in the study.

To find out more details about this request please call Tara Clinton-McHarg at the University of Newcastle on 02 49138187 or email tara.clinton-mcharg@newcastle.edu.au.

If receiving this letter has raised any questions or concerns about cancer and you would like to speak to a professional counsellor please call the Cancer Helpline on Free Call 13 11 20.

Thank you for considering this request. We look forward to hearing from you soon.
Yours sincerely

Dr Andrew Wei
Department of Haematology

Participant Information Form
The Alfred Hospital

Project Title: Development and psychometric evaluation of two measures of perceived need: one for young people with cancer; one for carers.

Principal Researchers:

Dr Andrew Wei, Haematologist, The Alfred Hospital

Prof Rob Sanson-Fisher, Professor of Health Behaviour, University of Newcastle

Ms Tara Clinton-McHarg, PhD Candidate, University of Newcastle

1. Introduction

You are invited to take part in this research project because our medical records indicate you are: 1) between the ages of 14-30 years; and 2) have been treated for cancer at The Alfred Hospital in the last 5 years. The research project aims to identify the needs of young people who have been diagnosed with cancer, and the needs of their parents, partners and carers.

This Participant Information Form tells you about the research project. It explains what is involved to help you decide if you want to take part.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or your local health worker.

Participation in this research is voluntary. If you don't wish to take part, you don't have to.

If you decide you want to take part in the research project and you are willing to be contacted by the researchers, you do not have to do anything. The researchers will contact you with some more specific information about the study in four weeks time. Receiving this information does **NOT** mean you are agreeing to take part in the study, only that you agree to receive more information about it.

If you do not wish to be contacted by the researchers, you will be asked to sign the 'Do Not Contact' Form at the end of this information sheet. By signing the 'Do Not Contact' Form, you are indicating that you do not wish to participate in the research project and you will not receive any further information about the study.

This copy of the Participant Information Form is for you to keep.

2. What is the purpose of this research project?

The purpose of this project is to identify the needs of young people with cancer, and the needs of their parents, partners and carers.

In order to improve the care provided to young people who have been diagnosed with cancer, it is important to ask them what they see as their main areas of need and to find out which of those needs they would most like help with. Since parents, partners and carers of these young people are also affected, it is important to ask them what their needs are too.

Two questionnaires have been developed: one for young people who have experienced cancer and the other for parents, partners, and carers of young people who have experienced cancer. These questionnaires will be sent to approximately 200 young people across Australia, and 200 parents, partners and carers so that we can identify the most common needs. This is a National study involving Hospitals in Victoria, New South Wales, Queensland, South Australia and Western Australia.

This research is being conducted by researchers at The Alfred Hospital (Dr Andrew Wei) and the University of Newcastle (Prof Rob Sanson-Fisher and Ms Tara Clinton-McHarg). The results of this research will be used by Ms Clinton-McHarg to obtain her PhD. This research has been funded by the National Health and Medical Research Council of Australia (NHMRC).

3. What does participation in this research project involve?

If you agree to take part in this research, you will be contacted by the researchers and invited to complete a questionnaire. The questionnaire will take approximately 20 minutes to complete, and asks about needs related to your daily life, emotions, relationships, information, treatment, work, and study. The questionnaire also includes items which assess its acceptability to young people with cancer and their carers.

Participants will be allocated to one of two groups. One group of participants will be sent a pen and paper version of the questionnaire. The other group will be emailed an online, web-based version of the questionnaire. A computer will allocate each participant into a group randomly, like the flip of a coin. Neither the researchers nor the participant will decide which version of the questionnaire each participant receives. In order to evaluate the test-retest reliability of the questionnaire, approximately half of the participants will be asked to complete the same survey again one week later. In order to send you a questionnaire, the research team will ask for your mail and email contact details.

You will not be paid for your participation in this project.

4. What are the possible benefits?

We cannot guarantee or promise that you will receive any personal benefits from participating in this study. However, 94% of cancer patients who took part in another cancer needs study indicated they appreciated the opportunity to comment on their cancer experience.

Findings of this research will be used to improve health care for young people who have experienced cancer and their parents, partners and carers.

5. What are the possible risks?

There are no known risks to you from being involved in this study. If you become upset or distressed as a result of your participation in the research, the researchers encourage you to call the following people who can support you:

→ Your local GP

→ The Cancer Council Helpline – Free Call 131 120

→ CanTeen – Free Call 1800 226 833

6. Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at a later stage.

If you decide to leave the project after you have returned your questionnaire, the researchers would like to keep any data that has already been collected. This is to help them make sure that the results of the research can be measured properly. If you do not want them to do this, you must tell them before you withdraw from the research project.

Your decision whether to take part or not, or to take part and then withdraw, will not affect your relationship with the researchers or The Alfred Hospital.

7. How will I be informed of the final results of this research project?

If you wish to obtain a final copy of the research report describing the results of this study, please tell the researchers and they will arrange for one to be sent to you. Results of the study will be published in professional journals, and presented at conferences and other professional forums. Results will also form part of Ms Tara Clinton-McHarg's PhD thesis.

8. What will happen to information about me?

Any information obtained in connection with this research project that can identify you will remain confidential and will only be used for the purpose of this research project. It will only be disclosed with your permission, except as required by law.

Of the people treating you, only the researchers named above will know whether or not you are participating in this study. All of your personal information will be coded so that you cannot be identified by name, and only the research team will have access to the master list that will link your name with your data. All information will be stored in a locked filing cabinet and password protected files at the University of Newcastle, and will be disposed of as confidential waste after 7 years.

In any publication and/or presentation, information will be provided in such a way that you cannot be identified.

9. Can I access research information kept about me?

In accordance with relevant Australian and Victorian privacy and other relevant laws, you have the right to access the information collected and stored by the researchers about you. Please contact one of the researchers named at the end of this document if you would like to access your information.

Further, in accordance with regulatory guidelines, the information collected in this research project will be kept for at least 7 years. You must be aware that the information may become de-identified at some point and access to information about you after this point will not be possible.

10. Is this research project approved?

The ethical aspects of this research project have been approved by the Human Research Ethics Committee of The Alfred Hospital and the University of Newcastle.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)* produced by the National Health and Medical Research Council of Australia. This statement has been developed to protect the interests of people who agree to participate in human research studies.

11. Consent

If you are willing to be contacted by the researchers, <u>you do not have to do anything</u>. The researchers will contact you with some more specific information about the study in four weeks time. Receiving this information does **NOT** mean you are agreeing to take part in the study, only that you agree to receive more information about it.

If you do not wish to be contacted by the researchers, <u>please sign the 'Do Not Contact' Form at the end of this information sheet</u>. By signing the 'Do Not Contact' Form, you are indicating that you do not wish to participate in the research project and you will not receive any further information about the study.

12. Who can I contact?

The person you may need to contact will depend on the nature of your query. Therefore, please note the following:

For further information:

If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project, you can contact the principal researcher **Dr Andrew Wei** on **(03) 90762828** or any of the following people:

Name: **Ms Tara Clinton-McHarg**

Role: **Project Coordinator**

Telephone: **(02) 49138187**

For complaints:

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Name: **Rowan Frew**

Position: **Ethics Manager**

Telephone: **(03) 90763848**

'DO NOT CONTACT' Form

Project Title: Development and psychometric evaluation of two measures of perceived need: one for young people with cancer; one for carers.

I do not wish to be contacted by the research team or receive further information about this study.

To be completed by the young person diagnosed with cancer aged 14 years and over

Name _____ Date of Birth _____ Male/Female

Address _____

Signature _____ **Date:** _____

The following questions are optional. You do not I do not have to answer them, however it will help our research if you could tell us something about yourself. Your answers are important because they will allow us to know more about the people we are trying to assist.

1. I do not wish to take part in this research at this time because:

- ☐ I am too busy
- ☐ I am not feeling well enough
- ☐ I never take part in research
- ☐ I just took part in research like this
- ☐ I don't like to talk or be reminded about cancer
- ☐ I consider myself cured of cancer
- ☐ Other: _____

2. What type of cancer were you FIRST diagnosed with?

*Please write*_____

3. When were you FIRST diagnosed with cancer?

_____/_____
Month Year

THANK YOU FOR YOUR HELP

Please return this form in the reply-paid envelope provided.

Appendix 5.14: Invitation letter, project information sheet and "do not contact" form from Peter MacCallum Cancer Centre

Letter of Invitation From Peter MacCallum Cancer Centre – Version 2 – 28/09/2009

Peter MacCallum Cancer Centre Logo

26 July 2010

FirstName LastName
Address 1
Suburb State Postcode

Cancer in Young Adulthood – Identifying Needs

Dear FirstName and Family,

I am writing to see if you would be willing to take part in a research study on the needs of young people diagnosed with cancer and the needs of their carers. Researchers at the University of Newcastle have developed a questionnaire to assess these needs.

Records at Peter MacCallum Cancer Centre indicate that FirstName LastName had their first inpatient visit to the Peter MacCallum Cancer Centre or their first referral to OnTrac@PeterMac between the ages of 14 and 25 years. **Would you be willing for Peter MacCallum Cancer Centre to pass on your contact details to the research team so that they can write to you and invite you to participate in this study?**

If you decide to participate your contribution will assist researchers to identify the specific needs of young people with cancer and their carers. Gathering this information will allow clinicians and researchers to design interventions and inform health services in order to more effectively meet these needs. I have enclosed an information sheet (blue) prepared by the researchers describing the study and what you would be asked to do if you take part.

Please read through the information sheet together and discuss it. **If you are willing to be contacted by the researchers, you do not have to do anything.** The researchers will contact you with some more specific information about the study in four weeks time. Receiving this information does **NOT** mean you are agreeing to take part in the study.

If you do not wish to be contacted by the researchers, please complete and sign the attached 'Do not contact' form (yellow) as soon as possible. A copy of the 'Do not contact' form is printed on the reverse side of this letter for you to keep. If we have not heard from you in four weeks we will assume that you are willing to be contacted by the researchers and you will be sent some more specific information about the study. Receiving this information does **NOT** mean you are agreeing to take part in the study.

To find out more details about this request please call Tara Clinton-McHarg at the University of Newcastle on 02 49138187 or email tara.clinton-mcharg@newcastle.edu.au.

If receiving this letter has raised any questions or concerns about cancer and you would like to speak to a professional counsellor please call the Cancer Helpline on Free Call 13 11 20.

Thank you for considering this request. We look forward to hearing from you soon.
Yours sincerely

Kate Thompson
Manager onTrac@PeterMac

PARTICIPANT INFORMATION AND DO NOT CONTACT FORM

Participant Information and Consent Form
Version 3 Dated 20 January 2010 Site: Peter MacCallum Cancer Centre

Project Title: Cancer in Young People – Identifying Needs

Researchers:

Prof Rob Sanson-Fisher, Professor of Health Behaviour, University of Newcastle

Ms Kate Thompson, Manager onTrac@PeterMac, Peter MacCallum Cancer Centre

Ms Tara Clinton-McHarg, PhD Candidate, University of Newcastle

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This Participant Information Form is 5 pages long. Please make sure you have all the pages.

1. Your Consent

You are invited to take part in this research project because you have been diagnosed with cancer.

This Participant Information Form contains detailed information about the research project. Its purpose is to explain to you as openly and clearly as possible all the procedures involved in this project before you decide whether or not to take part in it.

Please read this Participant Information Form carefully. Feel free to ask questions about any information in the document. You may also wish to discuss the project with a relative or friend, or your local health worker. Feel free to do this.

Once you understand what the project is about and **if you are willing to be contacted by the researchers, you do not have to do anything.** Peter MacCallum Cancer Centre will pass on your contact details (name, address, email address and phone number) to the researchers and they will contact you and your parents/carers with some more specific information about the study in four weeks time. Receiving this information does **NOT** mean you are agreeing to take part in the study, only that you agree to receive more information about it. For privacy reasons, only the parents and carers of young people who agree to be contacted about the research will be eligible to take part in the study.

If you do not wish to be contacted by the researchers, you will be asked to sign the 'Do Not Contact' Form at the end of this information sheet. By signing the 'Do Not Contact' Form, you are indicating that you do not wish to participate in the research project and neither you nor your parents or carers will receive any further information about the study.

2. Purpose and Background

The purpose of this project is to identify the needs of young people with cancer, and the needs of their parents, partners and carers.

In order to improve the care provided to young people who have been diagnosed with cancer, it is important to ask them what they see as their main areas of need and to find out which of those needs they would most like help with. Since parents, partners and

carers of these young people are also affected, it is important to ask them what their needs are too. Two questionnaires have been developed: one for young people who have experienced cancer and the other for parents and carers of young people who have experienced cancer. These questionnaires will be sent to approximately 562 young people and parents and carers so that we can identify the most common needs.

3. Procedures

If you agree to take part in this research, you will be contacted by the researchers and invited to complete a questionnaire. The questionnaire will take approximately 20 minutes to complete, and asks about needs related to your daily life, emotions, relationships, information, treatment, work, and study. The questionnaire also includes items which assess its acceptability to young people with cancer and their parents and carers.

Participants will be allocated to one of two groups. One group of participants will be sent a pen and paper version of the questionnaire. The other group will be emailed an online, web-based version of the questionnaire. A computer will allocate each participant into a group randomly, like the flip of a coin. Neither the researchers nor the participant will decide which version of the questionnaire each participant receives. In order to evaluate the test-retest reliability of the questionnaire, approximately half of the participants will be asked to complete the same survey again one week later.

4. Possible Benefits

We cannot guarantee or promise that you will receive any benefits from participating in this study. However, 94% of cancer patients who took part in another cancer needs study indicated they appreciated the opportunity to comment on their cancer experience.

Findings of this research will be used to improve health care for young people who have experienced cancer and their parents, partners and carers.

5. Possible Risks

There are no known risks to you from being involved in this study. If you have any worries or concerns about anything presented in this Patient Information Form or when completing the questionnaire, the researchers encourage you to call the following people who can support you:

- → Your local GP
- → The Cancer Council Helpline – Free Call 131 120
- → CanTeen – Free Call 1800 226 833

6. Privacy, Confidentiality and Disclosure of Information

As described earlier, participation in this study will involve completing a questionnaire. Of the people treating you, only the researchers named above will know whether or not you are participating in this study. All of your personal information will be coded so that you cannot be identified by name, and only the research team will have access to the master list that will link your name with your data. In this way all information will remain confidential, except as required by law. All information will be stored in a locked filing cabinet and password protected files in the office of the research team, and will be disposed of as confidential waste after 7 years.

We plan to publish group results in professional journals, and present them at conferences and other professional forums. Results will also form part of Ms Tara Clinton-

McHarg's PhD thesis. In any publication or presentation, information will be provided in such a way that you cannot be identified. You will not, for example, be mentioned by name in any future publication of the results.

7. New Information Arising During the Project

During the research project, new information about the risks and benefits of the project may become known to the researchers. If this occurs, you will be told about this new information. This new information may mean that you can no longer participate in this research. If this occurs, the person(s) supervising the research will stop your participation. In all cases, you will be offered all available care to suit your needs.

8. Results of Project

If you wish to obtain a final copy of the research report describing the results of this study, please tell the researcher and she will arrange for one to be sent to you.

9. Further Information or Any Problems

If you require further information or if you have any problems concerning this project (for example, if you feel any distress), you can contact Ms Tara Clinton-McHarg (phone: 02 4913 8187, email: tara.clinton-mcharg@newcastle.edu.au). The researchers responsible for this project are Prof Rob Sanson-Fisher (phone: 02 4913 8169, email: rob.sanson-fisher@newcastle.edu.au), and Ms Kate Thompson (phone: 03 9656 1652, email: kate.thompson@petermac.org).

10. Other Issues

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about your rights as a research participant, then you may contact:

Position: Ethics Co-ordinator

Telephone: (03) 9656 1699

Or

Position: Patient Advocate

Telephone: (03) 9656 1870

You will need to tell the Ethics Co-ordinator or Patient Advocate the name of one of the researchers given in section 9 above.

12. Participation is Voluntary

Participation in any research project is voluntary. If you do not wish to take part you are not obliged to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with Peter MacCallum Cancer Centre.

Before you make your decision, a member of the research team will be available to answer any questions you have about the research project. You can ask for any

information you want. You should consent to participate only after you have had a chance to ask your questions and have received satisfactory answers.

If you decide to withdraw from this project, please notify a member of the research team before you withdraw. This notice will allow that person or the research supervisor to inform you if there are any health risks or special requirements linked to withdrawing.

13. Ethical Guidelines

This project will be carried out according to the *National Statement on Ethical Conduct in Research Involving Humans* (June 1999) produced by the National Health and Medical Research Council of Australia. This statement has been developed to protect the interests of people who agree to participate in human research studies.

The ethical aspects of this research project have been approved by the Human Research Ethics Committee of Peter MacCallum Cancer Centre and the University of Newcastle.

14. Reimbursement for your costs

You will not be paid for your participation in this project.

'DO NOT CONTACT' Form

Version 2 Dated 28 May 2009 Site: Peter MacCallum Cancer Centre

Project Title: Cancer in Young People – Identifying Needs

☐ **I do not wish to be contacted by the research team or receive further information about this study.**

To be completed by the young person diagnosed with cancer aged 14 years and over

Name _____ Date of Birth _____ Male/Female

Address _____

Signature _____ **Date:** _____

The following questions are optional. You do not have to answer them, however it will help our research if you could tell us something about yourself. Your answers are important because they will allow us to know more about the people we are trying to assist.

1. I do not wish to take part in this research at this time because:

- ☐ I am too busy
- ☐ I am not feeling well enough
- ☐ I never take part in research
- ☐ I just took part in research like this
- ☐ I don't like to talk or be reminded about cancer
- ☐ I consider myself cured of cancer
- ☐ Other: _____

2. What type of cancer were you FIRST diagnosed with?

*Please write*_____

3. When were you FIRST diagnosed with cancer?

_____/_____
Month Year

THANK YOU FOR YOUR HELP

Please return this form in the reply-paid envelope provided.

Appendix 5.15: First invitation letter from the researchers at the University of Newcastle

FACULTY OF HEALTH

THE UNIVERSITY OF NEWCASTLE AUSTRALIA

26 July 2010

FirstName LastName
Address 1
Suburb State Postcode

Dear FirstName,

Cancer in Young Adulthood – Identifying Needs

You may recall receiving a letter from HospitalName and consenting to have your contact details forwarded to the University of Newcastle research team. We, the research team, are contacting you now to participate in a research study on the needs of young people diagnosed with cancer during their early life and the needs of their parents and carers.

Participation involves completing a questionnaire. Completing the questionnaire will be considered your consent for our research team to use your responses for our study following strict confidential guidelines. Participation in this study is purely voluntary and entirely your choice. If you decide to participate you can withdraw any time without reason.

The questionnaire asks about physical and emotional health and any needs that you may have, as well as some general background questions. The questionnaire will take approximately 20 minutes to complete.

Please complete the enclosed questionnaire and return it in the reply paid envelope provided.

Thank you for your help in this important research.

Yours Sincerely,

Laureate Professor Rob Sanson-Fisher
Professor of Health Behaviour

T +61 2 4913 8169
F +61 2 4913 8779
Rob.Sanson-Fisher@newcastle.edu.au

Appendix 5.16: Information sheet from the researchers at the University of Newcastle

RESEARCH PROJECT INFORMATION SHEET

Cancer in Young Adulthood – Identifying Needs

What is this research about?
In order to improve the care provided to young people who have experienced cancer, it is important to ask them what they see as their main areas of need and to find out which of those needs they would most like help with. Since parents, partners, and carers of these young people are also affected, it is also important to ask them what their needs are too. To date, this research has involved discussions with young people with cancer, and parents and carers of young people with cancer, in order to develop two questionnaires: one for young people who have experienced cancer and the other for parents and carers of young people who have experienced cancer. These questionnaires are now being sent to a larger number of young people and parents and carers so that we can identify the most common needs. You are being invited to participate by completing the enclosed questionnaire.

How will this project help?
This is one of the first times young people who have experienced cancer and their parents and carers have been directly asked to identify the areas in which they would most like help. Once this information is available, future health care can be made better by addressing the areas of need identified by young people and their parents and carers.

Why should you take part?
If we knew more about the physical, emotional and social issues faced by young people who have experienced cancer, along with the problems they face from treatment, it may be possible to identify ways to improve health care for them and for their parents and carers.

How will you benefit from taking part?
We cannot promise you any personal benefits from taking part. However, 94% of cancer patients who took part in another cancer-related project indicated that they appreciated the opportunity to comment on their cancer experience.

Who is doing the research?
Researchers from the University of Newcastle (Professor Rob Sanson-Fisher), the University of NSW (Dr Anthony Shakeshaft), and the Cancer Council NSW's Centre for Health Research and Psycho-Oncology (Associate Professor Afaf Girgis).

Who is paying for the research?
The National Health and Medical Research Council (NHMRC) of Australia.

Who will take part in the research?
Young people who have experienced cancer, aged 14 to 25 years at diagnosis, and parents, partners, and carers of young people who have experienced cancer. It is entirely your choice whether or not you participate.

Will your information be kept confidential?
Yes. All the information given to researchers will be kept strictly confidential, as per the strict privacy protection rules. Only authorised project staff will have access to the data. Names will not be associated with comments or ideas. Individuals will not be able to be identified, either directly or indirectly, when the results of the project are reported.

You will notice a unique identifying code in the top right hand corner of the questionnaire. The researchers will only use this unique identifying code to check if you return the questionnaire.

Those who agree to participate in this research will continue to receive usual care from their doctor and others. Neither the standard of care that young people receive for their cancer nor your relationship with your doctor will be affected in any way whether you agree to take part or not.

If we do not receive correspondence from you
If we do not receive your completed questionnaire within two weeks we will send you a reminder letter. If we have not received your questionnaire after four weeks, we will contact you by phone as a reminder.

What to do if you no longer want to take part
You may withdraw at any time after you have agreed to take part and you do not have to give a reason for doing so. Your decision will not disadvantage you in any way.

What to do if you are distressed by this information or during this study?
If you are distressed by anything presented in this information sheet or when completing the questionnaire, the researchers encourage you to call any of the following people, all of whom could support you. Please do not hesitate to call:

Your Local GP

Cancer Helpline

Free call on 13 11 20

Canteen

Free call on 1800 226 833

www.canteen.org.au

What if you have a complaint about this research?
If you have concerns about your rights as a participant in this research, or you have a complaint about the manner in which the research is conducted, it may be given to:

1. Professor Rob Sanson-Fisher, University of Newcastle: phone 02 4913 8169; fax 02 4913 8779; or email rob.sanson-fisher@newcastle.edu.au

2. The Human Research Ethics Officer: The Chancellery, The University of Newcastle, University Drive, Callaghan NSW 2308; phone 02 4921 6333; or email Human-Ethics@newcastle.edu.au

Want more information?
If you would like more information before deciding please call Professor Rob Sanson-Fisher: phone 02 4913 8169; fax 02 4913 8779; email rob.sanson-fisher@newcastle.edu.au; or Ms Tara Clinton-McHarg: phone 02 49138187; fax 02 4913 8779; email tara.clinton-mcharg@newcastle.edu.au.

Appendix 5.17: The Cancer Needs Questionnaire – Young People (CNQ–YP)

Y				1

THE UNIVERSITY OF NEWCASTLE AUSTRALIA

CANCER NEEDS SURVEY
YOUNG PEOPLE

We are trying to find better ways to help young people who have had cancer.

To do this we are asking young people about the **physical, psychological, and social needs** that they may have had since their cancer diagnosis.

For each question, please choose the answer that **best describes** your level of need. There are five choices:

No Need	All my needs were met for this issue or this was not a problem for me.
Low Need	I needed a low amount of help with this problem but was not able to get it.
Moderate Need	I needed a moderate amount of help with this problem but was not able to get it.
High Need	I needed a high amount of help with this problem but was not able to get it.
Very High Need	I needed a very high amount of help with this problem but was not able to get it.

There are no right or wrong answers. The survey will take around 20 minutes to complete. Your answers will remain strictly confidential.

For more information about this survey please contact:
Prof Rob Sanson-Fisher, Professor of Health Behaviour, University of Newcastle
email rob.sanson-fisher@newcastle.edu.au, phone 02 4913 8169

Ms Tara Clinton-McHarg, PhD Candidate, University of Newcastle
email, tara.clinton-mcharg@newcastle.edu.au, phone 02 4913 8187

The following questions ask about any needs you may have had **at any time since your cancer diagnosis.**

1. Cancer Treatment Staff

I had the following needs…

BEFORE TREATMENT

	Cancer treatment staff telling me:	No Need	Low Need	Moderate Need	High Need	Very High Need
1	about my diagnosis	○	○	○	○	○
2	what might happen during treatment	○	○	○	○	○
3	about different treatment options	○	○	○	○	○
4	whether I had the option to decline treatment	○	○	○	○	○
5	about the short term side-effects of treatment	○	○	○	○	○
6	about the long term side-effects of treatment	○	○	○	○	○
7	my chances of a full recovery	○	○	○	○	○
8	what would happen when treatment finished	○	○	○	○	○
9	whether I would be able to have children	○	○	○	○	○
10	how treatment might affect my studies or future career	○	○	○	○	○
11	what support services were available	○	○	○	○	○

DURING TREATMENT

	Cancer treatment staff telling me:	No Need	Low Need	Moderate Need	High Need	Very High Need
12	whether my treatment was working	○	○	○	○	○
13	my test results as soon as possible	○	○	○	○	○
14	the way I felt was normal	○	○	○	○	○

I had the following needs…						
AFTER TREATMENT						
	Cancer treatment staff telling me:	**No Need**	**Low Need**	**Moderate Need**	**High Need**	**Very High Need**
15	how to manage my medication	○	○	○	○	○
16	what I could do to stay healthy	○	○	○	○	○
17	what to do if I noticed a particular side-effect	○	○	○	○	○
WHEN TREATMENT FINISHED						
	Missing the:	**No Need**	**Low Need**	**Moderate Need**	**High Need**	**Very High Need**
18	safety of the cancer treatment centre	○	○	○	○	○
19	support of the cancer treatment staff	○	○	○	○	○
THROUGHOUT TREATMENT						
	Having cancer treatment staff who:	**No Need**	**Low Need**	**Moderate Need**	**High Need**	**Very High Need**
20	listened to my concerns	○	○	○	○	○
21	treated me as an individual	○	○	○	○	○
22	were respectful	○	○	○	○	○
23	were approachable	○	○	○	○	○
24	were friendly	○	○	○	○	○
25	could have a laugh with me	○	○	○	○	○
26	explained what they were doing	○	○	○	○	○
27	spoke to me in a way that I could understand	○	○	○	○	○
28	let me talk about my feelings	○	○	○	○	○
29	let me ask questions	○	○	○	○	○
30	let me make decisions about my treatment	○	○	○	○	○
31	talked to me in private, without my family	○	○	○	○	○
32	talked to me and my family together	○	○	○	○	○

2. Cancer Treatment Centre

I had the following needs…						
DURING TREATMENT						
	Being able to:	**No Need**	**Low Need**	**Moderate Need**	**High Need**	**Very High Need**
33	get treatment in my local area	○	○	○	○	○
34	get transport to or from the cancer treatment centre	○	○	○	○	○
35	get overnight accommodation near the cancer treatment centre	○	○	○	○	○
36	see people I care about	○	○	○	○	○
37	spend time with people my own age	○	○	○	○	○
38	talk to people my age who had been through a similar experience	○	○	○	○	○
39	have time to myself	○	○	○	○	○
40	express my feelings	○	○	○	○	○
AT THE CANCER TREATMENT CENTRE						
	Being able to have:	**No Need**	**Low Need**	**Moderate Need**	**High Need**	**Very High Need**
41	privacy	○	○	○	○	○
42	pleasant surroundings	○	○	○	○	○
43	good food	○	○	○	○	○
44	leisure spaces and activities	○	○	○	○	○
45	my family with me	○	○	○	○	○
46	a choice of cancer specialists	○	○	○	○	○
47	the same cancer treatment staff throughout treatment	○	○	○	○	○
48	a choice of times for appointments	○	○	○	○	○
49	enough time to make decisions about my treatment	○	○	○	○	○
50	access to professional counselling	○	○	○	○	○
51	opportunities to take part in research	○	○	○	○	○
52	someone to help me fill out forms	○	○	○	○	○

3. Education

Since my cancer diagnosis, I have had problems enrolling at: *(please choose as many as apply)*	
53	○ school ○ TAFE ○ university/college ○ other place of study *(please write)*_____ ○ none of the above
Since my cancer diagnosis, I have attended: *(please choose as many as apply)*	
54	○ school ○ TAFE ○ university/college ○ other place of study *(please write)*_____ ○ none of the above *(go to Question 64)*

I had the following needs…

WHEN STUDYING

	Being able to:	**No Need**	**Low Need**	**Moderate Need**	**High Need**	**Very High Need**
55	travel to or from my place of study	○	○	○	○	○
56	attend classes	○	○	○	○	○
57	catch up on assignments	○	○	○	○	○
58	get extensions or special consideration	○	○	○	○	○
59	get guidance about study options or future career paths	○	○	○	○	○

WHEN STUDYING

	Knowing:	**No Need**	**Low Need**	**Moderate Need**	**High Need**	**Very High Need**
60	how many classes I would miss	○	○	○	○	○
61	how to ask teachers/students for support	○	○	○	○	○
62	that teachers/students understood my situation	○	○	○	○	○
63	that teachers/students had support to help them cope with my situation	○	○	○	○	○

4. Work

Since my cancer diagnosis, I have had problems finding work: *(please choose as many as apply)*	
64	○ full-time ○ part-time/casual ○ unpaid voluntary work ○ other type of work *(please write)*_____ ○ none of the above
Since my cancer diagnosis, I have been employed: *(please choose as many as apply)*	
65	○ full-time ○ part-time/casual ○ unpaid voluntary work ○ other type of work *(please write)*_____ ○ none of the above (*go to Question 75)*

I had the following needs…

WHEN EMPLOYED

	Being able to:	**No Need**	**Low Need**	**Moderate Need**	**High Need**	**Very High Need**
66	return to work	○	○	○	○	○
67	travel to or from my place of work	○	○	○	○	○
68	attend work	○	○	○	○	○
69	catch up on work	○	○	○	○	○
70	work part-time/casual	○	○	○	○	○

WHEN EMPLOYED

	Knowing:	**No Need**	**Low Need**	**Moderate Need**	**High Need**	**Very High Need**
71	how much work I would miss	○	○	○	○	○
72	how to ask managers/co-workers for support	○	○	○	○	○
73	that managers/co-workers understood my situation	○	○	○	○	○
74	that managers/co-workers had support to help them cope with my situation	○	○	○	○	○

5. Information

I had the following needs…						
SINCE MY CANCER DIAGNOSIS						
	Finding information that:	**No Need**	**Low Need**	**Moderate Need**	**High Need**	**Very High Need**
75	was specifically designed for me	○	○	○	○	○
76	was easy to understand	○	○	○	○	○
77	was easy to get hold of	○	○	○	○	○
78	I could trust	○	○	○	○	○
79	came in different forms (brochure, CD, DVD, online)	○	○	○	○	○
80	talked about feelings or emotions	○	○	○	○	○
81	described relaxation techniques	○	○	○	○	○

The next group of questions ask about any needs you may have had **in the last month.**

We realise that your needs may have changed during different stages of your cancer experience. Please only tell us about needs you have had in the last month. If you have not had any needs in the last month, please select 'No Need'.

6. Feelings

I had the following needs…						
IN THE LAST MONTH						
	Feeling:	**No Need**	**Low Need**	**Moderate Need**	**High Need**	**Very High Need**
82	scared	○	○	○	○	○
83	bored	○	○	○	○	○
84	frustrated	○	○	○	○	○
85	helpless	○	○	○	○	○
86	anxious or nervous	○	○	○	○	○
87	distressed	○	○	○	○	○
88	embarrassed	○	○	○	○	○
89	sad or depressed	○	○	○	○	○
90	lonely	○	○	○	○	○
IN THE LAST MONTH						
	Worrying about:	**No Need**	**Low Need**	**Moderate Need**	**High Need**	**Very High Need**
91	my cancer spreading	○	○	○	○	○
92	my cancer returning	○	○	○	○	○
93	whether my cancer treatment has worked	○	○	○	○	○
94	going to the cancer treatment centre	○	○	○	○	○
95	having cancer treatment	○	○	○	○	○
96	test results	○	○	○	○	○
97	how my family is coping	○	○	○	○	○

I had the following needs…						
IN THE LAST MONTH						
	Finding:	**No Need**	**Low Need**	**Moderate Need**	**High Need**	**Very High Need**
98	inner strength	○	○	○	○	○
99	hope	○	○	○	○	○
100	meaning in my experience	○	○	○	○	○
101	enjoyment in life	○	○	○	○	○
IN THE LAST MONTH						
	Coping with:	**No Need**	**Low Need**	**Moderate Need**	**High Need**	**Very High Need**
102	changes in my physical ability	○	○	○	○	○
103	changes in my appearance	○	○	○	○	○
104	changes to me as a person	○	○	○	○	○
105	other people's reactions to me	○	○	○	○	○
106	friends passing away	○	○	○	○	○
107	not being able to do the same things as other people my age	○	○	○	○	○
IN THE LAST MONTH						
	Being able to:	**No Need**	**Low Need**	**Moderate Need**	**High Need**	**Very High Need**
108	focus on tasks	○	○	○	○	○
109	remember things	○	○	○	○	○
110	make plans or think about the future	○	○	○	○	○
111	accept changes to my future	○	○	○	○	○
112	accept my diagnosis	○	○	○	○	○
113	be independent	○	○	○	○	○

7. Relationships

I had the following needs…						
IN THE LAST MONTH						
	Coping with:	**No Need**	**Low Need**	**Moderate Need**	**High Need**	**Very High Need**
114	changes in my relationships with my parent/s	○	○	○	○	○
115	my parent/s giving me too much attention	○	○	○	○	○
116	my parent/s not giving me enough attention	○	○	○	○	○
117	my parent/s being overprotective	○	○	○	○	○
IN THE LAST MONTH						
	Knowing how to:	**No Need**	**Low Need**	**Moderate Need**	**High Need**	**Very High Need**
118	ask my parent/s for support	○	○	○	○	○
119	give support to my parent/s	○	○	○	○	○
IN THE LAST MONTH						
	Coping with:	**No Need**	**Low Need**	**Moderate Need**	**High Need**	**Very High Need**
120	changes in my relationships with my friends	○	○	○	○	○
121	not being able to see my friends	○	○	○	○	○
IN THE LAST MONTH						
	Knowing how to:	**No Need**	**Low Need**	**Moderate Need**	**High Need**	**Very High Need**
122	ask my friends for support	○	○	○	○	○
123	give support to my friends	○	○	○	○	○

124	**Do you have:** *(please choose as many as apply)* ○ a spouse/partner or boyfriend/girlfriend *(please answer Questions 125-130)* ○ sibling/s or step-brothers/sisters *(please answer Questions 131-133)* ○ none of the above *(go to Question 134)*

I had the following needs…

IN THE LAST MONTH

	Coping with:	**No Need**	**Low Need**	**Moderate Need**	**High Need**	**Very High Need**
125	changes in my relationship with my partner	○	○	○	○	○
126	my partner giving me too much attention	○	○	○	○	○
127	my partner not giving me enough attention	○	○	○	○	○
128	my partner being overprotective	○	○	○	○	○

IN THE LAST MONTH

	Knowing how to:	**No Need**	**Low Need**	**Moderate Need**	**High Need**	**Very High Need**
129	ask my partner for support	○	○	○	○	○
130	give support to my partner	○	○	○	○	○

IN THE LAST MONTH

	Coping with:	**No Need**	**Low Need**	**Moderate Need**	**High Need**	**Very High Need**
131	changes in my relationships with my sibling/s	○	○	○	○	○

IN THE LAST MONTH

	Knowing how to:	**No Need**	**Low Need**	**Moderate Need**	**High Need**	**Very High Need**
132	ask my sibling/s for support	○	○	○	○	○
133	give support to my sibling/s	○	○	○	○	○

8. Daily Life

I had the following needs…						
IN THE LAST MONTH						
	Managing:	**No Need**	**Low Need**	**Moderate Need**	**High Need**	**Very High Need**
134	pain	○	○	○	○	○
135	medication	○	○	○	○	○
136	physical side effects of treatment	○	○	○	○	○
137	feeling tired	○	○	○	○	○
138	loss of mobility	○	○	○	○	○
139	to sleep	○	○	○	○	○
140	to do chores/housework	○	○	○	○	○
141	to eat	○	○	○	○	○
142	to take part in social activities	○	○	○	○	○
143	to travel to social events	○	○	○	○	○
144	to maintain a normal life	○	○	○	○	○
145	**Compared to other months since my cancer diagnosis, <u>my overall level of need last month</u> was:** *(please choose one answer only)* ○ much higher than usual ○ a little higher than usual ○ the same as usual ○ a little lower than usual ○ much lower than usual					

Now we would like to ask you some questions about this survey.

Answering these questions will help us make a shorter and better version of the survey in the future.

When completing the survey I found the:		Strongly Disagree	Disagree	Unsure	Agree	Strongly Agree
146	instructions easy to follow	○	○	○	○	○
147	questions clear	○	○	○	○	○
148	answer choices easy to understand	○	○	○	○	○
149	questions distressing	○	○	○	○	○

Compared to paper surveys, web-based surveys are:		Strongly Disagree	Disagree	Unsure	Agree	Strongly Agree
150	easier to complete	○	○	○	○	○
151	easier to restart if you get interrupted	○	○	○	○	○
152	more convenient because I don't have to post them back	○	○	○	○	○
153	less likely to get lost	○	○	○	○	○
154	more private when completing	○	○	○	○	○

I would prefer to complete this survey:		Strongly Disagree	Disagree	Unsure	Agree	Strongly Agree
155	online using a web-based survey	○	○	○	○	○
156	at the cancer treatment centre while receiving treatment	○	○	○	○	○
157	at the cancer treatment centre when going for check-ups	○	○	○	○	○
158	at my GP's surgery	○	○	○	○	○
159	at home	○	○	○	○	○

In the future, the results of this survey could be fed back to:		Strongly Disagree	Disagree	Unsure	Agree	Strongly Agree
160	cancer treatment staff to inform better care for individuals	○	○	○	○	○
161	cancer treatment centres to inform better care for groups of patients	○	○	○	○	○
162	researchers to increase knowledge and design interventions	○	○	○	○	○
163	funding organisations to inform priority areas for research	○	○	○	○	○
164	**How many hours per week do you spend on a computer: :** *(please choose one answer only)* ○ less than 2 hours ○ 2 – 8 hours ○ more than 8 hours					
165	**Where did you complete this survey:** *(please choose one answer only)* ○ at home ○ at work ○ at school/TAFE/university ○ at the cancer treatment centre ○ at a friend's place ○ other *(please write)*_____					

Finally, we would like to know some information about you.

This information will help us understand whether some young people have the same needs. The information you provide is strictly confidential and you will not be identified.

166	**What is your date of birth?** ___ ___/___ ___/___ ___ ___ ___ dd mm yyyy
167	**What is your gender?** ○ Female ○ Male
168	**What is your current marital status?** ○ married or living with partner ○ partner, not living together ○ single ○ separated or divorced ○ widowed ○ other
169	**When were you first diagnosed with cancer?** ___ ___/___ ___ ___ ___ mm yyyy
170	**What type of cancer were you first diagnosed with?** *(please write)*_____
171	**Have you ever had a recurrence or a second cancer diagnosis?** *Please choose one answer only* ○ no *(go to Question 173)* ○ not sure *(go to Question 173)* ○ yes, same cancer ○ yes, new cancer *(please write)*_____

172	**When was your most recent cancer diagnosis?** ___ ___/___ ___ ___ ___ mm yyyy
173	**Have you received treatment at:** *Please choose one answer only* O a children's hospital/cancer treatment centre O an adult hospital/cancer treatment centre O both O none of the above
174	**Which treatment(s) have you received for your cancer?** *Please choose as many answers as apply* O surgery O chemotherapy O radiotherapy O hormone treatment O antibody treatment O bone marrow O stem cell transplant O none O not sure O other ***(please write)***_____
175	**What stage are you up to in your cancer care?** *Please choose one answer only* O recently diagnosed, not started treatment O receiving treatment O finished treatment and having check-ups O cured or in remission O not sure O other ***(please write)***_____

176	**What language do you prefer to speak?** *Please choose one answer only* ○ English ○ other ***(please write)***_____
177	**Do you live:** *Please choose as many answers as apply* ○ with your parent(s) ○ with your spouse or partner ○ with other family members ○ with flatmates ○ alone ○ other ***(please write)***_____
178	**What is the highest level of schooling you have <u>completed</u>?** *Please choose one answer only* ○ University degree ○ TAFE or trade certificate or diploma ○ Year 12 or Higher School Certificate ○ Year 10 or School Certificate ○ Primary School ○ Other ***(please write)***_____
179	**Would you be willing to complete this survey again in the future?** ○ yes, I am happy to be contacted again ○ no, I would not like to be contacted again

YOU HAVE NOW COMPLETED THE SURVEY
THANK YOU FOR YOUR TIME AND HELP

Comments

If you have any comments about this survey or any ideas about how it could be better, we would love to hear them. Please write your comments here.

If you are feeling any distress or have any questions about your cancer, please call the following people who can support you:

→ **Your local GP**

→ **The Cancer Council Helpline – Local Call 13 11 20**

The Cancer Council Helpline is a free, confidential telephone information and support service for cancer patients, people living with cancer, their families, carers and friends. Specially trained staff are available to answer your questions about cancer and offer emotional or practical support www.cancer.org.au

→ **CanTeen – Free Call 1800 226 833**

CanTeen is the national support organisation for young people (aged 12-24) living with cancer www.canteen.org.au

Appendix 5.18: Reminder letter from the researchers at the University of Newcastle

FACULTY OF HEALTH

THE UNIVERSITY OF NEWCASTLE AUSTRALIA

26 July 2010

FirstName LastName
Address 1
Suburb State Postcode

Dear FirstName,

Cancer in Young Adulthood – Identifying Needs

You may recall receiving a letter from me a few weeks ago inviting you to participate in a research study on the needs of young people diagnosed with cancer and the needs of their parents and carers. Along with the letter I had also enclosed an information sheet and a questionnaire. As I have not yet received your completed questionnaire, I am writing to you again.

If you have already completed the questionnaire I would like to thank you very much for your participation. If you have not completed the questionnaire but would still like to participate, I would like to invite you to take part again.

Participation involves completing a questionnaire. Completing the questionnaire will be considered your consent for our research team to use your responses for our study following strict confidential guidelines. Participation in this study is purely voluntary and entirely your choice. If you decide to participate you can withdraw any time without reason.

The questionnaire asks about physical and emotional health and any needs that you may have, as well as some general background questions. The questionnaire will take approximately 20 minutes to complete.

Please complete the enclosed questionnaire and return it in the reply paid envelope provided.

Thank you for considering this invitation.

Yours Sincerely,

Laureate Professor Rob Sanson-Fisher
Professor of Health Behaviour

T +61 2 4913 8169
F +61 2 4913 8779
Rob.Sanson-Fisher@newcastle.edu.au

Appendix 5.19: Re-test letter from the researchers at the University of Newcastle

FACULTY OF HEALTH

THE UNIVERSITY OF NEWCASTLE AUSTRALIA

26 July 2010

FirstName LastName
Address 1
Suburb State Postcode

Dear FirstName,

Cancer in Young Adulthood – Identifying Needs

Thank you for completing the Cancer Needs Questionnaire. You are being invited to complete the questionnaire on the needs of young people diagnosed with cancer and the needs of their parents and carers a second time. The purpose of this is to ensure that the questions are suitable for people who will use the questionnaire in the future.

The idea is that if, after about one week, the same person answers the same questions in the same way, then we can be more confident that the questions make sense. The selection process for being invited to complete the questions a second time is random (by chance), so everyone who completes the questionnaire has an equal chance of being invited to answer the questions a second time.

As before, I have enclosed an information sheet and a questionnaire. If you would like to participate in the research again, please complete the questionnaire. Returning the completed questionnaire will be considered your consent for our research team to use your responses for our study following strict confidential guidelines.

Participation in this study again is purely voluntary and entirely your choice. If you decide to participate you can withdraw any time without reason.

Please complete the enclosed questionnaire and return it in the reply paid envelope provided.

Thank you for considering this invitation.

Yours Sincerely,

Laureate Professor Rob Sanson-Fisher
Professor of Health Behaviour

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Rob.Sanson-Fisher@newcastle.edu.au

Appendix 5.20: Proportion of responses at each level of need, and proportion of missing values, for each item

		No Need n (%)	Low Need n (%)	Moderate Need n (%)	High Need n (%)	Very High Need n (%)	Missing Values* n (%)
CANCER TREATMENT STAFF (n=139)							
Before treatment − cancer treatment staff telling me:							
1	about my diagnosis	76 (55)	26 (19)	12 (8.7)	12 (8.7)	12 (8.7)	1 (0.7)
2	what might happen during treatment	81 (59)	24 (17)	8 (5.8)	10 (7.3)	15 (11)	1 (0.7)
3	about different treatment options	73 (53)	27 (20)	15 (11)	9 (6.6)	13 (9.5)	2 (1.4)
4	whether I had the option to decline treatment	94 (68)	19 (14)	12 (8.7)	4 (2.9)	9 (6.5)	1 (0.7)
5	about the short-term side-effects of treatment	83 (60)	23 (17)	13 (9.4)	8 (5.8)	11 (8.0)	1 (0.7)
6	about the long-term side-effects of treatment	55 (40)	32 (23)	25 (18)	9 (6.5)	17 (12)	1 (0.7)
7	my chances of a full recovery	75 (54)	21 (15)	14 (10)	10 (7.3)	18 (13)	1 (0.7)
8	what would happen when treatment finished	59 (43)	31 (23)	20 (15)	15 (11)	12 (8.8)	2 (1.4)
9	whether I would be able to have children	65 (48)	23 (17)	16 (12)	12 (8.8)	20 (15)	3 (2.2)
10	how treatment might affect my studies or future career	69 (50)	27 (20)	23 (17)	7 (5.1)	12 (8.7)	1 (0.7)
11	what support services were available	70 (51)	26 (19)	22 (16)	8 (5.8)	12 (8.7)	1 (0.7)
During treatment − cancer treatment staff telling me:							
12	whether my treatment was working	85 (62)	21 (15)	13 (9.4)	7 (5.1)	12 (8.7)	1 (0.7)
13	my test results as soon as possible	92 (67)	18 (13)	6 (4.4)	5 (3.6)	17 (12)	1 (0.7)
14	the way I felt was normal	83 (60)	24 (17)	8 (5.8)	13 (9.4)	10 (7.3)	1 (0.7)
After treatment − cancer treatment staff telling me:							
15	how to manage my medication	97 (71)	14 (10)	11 (8.1)	11 (8.1)	3 (2.2)	3 (2.2)
16	what I could do to stay healthy	72 (53)	22 (16)	19 (14)	12 (8.8)	11 (8.1)	3 (2.2)
17	what to do if I noticed a particular side-effect	76 (56)	25 (18)	19 (14)	6 (4.4)	10 (7.4)	3 (2.2)
When treatment finished − missing the:							
18	safety of the cancer treatment centre	77 (57)	34 (25)	9 (6.7)	8 (6.0)	6 (4.5)	5 (3.6)
19	support of the cancer treatment staff	70 (52)	36 (27)	15 (11)	8 (5.9)	6 (4.4)	4 (2.9)
Throughout treatment − having cancer treatment staff who:							
20	listened to my concerns	89 (65)	12 (8.8)	14 (10)	14 (10)	7 (5.2)	3 (2.2)
21	treated me as an individual	91 (67)	9 (6.7)	12 (8.9)	10 (7.4)	13 (9.6)	4 (2.9)
22	were respectful	99 (73)	12 (8.8)	5 (3.7)	12 (8.8)	8 (5.9)	3 (2.2)
23	were approachable	96 (71)	10 (7.4)	10 (7.4)	9 (6.6)	11 (8.1)	3 (2.2)
24	were friendly	102 (75)	8 (5.9)	11 (8.1)	6 (4.4)	9 (6.6)	3 (2.2)
25	could have a laugh with me	96 (71)	12 (8.8)	13 (9.6)	8 (5.9)	7 (5.2)	3 (2.2)
26	explained what they were doing	89 (65)	15 (11)	13 (9.6)	7 (5.2)	12 (8.8)	3 (2.2)
27	spoke to me in a way that I could understand	95 (70)	14 (10)	7 (5.2)	9 (6.6)	11 (8.1)	3 (2.2)
28	let me talk about my feelings	83 (61)	19 (14)	22 (16)	6 (4.4)	6 (4.4)	3 (2.2)
29	let me ask questions	96 (71)	13 (9.6)	5 (3.7)	9 (6.6)	13 (9.6)	3 (2.2)
30	let me make decisions about my treatment	77 (57)	27 (20)	12 (8.8)	5 (3.7)	15 (11)	3 (2.2)
31	talked to me in private, without my family	93 (68)	23 (17)	7 (5.2)	6 (4.4)	7 (5.2)	3 (2.2)
32	talked to me and my family together	106 (78)	8 (5.9)	9 (6.6)	6 (4.4)	7 (5.2)	3 (2.2)
CANCER TREATMENT CENTRE (n=139)							
During treatment − being able to:							
33	get treatment in my local area	77 (56)	17 (12)	25 (18)	9 (6.5)	10 (7.3)	1 (0.7)
34	get transport to or from the cancer treatment centre	93 (67)	22 (16)	11 (8.0)	4 (2.9)	8 (5.8)	1 (0.7)
35	get overnight accommodation near the cancer treatment centre	115 (83)	8 (5.8)	7 (5.1)	2 (1.5)	6 (4.4)	1 (0.7)
36	see people I care about	103 (74)	12 (8.6)	9 (6.5)	7 (5.0)	8 (5.8)	0 (0.0)
37	spend time with people my own age	63 (46)	17 (12)	24 (17)	10 (7.3)	24 (17)	1 (0.7)
38	talk to people my age who had been through a similar experience	44 (32)	36 (26)	23 (17)	14 (10)	22 (16)	0 (0.0)
39	have time to myself	81 (58)	24 (17)	17 (12)	6 (4.3)	11 (7.9)	0 (0.0)
40	express my feelings	83 (60)	20 (14)	21 (15)	7 (5.0)	8 (5.8)	0 (0.0)
At the cancer treatment centre − being able to have:							
41	privacy	65 (47)	23 (17)	22 (16)	13 (9.4)	16 (12)	0 (0.0)
42	pleasant surroundings	56 (40)	21 (15)	33 (24)	14 (10)	15 (11)	0 (0.0)
43	good food	42 (30)	18 (13)	26 (19)	21 (15)	31 (22)	1 (0.7)
44	leisure spaces and activities	54 (39)	25 (18)	23 (17)	12 (8.8)	23 (17)	2 (1.4)
45	my family with me	108 (78)	6 (4.3)	8 (5.8)	9 (6.5)	8 (5.8)	0 (0.0)
46	a choice of cancer specialists	82 (59)	20 (14)	18 (13)	9 (6.5)	9 (6.5)	1 (0.7)
47	the same cancer treatment staff throughout treatment	83 (60)	18 (13)	12 (8.6)	11 (7.9)	15 (11)	0 (0.0)

		No Need n (%)	Low Need n (%)	Moderate Need n (%)	High Need n (%)	Very High Need n (%)	Missing Values* n (%)
At the cancer treatment centre − being able to have:							
48	a choice of times for appointments	86 (62)	18 (13)	17 (12)	6 (4.3)	12 (8.6)	0 (0.0)
49	enough time to make decisions about my treatment	87 (63)	18 (13)	15 (11)	10 (7.2)	9 (6.5)	0 (0.0)
50	access to professional counselling	81 (58)	21 (15)	20 (14)	9 (6.5)	8 (5.8)	0 (0.0)
51	opportunities to take part in research	94 (68)	14 (10)	17 (12)	5 (3.6)	9 (6.5)	0 (0.0)
52	someone to help me fill out forms	110 (80)	12 (8.7)	8 (5.8)	5 (3.6)	3 (2.2)	1 (0.7)
EDUCATION (n=83)							
When studying − being able to:							
55	travel to or from my place of study	54 (68)	10 (13)	3 (3.8)	5 (6.3)	7 (8.9)	4 (4.8)
56	attend classes	45 (56)	9 (11)	13 (16)	7 (8.6)	7 (8.6)	2 (2.4)
57	catch up on assignments	47 (58)	8 (9.9)	12 (15)	7 (8.6)	7 (8.6)	2 (2.4)
58	get extensions or special consideration	54 (67)	10 (12)	7 (8.6)	5 (6.2)	5 (6.2)	2 (2.4)
59	get guidance about study options or future career paths	45 (56)	12 (15)	10 (12)	8 (9.9)	6 (7.4)	2 (2.4)
When studying − knowing:							
60	how many classes I would miss	46 (58)	15 (19)	10 (13)	2 (2.5)	7 (8.8)	3 (3.6)
61	how to ask teachers/students for support	49 (61)	9 (11)	13 (16)	3 (3.8)	6 (7.5)	3 (3.6)
62	that teachers/students understood my situation	44 (55)	9 (11)	13 (16)	5 (6.3)	9 (11)	3 (3.6)
63	that teachers/students had support to help them cope	44 (55)	12 (15)	14 (18)	3 (3.8)	7 (8.8)	3 (3.6)
WORK (n=115)							
When employed − being able to:							
66	return to work	76 (68)	11 (9.8)	10 (8.9)	9 (8.0)	6 (5.4)	3 (2.6)
67	travel to or from my place of work	84 (74)	12 (11)	8 (7.1)	6 (5.3)	3 (2.7)	2 (1.7)
68	attend work	74 (66)	15 (13)	7 (6.3)	8 (7.1)	8 (7.1)	3 (2.6)
69	catch up on work	86 (77)	8 (7.1)	7 (6.3)	8 (7.1)	3 (2.7)	3 (2.6)
70	work part-time/casual	81 (72)	9 (8.0)	12 (11)	5 (4.4)	6 (5.3)	2 (1.7)
When employed − knowing:							
71	how much work I would miss	60 (54)	24 (22)	17 (15)	4 (3.6)	6 (5.4)	4 (3.5)
72	how to ask managers/co-workers for support	75 (67)	16 (14)	9 (8.0)	7 (6.3)	5 (4.5)	3 (2.6)
73	that managers/co-workers understood my situation	69 (62)	16 (14)	14 (13)	6 (5.4)	7 (6.3)	3 (2.6)
74	that managers/co-workers had support to help them cope	68 (61)	22 (20)	11 (9.9)	4 (3.6)	6 (5.4)	4 (3.5)
INFORMATION (n=139)							
Since my cancer diagnosis − finding information that:							
75	was specifically designed for me	39 (28)	32 (23)	25 (18)	19 (14)	22 (16)	2 (1.4)
76	was easy to understand	63 (46)	33 (24)	17 (13)	13 (9.6)	10 (7.4)	3 (2.2)
77	was easy to get hold of	57 (42)	27 (20)	27 (20)	15 (11)	10 (7.4)	3 (2.2)
78	I could trust	62 (46)	30 (22)	19 (14)	10 (7.4)	15 (11)	3 (2.2)
79	came in different forms (brochure, CD, DVD, online)	66 (49)	32 (24)	15 (11)	6 (4.5)	15 (11)	5 (3.6)
80	talked about feelings or emotions	63 (46)	32 (24)	20 (15)	9 (6.6)	12 (8.8)	3 (2.2)
81	described relaxation techniques	61 (45)	33 (24)	17 (13)	9 (6.6)	16 (12)	3 (2.2)
FEELINGS (n=139)							
In the last month − feeling:							
82	scared	80 (58)	23 (17)	15 (11)	14 (10)	6 (4.4)	1 (0.7)
83	bored	91 (65)	16 (12)	14 (10)	9 (6.5)	9 (6.5)	0 (0.0)
84	frustrated	66 (48)	23 (17)	17 (12)	17 (12)	14 (10)	2 (1.4)
85	helpless	84 (61)	25 (18)	13 (9.4)	9 (6.5)	7 (5.1)	1 (0.7)
86	anxious or nervous	63 (46)	31 (22)	18 (13)	19 (14)	7 (5.1)	1 (0.7)
87	distressed	82 (59)	26 (19)	9 (6.5)	13 (9.4)	8 (5.8)	1 (0.7)
88	embarrassed	95 (69)	18 (13)	13 (9.5)	8 (5.8)	3 (2.2)	2 (1.4)
89	sad or depressed	70 (51)	28 (20)	17 (12)	11 (8.0)	11 (8.0)	2 (1.4)
90	lonely	86 (63)	19 (14)	14 (10)	9 (6.6)	9 (6.6)	2 (1.4)
In the last month − worrying about:							
91	my cancer spreading	78 (57)	20 (15)	15 (11)	10 (7.4)	13 (9.6)	3 (2.2)
92	my cancer returning	37 (27)	39 (28)	28 (20)	16 (12)	18 (13)	1 (0.7)
93	whether my cancer treatment has worked	75 (54)	24 (17)	19 (14)	7 (5.1)	13 (9.4)	1 (0.7)
94	going to the cancer treatment centre	108 (78)	13 (9.4)	6 (4.4)	5 (3.6)	6 (4.4)	1 (0.7)
95	having cancer treatment	103 (75)	9 (6.5)	15 (11)	3 (2.2)	8 (5.8)	1 (0.7)
96	test results	71 (51)	28 (20)	15 (11)	10 (7.2)	15 (11)	0 (0.0)
97	how my family is coping	80 (58)	16 (12)	15 (11)	16 (12)	11 (8.0)	1 (0.7)

		No Need n (%)	Low Need n (%)	Moderate Need n (%)	High Need n (%)	Very High Need n (%)	Missing Values* n (%)
In the last month − finding:							
98	inner strength	78 (57)	25 (18)	14 (10)	10 (7.4)	9 (6.6)	3 (2.2)
99	hope	86 (63)	21 (15)	14 (10)	8 (5.8)	8 (5.8)	2 (1.4)
100	meaning in my experience	85 (62)	19 (14)	11 (8.0)	11 (8.0)	12 (8.7)	1 (0.7)
101	enjoyment in life	85 (62)	24 (18)	7 (5.1)	10 (7.3)	11 (8.0)	2 (1.4)
In the last month − coping with:							
102	changes in my physical ability	70 (51)	19 (14)	19 (14)	12 (8.7)	18 (13)	1 (0.7)
103	changes in my appearance	72 (52)	20 (14)	13 (9.4)	15 (11)	18 (13)	1 (0.7)
104	changes to me as a person	69 (50)	24 (17)	21 (15)	10 (7.3)	14 (10)	1 (0.7)
105	other people's reactions to me	72 (52)	26 (19)	15 (11)	15 (11)	10 (7.3)	1 (0.7)
106	friends passing away	102 (75)	8 (5.9)	10 (7.4)	3 (2.2)	13 (9.6)	3 (2.2)
107	not being able to do the same things as other people my age	72 (53)	14 (10)	18 (13)	12 (8.8)	21 (15)	2 (1.4)
In the last month − being able to:							
108	focus on tasks	77 (57)	23 (17)	22 (16)	6 (4.4)	8 (5.9)	3 (2.2)
109	remember things	71 (52)	23 (17)	21 (15)	10 (7.3)	12 (8.8)	2 (1.4)
110	make plans or think about the future	77 (56)	17 (12)	16 (12)	12 (8.7)	16 (12)	1 (0.7)
111	accept changes to my future	78 (57)	21 (15)	18 (13)	11 (8.0)	10 (7.3)	1 (0.7)
112	accept my diagnosis	99 (72)	20 (15)	6 (4.4)	7 (5.1)	5 (3.7)	2 (1.4)
113	be independent	100 (73)	11 (8.0)	7 (5.1)	6 (4.4)	13 (9.5)	2 (1.4)
RELATIONSHIPS (n=139)							
In the last month − coping with:							
114	changes in my relationships with my parent/s	98 (72)	20 (15)	9 (6.6)	5 (3.7)	5 (3.7)	2 (1.4)
115	my parent/s giving me too much attention	99 (72)	17 (12)	10 (7.3)	5 (3.6)	7 (5.1)	1 (0.7)
116	my parent/s not giving me enough attention	119 (87)	13 (9.5)	3 (2.2)	0 (0)	2 (1.5)	2 (1.4)
117	my parent/s being over-protective	88 (64)	27 (20)	10 (7.3)	5 (3.7)	7 (5.1)	2 (1.4)
In the last month − knowing how to:							
118	ask my parent/s for support	100 (73)	22 (16)	8 (5.8)	1 (0.7)	6 (4.4)	2 (1.4)
119	give support to my parent/s	96 (70)	15 (11)	15 (11)	5 (3.7)	6 (4.4)	2 (1.4)
In the last month − coping with:							
120	changes in my relationships with my friends	90 (66)	18 (13)	12 (8.8)	9 (6.6)	8 (5.8)	2 (1.4)
121	not being able to see my friends	104 (76)	11 (8.1)	7 (5.2)	5 (3.7)	9 (6.6)	3 (2.2)
In the last month − knowing how to:							
122	ask my friends for support	93 (68)	16 (12)	15 (11)	7 (5.1)	6 (4.4)	2 (1.4)
123	give support to my friends	102 (74)	15 (11)	7 (5.1)	9 (6.6)	4 (2.9)	2 (1.4)
In the last month − coping with: (n=77)							
125	changes in my relationship with my partner	43 (61)	10 (14)	6 (8.6)	7 (10)	4 (5.7)	7 (9.1)
126	my partner giving me too much attention	55 (80)	11 (16)	2 (2.9)	1 (1.5)	0 (0)	8 (10)
127	my partner not giving me enough attention	54 (77)	8 (11)	4 (5.7)	1 (1.4)	3 (4.3)	7 (9.1)
128	my partner being over-protective	57 (83)	8 (12)	1 (1.5)	3 (4.4)	0 (0)	8 (10)
In the last month − knowing how to: (n=77)							
129	ask my partner for support	48 (69)	12 (17)	3 (4.3)	3 (4.3)	4 (5.7)	7 (9.1)
130	give support to my partner	45 (64)	9 (13)	6 (8.6)	6 (8.6)	4 (5.7)	7 (9.1)
In the last month − coping with: (n=118)							
131	changes in my relationships with my sibling/s	74 (67)	17 (15)	12 (11)	4 (3.6)	4 (3.6)	7 (5.9)
In the last month − knowing how to: (n=118)							
132	ask my sibling/s for support	78 (71)	15 (14)	8 (7.3)	4 (3.6)	5 (4.6)	8 (6.8)
133	give support to my sibling/s	79 (72)	12 (11)	11 (10)	5 (4.6)	3 (2.7)	8 (6.8)
DAILY LIFE (n=139)							
In the last month − managing:							
134	pain	100 (72)	15 (11)	16 (12)	4 (2.9)	3 (2.2)	1 (0.7)
135	medication	108 (78)	13 (9.4)	7 (5.1)	3 (2.2)	7 (5.1)	1 (0.7)
136	physical side-effects of treatment	77 (56)	22 (16)	16 (12)	13 (9.5)	9 (6.6)	2 (1.4)
137	feeling tired	61 (44)	33 (24)	16 (12)	11 (8.0)	17 (12)	1 (0.7)
138	loss of mobility	99 (72)	20 (14)	8 (5.8)	5 (3.6)	6 (4.4)	1 (0.7)
139	to sleep	83 (60)	25 (18)	18 (13)	5 (3.6)	7 (5.1)	1 (0.7)
140	to do chores/housework	107 (77)	16 (12)	6 (4.3)	6 (4.3)	4 (2.9)	0 (0.0)
141	to eat	113 (81)	13 (9.4)	3 (2.2)	4 (2.9)	6 (4.3)	0 (0.0)
142	to take part in social activities	95 (69)	16 (12)	20 (14)	4 (2.9)	3 (2.2)	1 (0.7)
143	to travel to social events	107 (78)	13 (9.5)	12 (8.8)	1 (0.7)	4 (2.9)	2 (1.4)
144	to maintain a normal life	85 (62)	23 (17)	19 (14)	4 (2.9)	7 (5.1)	1 (0.7)

**Missing values were excluded when calculating proportions of responses at each level of need for each item*

Appendix 5.21: Orthogonally rotated 18-factor solution with Eigenvalues > 1

Factor analysis/correlation — Number of observations= 111
Method: principal-component factors — Retained factors = 18
Rotation: orthogonal varimax (Kaiser off) — Number of parameters = 1863

Factor	Variance	Difference	Proportion	Cumulative
Factor 1	29.20226	11.72331	0.2607	0.2607
Factor 2	17.47894	8.81304	0.1561	0.4168
Factor 3	8.66590	4.72135	0.0774	0.4942
Factor 4	3.94455	0.78690	0.0352	0.5294
Factor 5	3.15765	0.32740	0.0282	0.5576
Factor 6	2.83025	0.00474	0.0253	0.5829
Factor 7	2.82551	0.01724	0.0252	0.6081
Factor 8	2.80827	0.10158	0.0251	0.6332
Factor 9	2.70669	0.18944	0.0242	0.6573
Factor 10	2.51725	0.17779	0.0225	0.6798
Factor 11	2.33946	0.08804	0.0209	0.7007
Factor 12	2.25141	0.08750	0.0201	0.7208
Factor 13	2.16392	0.08404	0.0193	0.7401
Factor 14	2.07987	0.05259	0.0186	0.7587
Factor 15	2.02728	0.13455	0.0181	0.7768
Factor 16	1.89273	0.14556	0.0169	0.7937
Factor 17	1.74717	0.27164	0.0156	0.8093
Factor 18	1.47553	-	0.0132	0.8225

Appendix 5.22: Orthogonally rotated forced factor structure for 3 factors

Factor analysis/correlation — Number of observations = 111
Method: principal-component factors — Retained factors = 3
Rotation: orthogonal varimax (Kaiser off) — Number of parameters = 333

Factor	Variance	Difference	Proportion	Cumulative
Factor 1	32.68537	14.20545	0.2918	0.2918
Factor 2	18.47992	4.77217	0.1650	0.4568
Factor 3	13.70775	-	0.1224	0.5792

Appendix 5.23: List of 17 items removed following the initial factor analysis with 3 factors (n=111)

Item number	Description of item	Factor loading		
		Factor 1	Factor 2	Factor 3
18	Missing the safety of the cancer treatment centre	0.61	-	0.46
80	Finding information that talked about feelings or emotions	0.55	-	0.42
83	Feeling bored	-	0.57	0.41
89	Feeling sad or depressed	-	0.68	0.40
90	Feeling lonely	-	0.61	0.51
101	Finding enjoyment in life	0.44	0.68	-
104	Coping with changes to me as a person	-	0.48	0.61
105	Coping with other people's reactions to me	-	0.52	0.61
106	Coping with friends passing away	-	-	-
111	Being able to accept changes to my future	0.40	0.64	0.42
115	Coping with my parent/s giving me too much attention	-	-	-
116	Coping with my parent/s not giving me enough attention	-	-	-
120	Coping with changes in my relationships with my friends	-	0.60	0.43
121	Coping with not being able to see my friends	-	0.41	0.56
122	Knowing how to ask my friends for support	-	0.53	0.46
139	Managing to sleep	-	0.52	0.48
144	Managing to maintain a normal life	-	0.41	0.76

Appendix 5.24: Number of factors following factor analysis with additional items from the Education and Work domains

Number of factors following inclusion of items from the Education domain

Factor analysis/correlation — Number of observations = 65
Method: principal-component factors — Retained factors = 4
Rotation: orthogonal varimax (Kaiser off) — Number of parameters = 414

Factor	Variance	Difference	Proportion	Cumulative
Factor 1	34.82068	22.78489	0.3316	0.3316
Factor 2	12.03579	1.86819	0.1146	0.4463
Factor 3	10.16760	0.69131	0.0968	0.5431
Factor 4	9.47630	-	0.0903	0.6333

Number of factors following inclusion of items from the Work domain

Factor analysis/correlation — Number of observations = 90
Method: principal-component factors — Retained factors = 4
Rotation: orthogonal varimax (Kaiser off) — Number of parameters = 414

Factor	Variance	Difference	Proportion	Cumulative
Factor 1	29.70646	14.52849	0.2829	0.2829
Factor 2	15.17797	5.44146	0.1446	0.4275
Factor 3	9.73651	1.39303	0.0927	0.5202
Factor 4	8.34348	-	0.0795	0.5997

Appendix 5.25: Number of factors following factor analysis with additional items from the Partner and Siblings sub-domains

Number of factors following inclusion of items from the Partner sub-domain

Factor analysis/correlation — Number of observations = 54
Method: principal-component factors — Retained factors = 4
Rotation: orthogonal varimax (Kaiser off) — Number of parameters = 394

Factor	Variance	Difference	Proportion	Cumulative
Factor 1	25.71373	7.22447	0.2571	0.2571
Factor 2	18.48926	10.74150	0.1849	0.4420
Factor 3	7.74776	0.91846	0.0775	0.5195
Factor 4	6.82930	-	0.0683	0.5878

Number of factors following inclusion of items from the Siblings sub-domain

Factor analysis/correlation — Number of observations = 96
Method: principal-component factors — Retained factors = 4
Rotation: orthogonal varimax (Kaiser off) — Number of parameters = 390

Factor	Variance	Difference	Proportion	Cumulative
Factor 1	26.41986	12.22900	0.2669	0.2669
Factor 2	14.19086	3.27502	0.1433	0.4102
Factor 3	10.91584	4.27353	0.1103	0.5205
Factor 4	6.64231	-	0.0671	0.5876

Appendix 5.26: List of 12 items removed following factor analysis with the additional domains and sub-domains

Item number	Description of item	Factor loading			
		Factor 1	Factor 2	Factor 3	Factor 4
(n=65)					
55	Being able to travel to or from my place of study	0.58	-	0.63	-
57	Being able to catch up on assignments	0.43	-	0.76	-
60	Knowing how many classes I would miss	0.43	-	0.81	-
62	Knowing that teachers/students understood my situation	0.41	-	0.65	-
(n=90)					
66	Being able to return to work	0.56	-	-	0.59
67	Being able to travel to or from my place of work	0.58	-	-	0.63
68	Being able to attend work	0.57	-	-	0.63
69	Being able to catch up on work	0.47	-	-	0.74
70	Being able to work part-time/casual	0.66	-	-	0.48
73	Knowing that managers/co-workers understood my situation	0.48	-	-	0.63
(n=54)					
127	Coping with my partner not giving me enough attention	-	-	-	-
129	Knowing how to ask my partner for support	-	-	-	-

Appendix 5.27: List of the 24 items removed following the calculation of test-retest reliability

Item number	Description of item	Weighted Kappa
3	Cancer treatment staff telling me about different treatment options	0.52
10	Cancer treatment staff telling me how treatment might affect my studies or future career	0.57
19	Missing the support of the cancer treatment staff	0.41
32	Having cancer treatment staff who talked to me and my family together	0.58
34	Being able to get transport to or from the cancer treatment centre	0.47
36	Being able to see people I care about	0.48
45	Being able to have my family with me	0.55
49	Being able to have enough time to make decisions about my treatment	0.44
52	Being able to have someone to help me fill out forms	0.56
61	Knowing how to ask teachers/students for support	0.55
63	Knowing that teachers/students had support to help them cope	0.37
79	Finding information that came in different forms (brochure, CD, DVD, online)	0.51
85	Feeling helpless	0.41
94	Worrying about going to the cancer treatment centre	0.29
96	Worrying about test results	0.46
99	Finding hope	0.41
100	Finding meaning in my experience	0.43
114	Coping with changes in my relationships with my parent/s	0.48
118	Knowing how to ask my parent/s for support	0.37
119	Knowing how to give support to my parent/s	0.47
123	Knowing how to give support to my friends	0.49
130	Knowing how to give support to my partner	0.09
140	Managing to do chores/housework	0.58
141	Managing to eat	0.34

Appendix 5.28: List of 14 items removed following the revised factor analysis (n=116)

Item number	Description of item	Factor loading			
		Factor 1	Factor 2	Factor 3	Factor 4
11	Cancer treatment staff telling me what support services were available	0.50	-	-	0.50
33	Being able to get treatment in my local area	-	-	-	-
35	Being able to get overnight accommodation near the cancer treatment centre	-	-	-	-
40	Being able to express my feelings	0.67	-	-	0.43
50	Being able to have access to professional counselling	0.53	-	-	0.47
51	Being able to have opportunities to take part in research	0.49	-	-	0.52
76	Finding information that was easy to understand	0.62	-	-	0.51
77	Finding information that was easy to get hold of	0.58	-	-	0.54
78	Finding information that I could trust	0.62	-	-	0.51
82	Feeling scared	-	0.42	0.68	-
87	Feeling distressed	-	0.44	0.68	-
88	Feeling embarrassed	-	0.41	0.49	-
108	Being able to focus on tasks	-	0.48	0.43	-
109	Being able to remember things	-	0.47	0.49	-

Appendix 5.29: Criteria used to review the psychometric properties of existing measures of psychosocial well-being developed for AYA cancer survivors

Psychometric Property	Criteria
Reliability	
Internal consistency degree to which responses to all items on a scale are consistent	Calculated correlations for total scale and domains – Cronbach's alpha (α) >0.70 – Kuder-Richardson 20 (KR-20) >0.70
Test-retest reproducibility of scores on a scale over repeated administrations	Second administration within 2-14 days Calculated correlations for total scale, domains and items – Cohen's kappa coefficient (κ) >0.60 – Pearson correlation coefficient (r) >0.70 – Intraclass correlation coefficient (ICC) >0.70
Validity	
Face subjective assessment of whether a scale "appears" to measure what it is designed to measure	Assessed as reasonable by those who administer/complete it
Content degree to which the content of a scale is representative of the issue being measured	Reported item selection process Content assessed by experts Reported which aspects of the measure were revised
Construct way in which the internal structure of a scale relates to other conceptual constructs	Stated hypothesis about correlations between measures – Convergent (r) >0.40 or Divergent (r) <0.30 Calculated correlations between known-groups Performed factor analysis – Eigenvalues > 1
Criterion how well a scale agrees with existing "gold standard" measurement of the same issue	Provided rationale for "gold standard" measure Stated type of criterion validity (concurrent or predictive) Reported proportions – Sensitivity: % with issue correctly classified – Specificity: % without issue correctly classified
Responsiveness sensitivity of a scale to detect clinically important change in an outcome/behaviour over time	Reported floor/ceiling effects – <5% of respondents have highest or lowest score Reported magnitude of change – Effect size >0.5
Acceptability level of burden placed on those who complete the measure	Reported response rate, missing items, reading level, time to complete
Feasibility level of burden placed on those who administer the measure	Reported perceived time to administer, score, interpret
Cross-cultural adaptation conceptually, linguistically equivalent and displays similar psychometric properties to the original form	Confirmed reliability and validity reflects the original version

Appendix 7.1: Final version of the CNQ–YP

THE UNIVERSITY OF NEWCASTLE AUSTRALIA

CANCER NEEDS QUESTIONNAIRE YOUNG PEOPLE

We are trying to find better ways to help adolescents and young adults who have had cancer.

To do this we are asking young people about the **physical, psychological, and social needs** that they may have had since their cancer diagnosis.

For each question, please choose the answer that **best describes** your level of need. There are five choices:

No Need	All my needs were met for this issue or this was not a problem for me.
Low Need	I needed a low amount of help with this problem but was not able to get it.
Moderate Need	I needed a moderate amount of help with this problem but was not able to get it.
High Need	I needed a high amount of help with this problem but was not able to get it.
Very High Need	I needed a very high amount of help with this problem but was not able to get it.

There are no right or wrong answers. The survey will take around 10 minutes to complete. Your answers will remain strictly confidential.

The following questions ask about any needs you may have had **at any time since your cancer diagnosis.**

1. Treatment Environment and Care

I had the following needs…						
BEFORE TREATMENT						
	Cancer treatment staff telling me:	**No Need**	**Low Need**	**Moderate Need**	**High Need**	**Very High Need**
1	about my diagnosis	○	○	○	○	○
2	what might happen during treatment	○	○	○	○	○
3	whether I had the option to decline treatment	○	○	○	○	○
4	about the short term side-effects of treatment	○	○	○	○	○
5	about the long term side-effects of treatment	○	○	○	○	○
6	my chances of a full recovery	○	○	○	○	○
7	what would happen when treatment finished	○	○	○	○	○
8	whether I would be able to have children	○	○	○	○	○
DURING TREATMENT						
	Cancer treatment staff telling me:	**No Need**	**Low Need**	**Moderate Need**	**High Need**	**Very High Need**
9	whether my treatment was working	○	○	○	○	○
10	my test results as soon as possible	○	○	○	○	○
11	the way I felt was normal	○	○	○	○	○
	Being able to have:	**No Need**	**Low Need**	**Moderate Need**	**High Need**	**Very High Need**
12	have time to myself	○	○	○	○	○

I had the following needs…						
AFTER TREATMENT						
	Cancer treatment staff telling me:	**No Need**	**Low Need**	**Moderate Need**	**High Need**	**Very High Need**
13	how to manage my medication	○	○	○	○	○
14	what I could do to stay healthy	○	○	○	○	○
15	what to do if I noticed a particular side-effect	○	○	○	○	○
THROUGHOUT TREATMENT						
	Having cancer treatment staff who:	**No Need**	**Low Need**	**Moderate Need**	**High Need**	**Very High Need**
16	listened to my concerns	○	○	○	○	○
17	treated me as an individual	○	○	○	○	○
18	were respectful	○	○	○	○	○
19	were approachable	○	○	○	○	○
20	were friendly	○	○	○	○	○
21	could have a laugh with me	○	○	○	○	○
22	explained what they were doing	○	○	○	○	○
23	spoke to me in a way that I could understand	○	○	○	○	○
24	let me talk about my feelings	○	○	○	○	○
25	let me ask questions	○	○	○	○	○
26	let me make decisions about my treatment	○	○	○	○	○
27	talked to me in private, without my family	○	○	○	○	○

I had the following needs…						
AT THE CANCER TREATMENT CENTRE						
	Being able to have:	**No Need**	**Low Need**	**Moderate Need**	**High Need**	**Very High Need**
28	privacy	○	○	○	○	○
29	pleasant surroundings	○	○	○	○	○
30	good food	○	○	○	○	○
31	a choice of cancer specialists	○	○	○	○	○
32	the same cancer treatment staff throughout treatment	○	○	○	○	○
33	a choice of times for appointments	○	○	○	○	○

2. Education

Since my cancer diagnosis, I have had problems enrolling at: *(please choose as many as apply)*	
S1	○ school ○ TAFE ○ university/college ○ other place of study *(please write)*_____ ○ none of the above
Since my cancer diagnosis, I have attended: *(please choose as many as apply)*	
S2	○ school ○ TAFE ○ university/college ○ other place of study *(please write)*_____ ○ none of the above *(go to Question S3)*

I had the following needs…

WHEN STUDYING

	Being able to:	No Need	Low Need	Moderate Need	High Need	Very High Need
34	attend classes	○	○	○	○	○
35	get extensions/special consideration	○	○	○	○	○
36	get guidance about study options or future career paths	○	○	○	○	○

3. Work

Since my cancer diagnosis, I have had problems finding work: *(please choose as many as apply)*	
S3	○ full-time ○ part-time/casual ○ unpaid voluntary work ○ other type of work *(please write)*_____ ○ none of the above
Since my cancer diagnosis, I have been employed: *(please choose as many as apply)*	
S4	○ full-time ○ part-time/casual ○ unpaid voluntary work ○ other type of work *(please write)*_____ ○ none of the above (*go to Question 40)*

I had the following needs…

WHEN EMPLOYED

	Knowing:	**No Need**	**Low Need**	**Moderate Need**	**High Need**	**Very High Need**
37	how much work I would miss	○	○	○	○	○
38	how to ask managers/co-workers for support	○	○	○	○	○
39	that managers/co-workers had support to help them cope with my situation	○	○	○	○	○

4. Information and Activities

I had the following needs…						
DURING TREATMENT						
	Being able to:	**No Need**	**Low Need**	**Moderate Need**	**High Need**	**Very High Need**
40	spend time with people my own age	○	○	○	○	○
41	talk to people my age who had been through a similar experience	○	○	○	○	○
AT THE CANCER TREATMENT CENTRE						
	Being able to have:	**No Need**	**Low Need**	**Moderate Need**	**High Need**	**Very High Need**
42	leisure spaces and activities	○	○	○	○	○
SINCE MY CANCER DIAGNOSIS						
	Finding information that:	**No Need**	**Low Need**	**Moderate Need**	**High Need**	**Very High Need**
43	was specifically designed for me	○	○	○	○	○
44	described relaxation techniques	○	○	○	○	○

The next group of questions ask about any needs you may have had **in the last month.**

We realise that your needs may have changed during different stages of your cancer experience. Please only tell us about needs you have had in the last month. If you have not had any needs in the last month, please select 'No Need'.

5. Feelings and Relationships

I had the following needs…						
IN THE LAST MONTH						
	Feeling:	**No Need**	**Low Need**	**Moderate Need**	**High Need**	**Very High Need**
45	frustrated	○	○	○	○	○
46	anxious or nervous	○	○	○	○	○
IN THE LAST MONTH						
	Worrying about:	**No Need**	**Low Need**	**Moderate Need**	**High Need**	**Very High Need**
47	my cancer spreading	○	○	○	○	○
48	my cancer returning	○	○	○	○	○
49	whether my cancer treatment has worked	○	○	○	○	○
50	having cancer treatment	○	○	○	○	○
51	how my family is coping	○	○	○	○	○
IN THE LAST MONTH						
	Finding:	**No Need**	**Low Need**	**Moderate Need**	**High Need**	**Very High Need**
52	inner strength	○	○	○	○	○
IN THE LAST MONTH						
	Being able to:	**No Need**	**Low Need**	**Moderate Need**	**High Need**	**Very High Need**
53	accept my diagnosis	○	○	○	○	○
54	be independent	○	○	○	○	○

S5	**Do you have:** *(please choose as many as apply)* ○ a spouse/partner or boyfriend/girlfriend *(please answer Question 55)* ○ sibling/s or step-brothers/sisters *(please answer Questions 56-58)* ○ none of the above *(go to Question 59)*

I had the following needs…						
IN THE LAST MONTH						
	Coping with:	**No Need**	**Low Need**	**Moderate Need**	**High Need**	**Very High Need**
55	changes in my relationship with my partner	○	○	○	○	○
IN THE LAST MONTH						
	Coping with:	**No Need**	**Low Need**	**Moderate Need**	**High Need**	**Very High Need**
56	changes in my relationships with my sibling/s	○	○	○	○	○
IN THE LAST MONTH						
	Knowing how to:	**No Need**	**Low Need**	**Moderate Need**	**High Need**	**Very High Need**
57	ask my sibling/s for support	○	○	○	○	○
58	give support to my sibling/s	○	○	○	○	○

6. Daily Life

I had the following needs…						
IN THE LAST MONTH						
	Being able to:	**No Need**	**Low Need**	**Moderate Need**	**High Need**	**Very High Need**
59	make plans or think about the future	○	○	○	○	○
IN THE LAST MONTH						
	Coping with:	**No Need**	**Low Need**	**Moderate Need**	**High Need**	**Very High Need**
60	changes in my physical ability	○	○	○	○	○
61	changes in my appearance	○	○	○	○	○
62	not being able to do the same things as other people my age	○	○	○	○	○
63	my parent/s being overprotective	○	○	○	○	○
IN THE LAST MONTH						
	Managing:	**No Need**	**Low Need**	**Moderate Need**	**High Need**	**Very High Need**
64	pain	○	○	○	○	○
65	medication	○	○	○	○	○
66	physical side effects of treatment	○	○	○	○	○
67	feeling tired	○	○	○	○	○
68	loss of mobility	○	○	○	○	○
69	to take part in social activities	○	○	○	○	○
70	to travel to social events	○	○	○	○	○

YOU HAVE NOW COMPLETED THE SURVEY
THANK YOU FOR YOUR TIME AND HELP