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Caregiver Information Sheet/Consent Form

Insert site name

Title	A randomised phase 3 trial of Palliative care Early in Advanced Lung Cancers.
Short Title	PEARL
Protocol Number	CTC 0145 / ALTG 13/008
Study Sponsor	University of Sydney
Coordinating Centre	NHMRC Clinical Trials Centre
Coordinating Principal Investigator/ Principal Investigator	*Coordinating Principal Investigator/ Principal Investigator*
Associate Investigator(s) *(if required by institution)*	*Associate Investigator(s)*
Location *(where CPI/PI will recruit)*	*Location*

1. Introduction

This Caregiver Participant Information and Consent Form is 9 pages long. Please make sure that you have all the pages.

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

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

Once you understand what the study is about and if you agree to take part in it, you will be asked to sign the Consent Form. By signing the Consent form, you indicate that you understand the information and that you give your consent to participate in the research study.

You will be given a copy of the Caregiver Participant Information and Consent form to keep as a record.

Participation in the study is voluntary. Below is more detailed information about the study.

2. What is the purpose of this research?

The purpose of this study is to investigate your experience as a caregiver of someone who has advanced lung cancer or mesothelioma, and specifically to help us work out if seeing a palliative care provider (doctor or nurse) early and in a routine, structured way, (together with standard cancer care) soon after diagnosis with advanced lung cancer or mesothelioma, is beneficial. This study involves randomly allocating patients to see their oncologist (cancer doctor) for ongoing

current standard cancer care PLUS a palliative care provider every 3-4 weeks, or seeing their oncologist (cancer doctor) for ongoing current standard cancer care.

Palliative care is care that helps people live their life as fully and as comfortably as possible when living with a life-limiting illness. Palliative care identifies and treats symptoms which may be physical, emotional, spiritual or social. Because palliative care is based on individual needs, the services offered will differ but may include:

1. Relief of pain and other symptoms e.g. nausea, shortness of breath
2. Resources such as equipment needed to aid care at home
3. Assistance for families to come together to talk about sensitive issues and enable appropriate decisions to be made
4. Links to other services such as home help and financial support
5. Support for emotional, social and spiritual concerns
6. Counselling and grief support
7. Referrals to respite care services

Palliative care is a family-centred model of care, meaning that family and carers as well as the patient can receive practical and emotional support. It is a government-funded service.

Palliative care is part of recommended care for patients with advanced lung cancer or mesothelioma to be referred to a palliative care service at some point in their illness. However, we know from prior studies that many patients are either never referred to palliative care or else only referred very close to the time of death.

A previous study done in the USA suggested that patients with lung cancer who were referred to palliative care soon after their initial diagnosis had better outcomes than those who were never referred or only referred late in their illness. Patients referred early appeared to have better control of their symptoms and improved quality of life, as well as a longer length of life. However, other international studies have not shown the same results. Because the model of health care in Australia and New Zealand is very different to the USA, we are running this study in Australia and New Zealand to determine if the same benefits from early palliative care do or do not occur in our health care system.

By your loved one seeing a palliative care provider in this model, the key effects we want to understand are whether or not this has an impact on:

1. How the cancer and its treatment have affected the health of your loved one and the wellbeing of you and your loved one
2. Your level of understanding of your loved ones health and treatment plan
3. Your loved one's use of healthcare resources and costs

Ultimately, the results of this study will help inform us about the best way to deliver palliative cancer care in Australia for patients with advanced lung cancer or mesothelioma.

We plan to enrol 200 participants and their carers to this study in Australia and New Zealand. We plan to enrol [N] participants at this institution.

3. What does participation in this research involve?

You have been invited to participate in this study because you are a carer for someone with advanced lung cancer or mesothelioma who requires input from a palliative care provider (doctor or nurse).

This research study will investigate if early referral to palliative care improves quality of life in those recently diagnosed with advanced lung cancer or mesothelioma.

This is a randomised controlled study. Sometimes we do not know which intervention is best for treating a condition. We put people into groups and give each group a different intervention. The results are compared to see if one is better.

To try to make sure the groups are the same, each participant is put into a group by chance (this is called randomisation). Your loved one will have an equal chance of receiving the referral to early palliative care or referral to palliative care at clinician's/patient's discretion. Neither you, your loved one, nor their doctor can choose the treatment they are allocated to.

If the study is suitable for your loved one, they will be randomised into one of two study groups:

- *Group 1:* Seeing their oncologist (cancer doctor) for ongoing current standard cancer care PLUS a palliative care provider every 3-4 weeks.

- *Group 2:* Seeing their oncologist (cancer doctor) for ongoing current standard cancer care

Your loved one will be asked to return to the clinic every 3-4 weeks for the first 24 weeks and then every 6-8 weeks for the duration of their illness.

Regardless of which group your loved one is allocated to they will receive optimal current standard treatment of the cancer.

If they are randomised to Group 1 they will also attend an appointment with the hospital based palliative care team, who will assess their current symptoms and needs for any additional supportive care that might be required to help you both cope with the illness. ***This consultation will be audio recorded and may be transcribed and audited later to allow us to analyse the consultation in detail so that we can understand the key important elements of the discussion.***

Within 4 weeks of this initial appointment a telephone call to discuss your loved ones care will be held between the palliative care team and their general practitioner, which you and your loved one may participate in if you wish.

If your loved one is randomised to Group 2, then they may be referred to a palliative care team at a time that your loved one and their doctor think is appropriate.

Assessments completed specifically for this study include:

- Completion of questions every 3-4 weeks for the first 24 weeks then 6-8 weekly thereafter, which ask about your caregiver-related activities and the impact of the diagnosis, illness and treatment of your loved one, on your life. These will take about 15-20 minutes to complete.
- Completion of questions about your understanding of your loved ones illness and how you felt and your satisfaction with your loved ones care at the start of the study, after 6-8, 12-16 and 24 weeks, and then every 12 weeks. These questionnaires will take about 10 minutes to complete.

Should your loved one pass away, you will also be asked to complete questions about how you felt about the quality of care provided towards the end of their life. You may also be asked to participate in an interview.

<u>Study costs</u>

There are no additional costs associated with taking part in this study, nor will you or your loved one be paid.

Your loved one may have to pay for non-study medicines that are given as routine treatment for their condition according to hospital policy, including the standard co-payment for PBS-listed drugs.

If you and your loved one decide to take part in this study, your loved ones study doctor will inform their local doctor. Please discuss with your loved one and advise your loved ones study doctor if you do not wish this to occur.

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

Taking part in any study 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 study at any stage.

Your decision on whether or not to take part, or to take part and then withdraw, will not affect the treatment of the person you are caring for now or in the future. Whatever your decision, it will not affect your relationship with those treating your loved one or your relationship with the *Institution*.

5. What are the alternatives to participation?

If you and your loved one decide not take part in the study, other options are available to your loved one; these include ongoing standard cancer care and referral to a palliative care team if and when this is considered appropriate. Your loved ones study doctor will discuss these options with you and your loved one before you decide whether or not to take part in this study. You can also discuss the options with your local doctor.

6. What are the possible benefits of taking part?

We cannot guarantee that you or your loved one will receive any benefits from this study, however, results may benefit patients who have advanced lung cancer or mesothelioma in the future. You may however benefit from understanding your loved one's illness and knowing what questions to ask.

7. What are the possible risks and disadvantages of taking part?

We believe that your participation in this research project will be of minimal direct risk to your health. However, you may find some of the questions in the questionnaires distressing. If you have any concerns or experience any undue distress, talk with your loved ones study doctor. The study doctor will also be looking out for any issues of concern. If you become upset or distressed as a result of participation in the research, the study doctor will be able to arrange for counselling or other appropriate support. Any counselling or support will be provided by qualified staff who are not members of the research project team.

There may be concerns that the researchers do not expect or do not know about and that may be serious. Tell your loved ones study doctor immediately about concerns, including any new or unusual symptoms.

If there are significant concerns about your well-being related to the research project, the study doctor may need to stop your participation. Your study doctor will discuss the best way of managing any concerns with you.

8. What if new information arises during this research project?

Sometimes during the course of a study, new information becomes available about the intervention that is being studied. If this happens, your loved ones study doctor will tell you about it and discuss with you and your loved one whether you want to continue in the research study. If you decide to withdraw, your loved ones study doctor will make arrangements for their regular healthcare to

continue. If you decide to continue in the research study you will be asked to sign a new consent form confirming that you have been made aware of the new information.

Also, on receiving new information, your study doctor might consider it to be in your best interests to withdraw your loved one from the study. If this happens, he/she will explain the reasons and arrange for your loved ones healthcare to continue.

9. What if I withdraw from this research project?

If you decide to withdraw from the study, please notify a member of the study team beforehand.

This notice will allow your loved ones study doctor to discuss any special recommendations linked to withdrawing.

If you decide to discontinue the study, you will be asked to attend follow-up visits with your loved one. If you decide to withdraw from the study your loved one may choose to continue in the study.

If you withdraw your consent for the collection of any future personal information, information already collected will be retained to ensure that the results of the study can be measured properly and to comply with law. You should be aware that data collected up to the time you withdraw consent will form part of the study results.

If you wish to completely withdraw from this study you will be asked to complete and sign a "Withdrawal of Consent" form. This will be provided to you by the study team.

10. Could this research project be stopped unexpectedly?

This study may be stopped unexpectedly for a variety of reasons. These may include reasons such as:

• The model of care is not effective

• Decisions made by local health authorities or the study sponsor.

11. What happens when the study ends?

Your study doctor can inform you of the results of the study after it has been analysed and reported. Once the study is complete and the results are known, a written plain-english summary of the results of the study will be made available to your loved ones study doctor for discussion. A summary of the results will also be published on the NHMRC Clinical Trials Centre website www.ctc.usyd.edu.au Search for 'trial results'). Public information is provided in such a way that you cannot be identified.

12. What will happen to information about me?

By signing the Consent Form you consent to the study doctor and relevant study staff collecting and using personal information about you for the study. Any information obtained in connection with this study that can identify you will remain confidential. The information collected in this study database will be identified by a code number. Only your study doctor and the study team will be able to link the code number to you personally. Your information will only be used for the purpose of this study and it will only be disclosed with your permission, except as required by law.

Your study data will be held by the NHMRC Clinical Trials Centre. This information will be held securely and confidentially.

The data from this study will be kept for at least 15 years from the end of the study, after which it will be destroyed under security.

The health records of your loved one, and any information you provide during the study are subject to inspection (for the purpose of verifying the procedures and the data) by the relevant authorities and authorised representatives of the Sponsor, University of Sydney, approving Human Research Ethics Committee (HREC) and institution, or as required by law. By signing the Consent Form, you authorise release of, or access to, this confidential information to the relevant study personnel and regulatory authorities as noted above.

It is anticipated that the results of this study will be published and/or presented at professional meetings. In any publication and/or presentation, information will be provided in such a way that you or your loved one cannot be identified.

In accordance with relevant Australian and State privacy and other relevant laws, you have the right to request access to your information collected and stored by the study team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this form if you would like to access your information.

13. Complaints and compensation

If you suffer any injuries or complications as a result of this study, you should contact the study team as soon as possible and you will be assisted with arranging suitable medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication.

You do not give up any legal right to take legal action to obtain compensation for any injuries or complications resulting from the study. Compensation may be available if your injury or complication is sufficiently serious and is caused by unsafe drugs or equipment, or by the negligence of one of the parties involved in the study (for example, the researcher, the hospital, or the treating doctor).

14. Who is organising and funding the research?

This is an investigator-initiated study being conducted in Australia and New Zealand by the NHMRC Clinical Trials Centre, University of Sydney, in collaboration with the Australasian Lung Cancer Trials Group (ALTG). This study is sponsored by the University of Sydney.

The study is partially funded by a grant from the Commonwealth of Australia, represented by Cancer Australia.

Institution will receive a payment from the University of Sydney for undertaking this study.

No member of the study team will receive a personal financial benefit from your involvement in this study (other than their ordinary wages).

15. Who has reviewed the research project?

This study will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007, updated 2014)*. This statement has been developed to protect the interests of people who agree to take part in human research studies.

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). This study has been approved by the HREC (RPAH Zone) of the Sydney Local Health District. Any person with concerns or complaints about the conduct of this study should contact the Executive Officer on 02 9515 6766 and quote X16-0340.

The conduct of this study at the *[name of hospital]* has been authorised by the *Local Health District*. Any person with concerns or complaints about the conduct of this study may also contact the Research Governance Officer *[or other officer]* on *telephone number* and quote protocol number *local protocol number*.

16. Further information and who to contact

If you want any further information concerning this study or if you have any medical problems which may be related to your involvement in the study (for example, any side effects), you can contact the principal study doctor on *phone number* or any of the following people:

Clinical contact person

Name	*Name*
Position	*Position*
Telephone	*Phone number*

Caregiver Consent Form

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Associate Investigator(s)	*Associate Investigator(s)*
Location *(where CPI/PI will recruit)*	*Location where the study will be conducted*

Declaration by Caregiver Participant

I have read this Caregiver Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the study described in this Caregiver Information Sheet.

I freely agree to take part in this study as described and understand that I am free to withdraw at any time during the study without affecting my loved ones future healthcare.

I understand that all of my loved ones consultations with the hospital based palliative care team will be audio recorded and may be transcribed and audited.

I give permission for the information collected during this study, by study doctors, other health professionals, hospitals or laboratories outside this hospital to release information to *Institution* concerning my involvement in this study. I understand that such information will remain confidential.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I understand that I will be given a signed copy of this document to keep.

Name of Caregiver Participant
(please print) _____

Signature _____ Date _____

Name of Witness* to
Participant's Signature (please print) _____

Signature _____ Date _____

* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

Declaration by Study Doctor/Senior Researcher†

I have given a verbal explanation of the study, its procedures and risks and I believe that the caregiver participant has understood that explanation.

Name of Study Doctor/

Senior Researcher† (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of, and information concerning, the study.

Note: All parties signing the consent section must date their own signature

Caregiver Form for Withdrawal of Participation

Title	A randomised phase 3 trial of Palliative care Early in Advanced Lung Cancers.
Short Title	PEARL
Protocol Number	CTC 0145 / ALTG 13/008
Study Sponsor	University of Sydney
Coordinating Principal Investigator/ Principal Investigator	*[Coordinating Principal Investigator/ Principal Investigator]*
Associate Investigator(s) *(if required by institution)*	*[Associate Investigator(s)]*
Location *(where CPI/PI will recruit)*	*[Location where the study will be conducted]*

Declaration by Participant

☐ I hereby wish to WITHDRAW from the above study and understand that such withdrawal will not jeopardise my loved ones future healthcare.

I understand that such withdrawal will not affect my loved ones routine treatment, my relationship with those treating my loved one or my relationship with *[Institution]*.

Name of Caregiver Participant (please print) _____

Signature _____ Date _____

Reason for withdrawal (study doctor):

Declaration by Study Doctor/Senior Researcher†

I have given a verbal explanation of the implications of withdrawal from the research study and I believe that the Caregiver participant has understood that explanation.

Name of Study Doctor/

Senior Researcher† (please print) _____

Signature _____ Date _____

† A senior member of the study team must provide the explanation of and information concerning withdrawal from the research study.

Note: All parties signing the consent section must date their own signature.