Participant 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*

Research Study Overview

We invite you to take part in this research study being led by the Australasian Lung Cancer Trials Group (ALTG) and coordinated by the National Health and Medical Research Council (NHMRC) Clinical Trials Centre (CTC). The purpose of the study is to investigate 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 a lung cancer or mesothelioma, is beneficial.

This study involves randomly allocating participants to see their oncologist (cancer doctor) for ongoing current standard cancer care PLUS a palliative care provider every 3-4 weeks, or seeing your oncologist (cancer doctor) for ongoing current standard cancer care.

You and your carer (if you have one) will be required to come to the clinic for study visits every 3 to 4 weeks for the first 24 weeks, then every 6-8 weeks for the duration of your illness, these visits are likely to coincide with your ongoing cancer care visits. In addition to the time with your oncologist the visits will vary in length between 30 - 60 minutes.

If you decide to take part in the study, at each study visit you will have a number of questionnaires to complete. These questionnaires are aimed at assessing your quality of life, functional status and symptoms.

Participation in the study is voluntary. If you decide not to take part, you will still receive treatment for your condition. If you decide to take part, you can withdraw from the study at any time. Either way it will not affect the care you receive at this hospital.

Below is more detailed information about the study.

1. Introduction

You are invited to participate in this research study because you have advanced lung cancer or mesothelioma and require 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 Participant Information Sheet/Consent Form tells you about the study. It explains what is involved for you and your carer. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information sheet 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 doctor.

If you decide you want to take part in the study, you will be asked to sign the Consent Form.

You will be given a copy of this Participant Information and Consent Form to keep.

If you have a nominated carer, he/she will also be invited to participate, and will be given a Participant Information and Consent Form as well.

2. What is the purpose of this research?

The purpose of this study is 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.

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. This study will investigate the timing of the referral to palliative care and if early referral improves quality of life for those with advanced lung cancer or mesothelioma.

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 seeing a palliative care provider early in your illness, 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 your health and wellbeing and the wellbeing of your nominated carer
2. You and your nominated carers understanding of your health and treatment plan
3. Your 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 in this study in Australia and New Zealand. We plan to enrol *[N]* participants at this institution.

3. What does participation in this research involve?

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). You will have an equal chance of receiving ongoing standard cancer care or ongoing standard cancer care plus palliative care. Neither you nor your doctor can choose the treatment that you are allocated to.

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

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

Group 2: Seeing your oncologist (cancer doctor) for ongoing current standard cancer care.

You 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 your illness.

Regardless of which group you are allocated to you will receive optimal current standard cancer treatment.

If you are randomised to Group 1 you also will attend an appointment for a consultation with the hospital based palliative care team, who will assess your current symptoms and needs for any additional supportive care that you or your carer might require to help you cope with your 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 care will be held between the palliative care team and your general practitioner, which you and your carer may attend if you wish. You will then have follow-up consultations with the hospital based palliative care team every 3-4 weeks.

If you are randomised to Group 2, you may be referred to a palliative care team at a time that you and your doctor think is appropriate.

We will carry out further assessments during the study. Many of these are standard for people receiving treatment for advanced lung cancer or mesothelioma and include:

- Examination by your doctor at the start of the study.

Additional assessments are being done specifically for this study and include:

- Every 3-4 weeks completion of questions about:
    - How the cancer and its treatment have affected your health and wellbeing
    - Any other health care professionals seen since your last study visit
    - The number of days in hospital, number of emergency admissions, or any new medications since your last study visit
    - Any out-of-pocket costs and other financial difficulties as a result of your cancer or treatment

  These will take about 30 minutes to complete.

- Completion of a daily patient diary about how many excellent, very good, good, fair or poor days you feel you have had (completed on a daily basis at home and collected at your 3-4 weekly visit by a member of the study team)
- Completion of questions about your understanding of your illness and how you felt at the start of the study, after 6-8, 12-16 and 24 weeks, and then every 12 weeks. Both questionnaires will take about 10 minutes to complete.

It is important to attend all scheduled visits while you are taking part in the study. Missed appointments could limit the effectiveness of the intervention. If you do miss a visit for an unexpected reason, then you will be asked to re-schedule the appointment as soon as possible.

Study costs

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

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

If you decide to take part in this study, the study doctor will inform your local doctor. Please advise your study doctor if you do not wish this to occur.

4. What else do I have to do?

There are no specific restrictions associated with this study, for example lifestyle modifications, or medications restrictions. Please clarify with the study staff should you need clarification about any issues.

5. 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 your routine treatment, your relationship with those treating you or your relationship with *Institution*.

6. What are the alternatives to participation?

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

7. What are the possible benefits of taking part?

We cannot guarantee that you will receive any benefits from this study, however, results may benefit patients who have advanced lung cancer or mesothelioma in the future.

8. 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 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 team. This counselling will be provided free of charge.

There may be risks that the researchers do not expect or do not know about and that may be serious. Tell your 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 recommend to stop your participation. Your study doctor will discuss the best way of managing any concerns with you.

9. 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 study doctor will tell you about the new information and discuss with you whether you want to continue in the research study. If you decide to withdraw, your study doctor will make arrangements for your regular health care 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 you from the study. If this happens, he/she will explain the reasons and arrange for your health care to continue.

10. 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 study doctor to discuss any special recommendations linked to withdrawing.

If you decide to discontinue the study treatment, you will be asked to attend follow-up visits to allow the collection of personal information regarding your health. If you do not wish to attend follow-up visits, your study doctor will request permission to collect information on your health from your medical records and from relevant health registries. Even if you stop treatment early, we would like to keep track of your health for the rest of your life to look at the long-term effects of your participation on this 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.

11. 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.

12. What happens when the study ends?

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 study doctor for discussion with you. 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.

13. What will happen to information about me?

By signing the Consent Form you consent to your 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.

Information about your participation in this study will be recorded in your health records.

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

Information about you may be obtained from your health records held at this and other health services for the purpose of this study. By signing the Consent Form you agree to the study team accessing health records if they are relevant to your participation in this study.

You will be asked to fill out a consent form authorising the study access to your complete Medicare and Pharmaceutical Benefits Scheme (PBS) data as outlined on the back of the consent form. Medicare collects information on your medical visits and procedures, and the associated costs, while the PBS collects information on the prescription medications you have filled at pharmacies. The consent form is sent securely to the Department of Human Services who holds this information confidentially. This information will remain confidential and will not be disclosed without your permission, except as required by law. However, you may also withdraw this consent later. Your study data will be held electronically by the NHMRC CTC. This information will be held securely and confidentially. In addition, the NHMRC CTC will have access to the information about your use of health services and prescription medicines via the Department of Human Services. 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.

Your health records and any information obtained 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 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.

14. 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).

15. 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).

16. 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 protocol number 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*.

17. 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*

Consent Form

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Short Title	PEARL
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Coordinating Principal Investigator/ Principal Investigator	*Coordinating Principal Investigator/ Principal Investigator*
Associate Investigator(s)	*Associate Investigator(s)*
Location *(where CPI/PI will recruit)*	*Location where the study will be conducted*

Declaration by Participant

I have read the 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 the study.

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 future health care.

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

I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to *Institution* concerning my disease and treatment for the purposes of 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, if I decide to discontinue the study intervention, I may be asked to attend follow-up visits to allow collection of information regarding my health. Alternatively, a member of the study team may request my permission to obtain access to my medical records for collection of follow-up information for the purposes of research and analysis.

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

Name of 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 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.

Participant ID:

PARTICIPANT CONSENT FORM

Consent to release of Medicare and Pharmaceutical Benefits Scheme (PBS) claims information for the purposes of the PEARL study.

Important Information

Complete this form to request the release of personal Medicare claims information and/or PBS claims information to the PEARL Study.

Any changes to this form must be initialled by the signatory. Incomplete forms may result in the study not being provided with your information.

By signing this form, I acknowledge that I have been fully informed and have been provided with information about this study. I have been given an opportunity to ask questions and understand the possibilities of disclosures of my personal information.

PARTICIPANT DETAILS

1. Mr ☐ Mrs ☐ Miss ☐ Ms ☐ Other ☐

Family name: _____ First given name: _____

Other given name (s): _____

Date of birth: DD/MM/YYYY

2. Medicare card number: _____

3. Permanent address: _____

Postal address (if different to above): _____

AUTHORISATION

4. I authorise the Department of Human Services to provide my:

☐ Medicare & PBS claims history

for the period* DD/MM/YYYY to: DD/MM/YYYY to the PEARL Study.

*Note: The Department of Human Services can only extract 4.5 years of data (prior to the date of extraction), the consent period above may result in multiple extractions.

DECLARATION

I declare that the information on this form is true and correct.

5. Signed: _____ (participant's signature) Dated: DD/MM/YYYY **OR**

6. Signed by _____ (full name) _____ (signature) on behalf of participant

Dated: DD/MM/YYYY

☐ Parent (where the participant is under the age of 14 years old*)

☐ Legal guardian** (where the participant is under the age of 14 years old*)

☐ Power of attorney** ☐ Guardianship order**

* Once a young person has turned 14 years old they must consent to their own information being released.

** Please attach supporting evidence

APP 5 – PRIVACY NOTICE

Your personal information is protected by law, including the Privacy Act 1988, and is collected by the Australian Government Department of Human Services. The collection of your personal information by the department is necessary for administering requests for statistical and other data.

Your information may be used by the department or given to other parties for the purposes of research, investigation or where you have agreed or it is required or authorised by law.

You can get more information about the way in which the Department of Human Services will manage your personal information, including our privacy policy at humanservices.gov.au/privacy or by requesting a copy from the department.

Power of attorney – A power of attorney is a document that appoints a person to act on behalf of another person who grants that power. In particular, an enduring power of attorney allows the appointed person to act on behalf of another person even when that person has become mentally incapacitated. The powers under a power of attorney may be unlimited or limited to specific acts.

Guardianship order – A Guardianship order is an order made by a Guardianship Board/Tribunal that appoints a guardian to make decisions for another person. A Guardianship order may be expressed broadly or limited to particular aspects of the care of another person.

A sample of the information that may be included in your Medicare claims history:

Date of service	Item number	Item description	Provider charge	Schedule Fee	Benefit paid	Patient out of pocket	Hospital indicator
20/04/09	00023	Level B consultation	$38.30	$34.30	$34.30	$4.00	N
22/06/09	11700	ECG	$29.50	$29.50	$29.50		N

A sample of the information that may be included in your PBS claims history:

Date of supply	PBS item code	Item description	Patient category	Patient contribution (this includes under copayment amounts**)	Net Benefit (this includes under copayment amounts**)
06/03/09	03133X	Oxazepham Tablet 30 mg	Concessional Ordinary	$5.30	$25.55
04/07/09	03161J	Diazepam Tablet 2 mg	General Ordinary	$30.85	

ATC Name
Oxazepam
Diazepam

** Under co-payments can now be provided for data after 1 June 2012

Form for Withdrawal of Participation

Title	A randomised phase 3 trial of Palliative care Early in Advanced Lung Cancers.
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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 STUDY TREATMENT but agree to continue study follow-up

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

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

Name of 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 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.