Insert Header with institution's name
or institution's letterhead

Person Responsible Information and Consent Form

Interventional Study - Person responsible consenting on behalf of participant

[Insert site name]

Title	A multi-centre randomised controlled trial of an Open Lung Strategy including **P**ermissive **H**ypercapnia, **A**lveolar **R**ecruitment and **L**ow **A**irway **P**ressure in patients with acute respiratory distress syndrome
Short Title	PHARLAP
Protocol Number	ANZIC-RC/AD002 Version 6~~5~~
Principal Investigator	*[Principal Investigator]*
Associate Investigator(s)	*[Associate Investigator(s)]*
Version	5~~4~~
HREC Reference Number	HREC/12/Alfred/41
Local Project Number	*[Local project number]*
Date	18~~20~~ September~~February~~ 2013

Part 1 What does participation involve?

1. Introduction

As the 'person responsible' for the patient, you are invited to consider the patient's participation in this research project. Victorian law allows the person responsible for a patient to consent to the patient taking part in medical research where the patient is unable to provide consent for themselves.

The patient is eligible to participate in this research project because they are an intensive care unit patient, connected to a ventilator (breathing machine) and have been diagnosed with having acute respiratory distress syndrome (ARDS, a disorder where the lungs become inflamed and work poorly). This research project is aiming to see if a specific strategy using the ventilator is more effective then current best practice in improving outcome for patients with ARDS.

This Person Responsible Information and Consent Form tells you about the research project. It explains the procedures involved. Knowing what is involved will help you decide if you are willing for the person you are responsible for to take part in the research.

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 the patient should take part, you might want to talk about it with a relative, friend or healthcare worker.

Participation in this research is voluntary. If you don't wish for the patient to take part, they don't have to. They will receive the best possible care whether they take part or not.

If you decide you want the patient to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

- understand what you have read;
- consent to the person you are responsible for to take part in the research project;
- consent to the person you are responsible for to participate in the research processes that are described;
- consent to the use of the patient's personal and health information as described.

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

2. What is the purpose of this research?

Your relative or person you are responsible for has a condition called acute respiratory distress syndrome (ARDS). This is a medical term for a condition where the lungs have become injured and inflamed from one of various causes, and do not work as they normally do to provide oxygen and remove carbon dioxide from the body. This can lead to a reduced amount of oxygen in their blood. They have been admitted to the intensive care unit (ICU) and need help with their breathing by being connected to a ventilator (breathing machine). ARDS can lead to injury in other organs of the body causing other problems but also death.

Over the past few years, reducing the size of each breath delivered by the ventilator in conjunction with the use of sustained deep breaths, called a "recruitment manoeuvre", have been used to try to prevent further damage to the lungs in people with ARDS. This ventilator strategy (termed the PHARLAP strategy) has been shown in a small research study to have some beneficial effects without causing any obvious harm, when compared to a current best practice ventilator strategy. The main beneficial effects of the PHARLAP strategy are to increase the amount of oxygen in the blood and to reduce markers of inflammation (the body reacting to a disease process) in the body. This initial study was too small to make a strong conclusion, so we are undertaking a much larger study. What we are aiming to do in this larger study is to find out whether patients who have developed ARDS are truly better off when we use the PHARLAP strategy.

The study is funded by the National Health and Medical Research Council and The Alfred Hospital. It is what we call investigator initiated (set up by doctors, rather than a drug company) and is endorsed by the Australian and New Zealand Intensive Care Society Clinical Trials Group (ANZICS CTG). The study is managed by the Australian and New Zealand Intensive Care Research Centre (ANZIC-RC) at Monash University. Three hundred and forty patients will be enrolled into this study in multiple ICUs across Australia and New Zealand.

Patients will be randomly (like flipping a coin) allocated to either the PHARLAP (treatment) group or the control (current best practice) group.

3. What does participation in this research involve?

At the start of the study patients with ARDS will be randomly placed into either the PHARLAP strategy group or the current best practice group. The patient will be placed into a particular group based on a 50% chance and neither the treating doctors, the patient, nor you will be able to decide which one they will receive.

- In the PHARLAP study treatment group the size of each breath the ventilator will deliver will be reduced to keep the pressure on the patient's lungs low. Up to three times a day the pressure of the ventilator will be set to increase slightly and then reduced slowly to a level that provides the best oxygen levels to the blood. In the PHARLAP group patients will not be denied any treatments or medications that have been show to improve survival.
- In the current best practice group patients will receive the best standard of care and will not be denied any treatments or medications that have been shown to improve survival.

We will monitor the patient's heart and lungs (oxygen levels, heart rate, blood pressure, ventilator settings) using the standard equipment attached to them in the ICU throughout this time.

The only tests that will be performed in addition to routine care will be the collection of 2 blood samples – one at enrolment and one on day 3 of the study. Ten (10) mls (or 2 teaspoons) of blood will be collected for testing at the two time points. The blood samples will be taken from the drips that are already in place for treatment and monitoring of the patient. We will also collect a sputum sample (the phlegm that is usually coughed up by people) by suctioning this from their breathing tube at the start of the study and on day 3.
At times it might not be feasible for the study staff to collect the sputum samples however the two blood samples will be collected.

Data will be collected during the hospital stay. A copy of the participant's chest x-ray (CXR, an image taken by an x-ray machine) that told us that they had developed ARDS will be reviewed by an x-ray specialist at Flinders Medical Centre (South Australia). The CXR will not have the patient's name or details linked to it, but will have the date and the participant's unique study code number when it is sent to South Australia.

The participant will be contacted by telephone at 6 months after their hospital stay to complete a questionnaire in regards to how their health is. If the participant is unable to complete this we will ask you as the person responsible to help them complete the questionnaire on the participants behalf.

4. What will happen to the test samples?

The collection of the blood samples is a mandatory component of the study and sputum will be collected if feasible. ~~samples is a mandatory component of the study.~~ The blood tested for the study is in addition to the patient's routine blood tests. Samples will be processed in [*insert hospital name]* Laboratory. The samples will be coded with the patient's unique study code number to link the results of the samples to the patient's study information. The samples will then be sent to Flinders Medical Centre (South Australia) to measure the levels of inflammatory markers (special proteins in the blood that if elevated tell us how inflamed the lung and the body are). All samples will be destroyed after testing has been completed.

By consenting for the patient to take part in this study, you also consent to the collection, storage and use of the test samples as specified above.

5. What are the possible benefits?

We cannot guarantee or promise that the patient will receive any benefits from this research, however, possible benefits may include:

- Reduction in inflammation in the lungs and body which may reduce problems in other organs of the body
- The patient may receive greater amounts of oxygen in the blood which can assist all of the body's functions.

These effects may contribute to shortening the time the patient needs to stay in either the ICU or the hospital.

6. What are the possible risks?

Like any medical treatment there may be risks. Because of the nature of the patient's illness it is often difficult to tell the difference between risks associated with his/her condition and risks associated with the study treatment. Nevertheless we will be watching out for these potential problems.

Risk/Side effect	Likelihood	Comment
Low blood pressure	Common but unlikely to result in harm	At the beginning stages of the treatment the lungs are expanded which results in increased pressure in the lungs and chest.

		This may cause the blood pressure to decrease for a short period of time (ie. seconds to a minute or two). Blood pressure is measured continuously as part of standard care and treatments (such as increased fluids and blood pressure increasing medicines) can be given to increase the blood pressure.
Low levels of oxygen	Common but unlikely to result in harm	Low levels of oxygen may occur for a short period (ie. seconds to a minute or two) as the pressure in the lungs is increased. We have previously studied this and found that the oxygen levels increase as soon as the pressure in the lungs is reduced. All patients will be monitored for oxygen levels and the pressure will be reduced as necessary.
Development of infections	Unlikely to be related to the study	This may occur in patients with severe lung injury on a mechanical ventilator regardless of the type of treatment they receive.
Injury to other organs of the body	Unlikely to be related to the study	This may occur in patients with severe lung problems regardless of the type of treatment they receive.
Blood samples	No increased risk above standard practice	The blood samples will be collected through an existing drip that is regularly accessed for collection of routine blood samples.
BAL/s~~S~~putum samples	Low risk of decreased oxygen levels (hypoxemia) ~~Unlikely to increase risk above standard practice~~	~~Sputum samples will be collected by the patient's nurse or a member of the medical team in ICU. Tubing is inserted into the breathing tube to collect the sputum for the study. This tubing is slightly longer then the tubing used for standard care suctioning.~~Samples of lung secretions are collected from all study patients, using either a bronchoscope or a bronchial catheter. Physicians usually use a bronchoscope, which has a camera that allows them to see directly into the lower airways of the lungs. For the study, we provide the option of the bronchial catheter, which is longer than standard suction catheters but smaller than a bronchoscope. Either approach can lead to lower oxygen levels.
Chest x-rays	No risk of increased radiation above standard practice	Chest x-rays are performed regularly as part of routine care while patients are mechanically ventilated in intensive care

There may be additional risks that the researchers do not expect or do not know about.

7. What if new information arises during this research 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 and the researcher will discuss whether this new information affects the patient.

8. Can my relative have other treatments during this research project?

It is important to tell the patients doctor and the research staff about any treatments or medications the patient may have been taking before being admitted to the ICU, including over-the-counter medications, vitamins or herbal remedies, acupuncture or other alternative treatments.

9. Does my relative have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to enrol the patient in this study you are not obliged to. If you decide for the patient to take part and later change your mind, you are free to withdraw the patient from the project at any stage.
Your decision for the patient to take part or not to take part, or to take part and then withdraw, will not affect the patient's relationship with *[insert hospital name]* or its staff.

10. What if I withdraw the participant from this research project?

If you decide to withdraw the patient from the project, the researchers would like to keep the personal and health information about the patient and the tissue samples that have 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 when you withdraw consent.

11. Could this research project be stopped unexpectedly?

Occasionally research projects may be stopped early. There are a variety of reasons why this might occur including:

- Unacceptable side effects;
- The treatment being shown not to be effective;
- The treatment being shown to be effective beyond the need for proof such that no further testing is needed.

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

Once the project has been completed, a summary of the results will be available from the researchers on request. The findings of the study will be published in a medical journal on completion.

Part 2 How is the research project being conducted?

13. What will happen to information about the participant?

No identifying material will be used in any reports of this study. Records for the study will be kept in a secure filing cabinet in a secure office located at *[insert hospital name]*. A database with study information will be generated and this will be kept in a computer that is password protected. The database will be located at the Department of Epidemiology & Preventive Medicine, Monash University. Records relating to the study will be kept indefinitely.

The data collected for the study will be transferred to the database in a de-identified format (ie. where information that might identify the name or details of the patient) have been removed). Study data in this de-identified format may be published or given to regulatory authorities in Australia if required. By signing this consent form, you do not object to the recording, review, information storage and data transfer of information as described above.

Identifying contact details will be sent to the coordinating centre at ANZIC-RC, Monash University Melbourne. These details are required to allow the follow up assessment (ie. the telephone call 6 months after the study began) to take place. Any information collected during the follow up assessments will also be presented in a de-identified format.

Information about the patient may be obtained from their health records held at this, and other, health services for the purposes of this research. Information about the participation in this research project may be recorded in the patient's health records.

ICU Research Co-ordinators and the Investigators listed on the front of this consent form will have access to the patient's study data. The patient's 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 from ANZIC RC, *[insert hospital name]* or as required by the law. By signing the consent section, you authorise release of, or access to, this confidential information to the relevant study personnel and regulatory authorities as noted above.

14. How can the participant access their information?

In accordance with relevant Australian and/or Victorian privacy and other relevant laws, the patient has the right to access the information collected and stored by the researchers about them. They also have the right to request that any information, with which they disagree with, be corrected. Please contact one of the researchers named at the end of this document if you or they would like to access their information.

15. What happens if the participant is injured as a result of participating in this research project?

If the patient suffers an injury as a result of their participation in this research project, please contact the research staff. Hospital care and treatment will be provided by the public health care system (Medicare) at no cost to the patient if they are eligible for Medicare benefits and elect to be treated as a public patient.

16. Is this research project approved?

The ethical aspects of this research project have been approved by the Human Research Ethics Committee of *[insert hospital name]*, the Alfred Hospital and Monash University. 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.

17. Further information and who to contact

The person you may need to contact will depend on the nature of your query. If you want any further information concerning this project or if the participant has any medical problems which may be related to their involvement in the project (for example, any side effects), you can contact the principal study doctor on *[Contact phone number]* or any of the following people:

Principal Investigator

Name	[Name]
Position	[Position]
Telephone	[Phone number]
Email	[Email address]

Associate Investigator

Name	[Name]
Telephone	[Phone number]
Name	[Name]
Telephone	[Phone number]
Name	[Name]
Telephone	[Phone number]

Research Coordinator

Name	[Name]
Position	[Position]
Telephone	[Phone number]
Email	[Email address]

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:

Reviewing HREC approving this research and HREC Executive Officer details

Reviewing HREC name	The Alfred Hospital Ethics Committee
HREC Executive Officer	Ms Rowen Frew
Telephone	(03) 90763848
Email	r.frew@alfred.org.au

Local HREC Office contact

Name	[Name]
Position	[Position]
Telephone	[Phone number]
Email	[Email address]

Consent Form – Person Responsible

Title	A multi-centre randomised controlled trial of an Open Lung Strategy including **P**ermissive **H**ypercapnia, **A**lveolar **R**ecruitment and **L**ow **A**irway **P**ressure in patients with acute respiratory distress syndrome
Short Title	PHARLAP
Protocol Number	ANZIC-RC/AD002 Version 6~~5~~
Principal Investigator	[Principal Investigator]
Location	[Location where the research will be conducted]

Declaration by Person Responsible

I am the Person Responsible for *[Participant's Name]* (the 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 research described in the project.

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

I believe that the participation of the participant in this study is not contrary to their best interests.

I freely agree to the participant participating in this research project as described and understand that I am free to withdraw the participant at any time during the research project without affecting their future health care.

I am aware of my responsibilities as the Person Responsible for the participant and I understand that I will be assisting the participant in meeting their responsibilities whilst they are participating in this study.

I understand that I will be given a signed copy of this document to keep on behalf of the participant.

I give permission for the participant's doctors, other health professionals, hospitals or laboratories outside this hospital to release information to *[Name of Institution]* concerning the particpant's disease and treatment for the purposes of this research project. I understand that such information will remain confidential.

Name of Participant (please print) _____

Name of Person Responsible (please print) _____

Relationship of Person Responsible to Participant _____

Signature of Person Responsible _____ Date _____

Name of Witness* to
Person Responsible'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 research project, its procedures and risks and I believe that the person responsible 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 research project.

Participant Samples

I consent to the storage and use of blood and tissue samples taken from the participant for use, as described in the relevant section of the Participant Information Sheet, for:

- ☐ This specific research project
- ☐ Other research that is closely related to this research project
- ☐ Any future research

(select all that apply)

Name of Participant (please print) _____

Name of Person Responsible (please print) _____

Relationship of Person Responsible to Participant _____

Signature of Person Responsible _____ Date _____

Name of Witness* to
Person Responsible'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.

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 research project.

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

Form for Withdrawal of Participation – Person Responsible

Title	A multi-centre randomised controlled trial of an Open Lung Strategy including **P**ermissive **H**ypercapnia, **A**lveolar **R**ecruitment and **L**ow **A**irway **P**ressure in patients with acute respiratory distress syndrome
Short Title	PHARLAP
Protocol Number	ANZIC-RC/AD002 Version 6~~5~~
Principal Investigator	*Principal Investigator*
Location	*[Location where the research will be conducted]*

Declaration by Person Responsible

I wish to withdraw the participant from taking part in the above research project and understand that such withdrawal will not affect the participant's routine treatment, relationship with those treating them or their relationship with *[Institution]*.

I agree to the use of the participants data that has been collected prior to withdrawal of consent:

Yes ☐ No ☐

I agree to the use of the participants blood and sputum samples collected prior to the withdrawal of consent:

Yes ☐ No ☐

I agree to be contacted at 6 months after enrolment the enrolment date of the participant to answer a questionnaire on their behalf:

Yes ☐ No ☐ (Tick all that apply)

Name of Participant (please print) _____

Name of Person Responsible (please print) _____

Relationship of Person Responsible to Participant _____

Signature of Person Responsible _____ Date _____

Name of Study Doctor/
Senior Researcher (please print) _____

Signature _____ Date _____

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