  
**Participant Information Sheet/Consent Form**

PATIENT LABEL

**Health/Social Science Research**

**ICU Survivor (Patient or Family Member) Participant Consent Form Phase 2**

**Western Health**

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| **Title** | icuRESOLVE (Intensive Care Unit **RE**covery **S**olutions c**O**-**L**ed through sur**V**ivor **E**ngagement)  Co-designing Peer Support With ICU Survivors  Phase 2 |
| **Short Title** | icuRESOLVE Phase 2 |
| **Protocol Number** | 2017.371 Protocol Version 2 19/12/2017 |
| **Coordinating Principal Investigator/ Principal Investigator** | Dr Kimberley Haines |
| **Associate Investigator(s)** | Ms Clare Holdsworth, Ms Samantha Bates,Mr Grey Searle, Ms Kathryn Cranwell, Ms Belinda Smith, Ms Jacki Carmody & Ms Sarah Booth |
| **Location** | Western Health- Sunshine Hospital |

**Part 1 What does my participation involve?**

**1 Introduction**

You are invited to take part in this research project, which is called icuRESOLVE (Intensive Care Unit **RE**covery **S**olutions c**O**-**L**ed through sur**V**ivor **E**ngagement).

You have been invited because you or your family member have previously been admitted to the intensive care unit (ICU) at Sunshine Hospital. Your contact details were obtained from our hospital records of patients admitted to intensive care.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the processes involved with taking part. Knowing what is involved will help you decide if you want 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 to take part, you might want to talk about it with a relative, friend or 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, 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 take part in the research project

• Consent to be involved in the research described

• Consent to the use of your personal and health information as described.

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

**2 What is the purpose of this research?**

You may be aware that being admitted to the intensive care unit and experiencing a period of critical illness, can affect a person mental, physical and cognitive health and well-being in different ways as well as their family’s mental health. This is called ‘Post Intensive Care Syndrome’.

Currently, once patients and their families leave the ICU, they are provided very little support from the health system at what can be a challenging time for some. At Sunshine Hospital, we have recently developed a Peer Support Group for people who have been in intensive care as a patient as well as their family members or carers. Peer support is a way of connecting people with similar experiences to give each other practical, emotional or social support. A ‘peer’ is someone who has ‘been there, done that’ and can relate to others in a similar situation.

We think that attending a peer support group may help improve recovery following critical illness and reduce the burden of Post Intensive Care Syndrome.

The purpose of this research is to test whether attending the Peer Support group improves recovery following an ICU admission for ICU survivors and their carers/family members and to test the feasibility of running the group.

This research has been initiated by the researcher Dr Kimberley Haines.

This research has been funded by the Western Health Research Grant Program and the Society of Critical Care Medicine in the United States

**3 What does participation in this research involve?**

To find out if the Peer Support is effective, we need to compare this to standard care (no peer support). We randomly allocate people to either group and then look at the results to see if peer support is beneficial or not. With randomisation, you have a one in two chance of being in the intervention or control, like flipping a coin. If you consent to participate in this study, one of our research assistants will then randomly allocate you to one of the two groups and we will let you know what group you are in.

If randomised to the standard care group, you would be required to:

1. Participate in two telephone interviews – A research assistant will phone you to ask you a series of questions about your recovery from your illness. These questions will focus on your resilience, social supports and emotional recovery. The interview is anticipated to take about half an hour and it will be completed twice:
   1. Within the first 2 weeks after you are discharged home
   2. At 14 – 15 weeks after discharge home

Total time commitment if you are randomised to the control (no peer support) group is estimated as 1 hour.

If randomised to the Intervention (Peer Support Group), you will be required to:

1. Attend and participate in six Peer Support Group Sessions over 12 weeks
   * Begin attending the session at approximately 2 weeks after discharge
   * Sessions are held fortnightly and go for 2 hours
   * Sessions are at Sunshine Hospital in a separate building and room to the ICU
   * Sessions involve in-person group meetings with other ICU survivors (patients and family members).
   * Session content includes an educational component on common problems faced after ICU as well as group/peer to peer discussions of shared experiences
2. Participate in two telephone interviews – A research assistant will phone you to ask you a series of questions about your recovery from your illness. These questions will focus on your resilience, social supports and emotional recovery. At the end of the group sessions, you will also be asked a series of questions about how satisfied you were with involvement in the group. The interview is anticipated to take about half an hour and it will be completed twice:
   1. Within the first 2 weeks after you are discharged home
   2. At 14 – 15 weeks after discharge home

Your total time commitment if you are randomised to the intervention (Peer Support) group is estimated as 13 hours over approximately 14 weeks. Ideally we would anticipate that you are able to attend all of the Peer Support sessions but understand you may be unavailable some of the time.

There are no costs associated with participating in this research project. If you are randomised to the intervention group, you will be reimbursed for any reasonable travel and parking expenses to attend the peer support group sessions.

The conduct of this research will be monitored by a group of local and international expert researchers, clinicians and patient and family representatives.

This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids study doctors or participants jumping to conclusions.

**4 Other relevant information about the research project**

We plan to recruit 60 participants in total, including intensive care patients and family members / carers.

**5 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 any stage.

If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine care, your relationship with professional staff or your relationship with Western Health.

**6 What are the possible benefits of taking part?**

We cannot guarantee or promise that you will receive any benefits from this research; however, possible benefits for those in the intervention (peer support) group include improved psychological recovery following critical illness (such as improved depression, anxiety, resilience and social support) due to attending the peer support sessions.

For all participants, the benefit of taking part is to help us determine if Peer Support is a useful way to improve recovery post ICU and your involvement will be helping us work towards improving the care for other ICU survivors in the future.

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

We believe there are minimal risks with your participation.

During the interviews, you may feel that some of the questions we ask are stressful or upsetting. If you do not wish to answer a question, you may skip it and go to the next question, or you may stop immediately.

For those in the intervention (peer support) group, during participation in the group sessions with other ICU survivors and staff you may become upset in recounting your experiences of the ICU and experiences.

If you become upset or distressed as a result of your participation in the research project, the research team will arrange for counselling or other appropriate support. Any counselling or support will be provided by qualified staff who are not a member of the research team. This counselling will be provided free of charge and will be organised through your General Practitioner (GP) and you will be encouraged to contact your GP to discuss your specific requirements further.

**8 What if I withdraw from this research project?**

If you do consent to participate, you may withdraw at any time. If you decide to withdraw from the project, please notify a member of the research team before you withdraw. A member of the research team will inform you if there are any special requirements linked to withdrawing. If you do withdraw, you will be asked to complete and sign a ‘Withdrawal of Consent’ form; this will be provided to you by the research team.

If you decide to leave the research project, the researchers will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected up to the time you withdraw will form part of the research project results. If you do not want your data to be included, you must tell the researchers when you withdraw from the research project.

**9 What happens when the research project ends?**

At the conclusion of the project a written summary of the results of the study will be sent to you by mail.

**Part 2 How is the research project being conducted?**

**10 What will happen to information about me?**

By signing the consent form you consent to the research team collecting and using personal information about you for the research project. Any information obtained in connection with this project and that can identify you will remain confidential. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

If you are a patient, information about you such as your age, reason for admission to ICU may be obtained from your health records held at this and other health organisations for the purpose of this research. By signing the consent form you agree to the research team accessing health records if they are relevant to your participation in this research project. If you are a family member you will be asked information such as your age and relationship to the patient.

We will also collect data about you in the form of questionnaires completed during the research project. These health related questionnaires will include questions on your resilience, social supports and emotional recovery.

During the research project the data will be stored electronically on a password protected computer. Following analysis it will be stored electronically on one password protected computer in a lockable office. All manual data will be stored in a locked cupboard in the office of Dr Kimberley Haines, Principal Investigator. All manual datawill be destroyed after seven years. All electronic data will be deleted from computers after seven years.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. The results will be shared with other health care services so that they may improve. 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/or Victorian privacy and other relevant laws, you have the right to request access to the information about you that is collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please inform the research team member named at the end of this document if you would like to access your information.

**11 Complaints and compensation**

If you suffer any distress or psychological injury as a result of this research project, you should contact the research team as soon as possible. You will be assisted with arranging appropriate treatment and support.

If you have a complaint related to your treatment by members of the research team during or following your participation in the research you will be directed to speak with Western Health’s, Office for Research Manager who is independent to the project.

**12 Who has reviewed the research project?**

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC).

The ethical aspects of this research project have been approved by the HREC of Melbourne Health.

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

**13 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 you have any problems which may be related to your involvement in the project, you can contact the researcher on 0466 417 689 or any of the following people:

**Research contact person**

|  |  |
| --- | --- |
| Name | Dr Kimberley Haines |
| Position | Project Lead, Allied Health and Physiotherapy Research Lead |
| Telephone | 0466 417 689 |
| Email | Kimberley.haines@wh.org.au |

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

**Complaints contact person**

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| Name | Mr Bill Karanatsios |
| Position | Manager Officer for Research, Western Health |
| Telephone | (03) 8395 8073 |
| Email | ethics@wh.org.au |

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:

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| --- | --- |
| Reviewing HREC name | Melbourne Health |
| HREC Executive Officer | Manager HREC |
| Telephone | (03) 9342 8530 |
| Email | Research@mh.org.au |

**Reviewing HREC approving this research** **and HREC Executive Officer details**

**Local HREC Office contact**

|  |  |
| --- | --- |
| Name | Mr Bill Karanatsios |
| Position | Manager Officer for Research, Western Health |
| Telephone | (03) 8395 8073 |
| Email | ethics@wh.org.au |



**Consent Form -** *Adult providing own consent*

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| **Location** | Western Health- Sunshine Hospital |

**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 research described in the project.

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

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

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

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|  | | | | | | | |
|  | Name of Participant (please print) | |  | |  |  |  |
|  | | | | | | | |
|  | Signature |  | | Date | |  |  |
|  | | | | | | | |

**Declaration by Researcher†**

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

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|  | | | | | | |
|  | Name of Researcher† (please print) | |  | | |  |
|  | | | | | |  |
|  | Signature |  | | Date |  |  |
|  | | | | | | |

† An appropriately qualified 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 -** *Adult providing own consent*

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| **Location** | Western Health- Sunshine Hospital |

**Declaration by Participant**

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine care, or my relationships with the researchers or Western Health.

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|  | | | | | | | |
|  | Name of Participant (please print) | |  | |  |  |  |
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|  | Signature |  | | Date | |  |  |
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In the event that the participant’s decision to withdraw is communicated verbally, the Senior Researcher must provide a description of the circumstances below.

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**Declaration by Researcher†**

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

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|  | | | | | | |
|  | Name of Researcher (please print) | |  | | |  |
|  | | | | | |  |
|  | Signature |  | | Date |  |  |
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† An appropriately qualified member of the research team must provide information concerning withdrawal from the research project.

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