Participant Information Sheet/Consent Form

Health/Social Science Research - *Adult providing own consent*

Title	Improving integration between primary and intensive care after critical illness
Short Title	Integrate
Protocol Number	2020.228
Project Sponsor	Western Health
Coordinating Principal Investigator/ Principal Investigator	A/Prof Kimberley Haines
Associate Investigator(s)	Dr Yasmine Ali Abdelhamid Ms Nina Leggett A/Prof Jo-Anne Manski-Nankervis A/Prof Craig French Prof Rinaldo Bellomo A/Prof Adam Deane Mr Glenn Eastwood

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this research project, which is called Integrate: Improving integration between primary and intensive care after critical illness. You have been invited because as you are a General Practitioner. You are being sent this information as you are associated with the Department of General Practice Victorian Research and Education Network (VicREN).

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?

The results of this research will be used by the research team to explore perspectives on what aspects of recovery after intensive care are managed well in the community, and any ideas for ways to improve this care that might help future patients and their families. This research is being conducted by Western Health in collaboration with Melbourne Health, Austin Health and the Department of General Practice, University of Melbourne.

3 What does participation in this research involve?

Participation in this project will involve a single phone or zoom interview for half an hour (at a time of your convenience) that will be audio recorded.

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.

There are no costs associated with participating in this research project, nor will you be paid.

4 Other relevant information about the research project

There will be 45 participants included in this study, including patients and their carers, ICU Consultants and GPs, from across metropolitan Melbourne.

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 relationship with colleagues or your relationship with Western Health or the other collaborating organisations involved in this study..

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 may include a feeling of helping others, as the results from this research study will help future patients and their carers and contribute towards optimising care pathways for ICU survivors.

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

We do not anticipate any risks or disadvantages to you by taking part in this study.

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. 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.

9 Could this research project be stopped unexpectedly?

This research project may be stopped unexpectedly for a variety of reasons. These may include reasons such as a surge of the COVID-19 pandemic.

10 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?

11 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 research project that can identify you will remain confidential. It will only be disclosed with your permission, except as required by law. If you give us your permission by signing the Consent Form, we plan to publish the results in a peer-reviewed journal and present the results at international conferences.

Your interview data will be audio-recorded via a secure online platform called Zoom so that the interviews can be transcribed.

Once your audio-recorded interview has been transcribed, it will be re-identifiable, using a unique code only accessible to the research team. All data will be stored on a secure drive at Western Health. Only the researchers will be able to view and access these interviews. You will be invited to review the transcript and verify the information is correct. After the transcript has been verified, the audio recording will be destroyed.

Data will be kept for 7 years and then destroyed/deleted.

In accordance with relevant Australian and/or Victorian privacy and other relevant laws you have the right to access the information collected and stored by the researchers about you. You also have the right to request that any information with which you disagree be corrected. Please contact one of the researchers named below if you would like to access your information.

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.

The personal information that the research team collect and use is information from questionnaires.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your express permission. For example, the perspectives you share in no way will be able to be linked to you as an individual. Any of your personal details such as age will not be linked to you in any way but this sort of information for the group of participants will be presented as a group average.

In accordance with relevant Australian and/or Victoria 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.

Any information obtained for the purpose of this research project that can identify you will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law.

12 Complaints and compensation

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

Position:	Manager, Melbourne Health Office for Research
Telephone:	(03) 9342 8530
Email:	research@mh.org.au

(You will need to tell the Manager the name of one of the researchers given above.)

13 Who is organising and funding the research?

This research project is being conducted by A/Prof Kimberley Haines and sponsored by Western Health.

14 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 Western 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.

15 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	Nina Leggett
Position	Physiotherapist, Researcher
Telephone	0466 417 689
Email	Nina.Leggett@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

Name	Melbourne Health HREC
Position	Manager, Melbourne Health Office for Research
Telephone	(03) 9342 8530
Email	research@mh.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:

Reviewing HREC approving this research and HREC Executive Officer details

Reviewing HREC name	Melbourne Health HREC
HREC Executive Officer	Office for Research
Telephone	(03) 9342 8530
Email	research@mh.org.au

Local HREC Office contact

Name	Melbourne Health HREC
Position	Office for Research
Telephone	(03) 9342 8530
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Declaration by Participant

I have read and understood the Participant Information Sheet.

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 relationships with the investigators or Western Health.

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

Name of Participant (please print) _____

Signature _____ Date _____

Witness to the informed consent process
Name (please print) _____
Signature _____ Date _____
* Witness is not to the Investigator, a member of the study team or their delegate. Witness must be 18 years or older.

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.

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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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.

Name of Participant (please print) _____

Signature _____ Date _____

In the event that the participant's decision to withdraw is communicated verbally, the Senior Researcher must provide a description of the circumstances below.

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.

Name of Researcher (please print) _____

Signature _____ Date _____

† 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.