Participant Information Sheet/Consent Form

Interventional Study - *Adult providing own consent*

Sunshine Hospital / Footscray Hospital (Western Health)

Title	Early Discharge to Clinic-based Therapy of Patients Presenting with Decompensated Heart Failure: A Multi-Centre Randomised Controlled Trial
Short Title	EDICT-HF Trial
Protocol Number	HREC 2022.268 / ERM 89710
Project Sponsor	
Coordinating Principal Investigator/ Principal Investigator	Dr Ben Costello / Dr Mark Ranasinghe
Location	Sunshine Hospital / Footscray Hospital

Part 1 What is this research study?

You are being invited to participate in this research study which aims to look at how effective and safe an out-of-hospital management strategy involving clinic-based and home-based care of your heart failure presentation is compared to needing to be admitted to hospital. We believe you may be suitable for this study where the management of your heart failure and other associated medical issues may take place in the hospital as an admitted patient or in an out-of-hospital clinic with additional monitoring in your home environment in between visits.

There are two different groups of participants – one will be managed in the out-of-hospital environment while the other will be admitted to the hospital ward.
If you have been selected to the out-of-hospital group as part of this study, you will be discharged from the emergency department or within 48 hours of your hospital admission if it is safe to do so. Shortly after discharging home, you will be seen by a heart doctor and nurses in a specialised clinic to guide your management. If you have been selected to be part of the other group, you will be managed through being admitted to the hospital ward. Selection to either group is completely random.

1 Introduction

You are invited to take part in this research project because your heart failure has worsened (acute heart failure). Acute heart failure is a major cause of hospital readmissions and seriously worsens the quality of life of patients. Patients who are admitted to hospital are at high risk for both short- and long-term consequences, especially those who are older and have other medical conditions. During the COVID-19 pandemic, due to hospitals being filled with patients, a new pathway was developed in which patients presenting with acute heart failure were discharged from the emergency department and managed in outpatient clinics. These patients performed very well and received optimal care without having to be admitted to hospital. Based on this experience, our research project is investigating a similar treatment approach for acute

heart failure. The new treatment involves management in the out-of-hospital setting through a new clinic-based strategy along with at-home reviews. This will be compared with what we normally do for acute heart failure, which involves a hospital admission.
You are being invited to participate in this study as we have identified you as someone who may benefit from clinic-based management of your heart failure.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and treatments involved. 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 your local doctor.

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

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 have the tests and treatments that are described
• Consent to the collection and 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 aim of this project is to determine how effective and safe an early discharge with out-of-hospital management is compared to hospital care requiring admission. If no differences or positive differences between the approaches are seen, then hospitals like ours may implement this new model of care where patients will benefit from the comfort of safe home and clinic-based care and avoid the serious consequences often seen with hospital admissions. Although the benefits of outpatient care are well-established, there are no high-quality studies comparing clinic-based management of acute heart failure – this study is required to investigate this further to determine whether this model of care may benefit future patients.

This research has been initiated by the study doctors, Dr Mark Ranasinghe and Dr Ben Costello.

This research is being conducted at Western Health.

3 What does participation in this research involve?

You have been identified as someone eligible for this study as you have presented with acute heart failure which can be managed as either a hospital admitted patient or an outpatient, and have satisfied other safety requirements. You will be participating in a randomised controlled research project. Sometimes we do not know which treatment is best for treating a condition. To find out we need to compare different treatments by placing people into groups and giving each group a different treatment. The results are compared to see if one is better. To try to make sure the groups are fair and free from bias, each participant is put into a group by chance (random). There is a 1 in 2 chance of being allocated to either of the groups. The two groups you could be randomised to are:

1. Inpatient (control group) – You will be admitted to hospital and receive usual inpatient care for your heart failure.

2. Out-of-hospital (intervention group) – You will be discharged directly from the emergency department or within 48 hours of your hospital admission. You will receive outpatient clinic reviews and in-home services as outlined below.

All participants will require the following as a minimum:

1. Baseline information regarding your personal information, health and medications will be obtained and recorded
2. Venepuncture for blood tests
3. Ultrasound of your heart and lungs to assess your heart function and level of fluid in your lungs.
4. Heart Failure Rapid Access Clinical Review 1 week after discharge as a hospital inpatient if you are in the control group, or discharge from the outpatient clinic if you are in the intervention group.
5. Heart Failure Clinic review 90 days after discharge as a hospital inpatient if you are in the control group, or discharge from the outpatient clinic if you are in the intervention group.
6. Follow-up phone calls or in-person reviews at 72 hours, 7 days, 30 days, 90 days, and 6 months after initial presentation

Inpatient (Control) Group will require the following in addition:

1. Admission to hospital for usual inpatient care of acute decompensated heart failure

Outpatient (Intervention) Group will require the following in addition:

1. Discharge directly from Emergency Department or within 48 hours of hospital admission
2. If you require ongoing medication through a drip in your arm, one will be inserted in your arm prior to discharge. A drip is a small tube that is inserted using the help of a small needle into your arm. This will be done in one of two ways – by either inserting a shorter and smaller tube into your arm or a longer tuber into your arm. The shorter tube is called a peripheral intravenous cannula (PIVC), and the longer tube is called a peripherally inserted central catheter (PICC). The longer tube (PICC) may be placed if we think you will need a longer course of medications through the drip. The shorter tube (PIVC) is generally safe to use for a maximum of 3 days. There are more details on these types of drips below. These procedures are also performed when patients are admitted to the hospital ward, and the need for medications through the drip is made based on a number of factors looking at your clinical state regardless of which group you are in.
3. Regular EDICT clinic reviews at Sunshine Hospital until the heart doctor discharges you from the clinic. This will occur on Mondays, Wednesdays and Fridays.
4. Complex Care Nursing Reviews by a nurse practitioner on days you are not attending the EDICT clinic for a review, to assess your wellbeing, safety and to guide ongoing management of your heart failure and any other active medical issues.
5. If a PICC line is inserted, Hospital in the Home (HITH) also will visit on the days you do not attend the EDICT clinic, to assess your wellbeing, safety and manage the PICC
6. Once discharged from EDICT clinic and HITH, you will return to having usual outpatient appointments and care, which will involve a review in the Rapid Access clinic after 1 week of discharge, and a review in the heart failure clinic 3 months after discharge, or as directed by your heart doctor.

Procedures:

1. Venepuncture
    - A venepuncture is when a small needle is inserted into a vein in your arm to take blood which can then be analysed
    - Venepuncture will be performed by trained nurses or doctors and is part of standard care of patients presenting with decompensated heart failure
    - The venepuncture should only cause very mild discomfort as the needle is inserted into the skin, but will not cause more pain than that
2. Peripheral intravenous cannula (IVC)

- If randomised to the intervention group, you may require a peripheral IVC to be inserted into your arm so that we can continue to give you medications at home if you require a longer duration of intravenous therapy.
- A peripheral IVC is a short thin tube which is inserted into a vein that can be accessed from anywhere between your hand up to your elbow
- It allows us to give you medication straight into your bloodstream which is useful if you have too much fluid in your body which may be the case since you presented with decompensated heart failure.
- The peripheral IVC will be inserted by either a trained nurse practitioner or trained medical staff and should not cause much pain
- The peripheral IVC will be managed and reviewed in your home by the complex care nursing team who will visit you regularly and during outpatient clinic reviews
- With any invasive procedure there are risks – although the chances are low, there is a risk of infection with peripheral IVC insertion. This will be monitored by the complex care nurses and if you develop an infection, you will require admission to hospital, removal of the peripheral IVC and antibiotics.
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3. Peripherally inserted central catheter (PICC)
    - If selected to the intervention group (out-of-hospital care group), you may require a PICC to be inserted into your arm so that we can continue to give you medications at home if you require a longer duration of intravenous therapy.
    - A PICC is a long thin tube which is inserted up your arm and sits near your heart.
    - It allows us to give you medication straight into your bloodstream which is useful if you have too much fluid in your body which may be the case since you presented with decompensated heart failure.
    - The PICC will be inserted by trained medical staff and should not cause much pain
    - The PICC will be managed and reviewed in your home by the HITH team who will visit you regularly and during outpatient clinic reviews
    - With any invasive procedure there are risks – although the chances are low, there is a risk of infection with PICC insertion. This will be monitored by the HITH team and if you develop an infection, you will require admission to hospital, removal of the PICC and antibiotics.

Time commitment:

1. Inpatient (Control) group – if you are part of the inpatient group, you will receive standard care in the hospital and thus there will be limited additional time commitment required as part of participating in this trial. You will receive follow-up calls at the intervals specified above to check on your wellbeing.
2. Out-of-hospital (Intervention) group – if you are allocated to the outpatient group, you will be required to attend clinic appointments on alternate days. Clinic appointment will only take up to 30 minutes. The total number of clinic appointments required prior to being discharged will depend on your health status and is up to the discretion of your treating heart doctor. You will also receive home visits on alternate days by nurses who will check on your wellbeing and peripheral IVC or PICC if you have one inserted. The duration of these visits will depend on your health status and is up to the discretion of treating heart doctors in discussion with the nursing team. You will receive follow-up calls at the intervals specified above to check on your wellbeing.

<u>There are no additional costs associated with participating in this research project, nor will you be paid. All medication, tests and medical care required as part of the research project will be provided to you free of charge.</u>

This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way.

It is desirable that your local doctor be advised of your decision to participate in this research project. If you have a local doctor, we strongly recommend that you inform them of your participation in this research project.

4 What do I have to do?

There are no restrictions on your day to day life that are specifically required for study, apart from those specified by your treating team. Participation in this study does not restrict you from taking your regular medications or donating blood. We just encourage you to follow the management plan set out for you by your treating team.
Certain things which may restrict your ability to participate in this study include:

- Being too unwell to be discharged from emergency or within 48 hours of admission
- If you are requiring certain types of medications in hospital
- If you have a fever or signs of infection
- If you have been already admitted in hospital for >48 hours
- If you are deemed to have had a heart attack
- If your heart is beating in a dangerous rhythm
- If you have signs of severe organ disease

5 Other relevant information about the research project

We are aiming to have 215 patients in this study, half of which will be allocated to the inpatient group and the other half to the outpatient group. Currently the study only involves Western Health (Sunshine and Footscray Hospital) but if the results of this study are promising we may expand this to include other hospitals as well. This study involves researchers from a number of organisations working in collaboration. This includes researchers from the Baker Heart and Diabetes Institute and The Alfred Hospital.

6 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 treatment, your relationship with those treating you or your relationship with Western Health.

7 What are the alternatives to participation?

You do not have to take part in this research project to receive treatment at this hospital. Other options are available; these include admission to hospital and management of your heart failure as an inpatient which is currently standard care. Your study doctor will discuss these options with you before you decide whether or not to take part in this research project. You can also discuss the options with your local doctor.

8 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 being able to receive treatment at home as opposed to in the hospital, and avoiding complications that may occur in patients admitted to hospital. The results of this study may benefit the wider population by changing the way we manage acute heart failure and allow patients to receive safe care in the comfort of their homes.

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

With any research study, there are risks and disadvantages that need to be discussed. In our study the risks are:

- While the safety and efficiency of outpatient care for acute heart failure have been seen, it is not yet the standard of care. Therefore there is a possibility that for patients allocated to this group, they may not receive the same level of care that inpatients may receive.
- Participants that are allocated to the inpatient group may not receive the potential benefits seen in the outpatient group.
- As mentioned before, if you require a PICC, there is a small risk of infection, bleeding or failure of the line, which will require hospitalisation and management.
- There is also a risk of your disease becoming worse while enrolled under either group. If you are in the inpatient control group, your care will be managed as per the hospital. If you are enrolled in the outpatient intervention group, your care will continue to be managed by the treating heart doctors, complex care nursing service +/- hospital in the home. Key indicators of your health are checked regularly, and if you are deemed to no longer meet the requirements for safety to be enrolled in the trial (including, but not limited to, increasing oxygen requirements, unstable vital signs or raised markers of infection), you will be admitted to the hospital for ongoing care.
- There is also a risk that if randomised to the intervention outpatient group, while you may have been deemed safe to continue living in your usual home environment, these circumstances may change. If so, allied health staff such as physiotherapist, occupational therapists and social workers may be involved to review your circumstances. There is a chance that you may be required to be admitted to the hospital if it is deemed appropriate to do so because your living situation is no longer safe.

If you become upset or distressed as a result of your 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. This counselling will be provided free of charge.

Participation in this study might diagnose previously unknown conditions that may affect insurance in the future.

10 What will happen to my test samples?

You will be asked to provide additional consent for the collection of your blood during the research project. This blood collection is a part of routine care for patients presenting with acute decompensated heart failure and is also a mandatory component of our study.
Blood will be taken to look at the amount of haemoglobin your blood, whether or not you may have an infection, your kidney function and how stretched out your heart is because of the heart failure. Your blood samples will initially be identifiable so that the pathology lab can analyse them. However, they will be changed to a unique code specific to you when used in the statistical analysis part of the study.

Blood samples will be stored in the Dorevitch Pathology Sunshine Hospital laboratory for a period of up to 5 years. It will be destroyed after this period as per institutional protocols. Your blood sample and analysis will only be utilised for the purposes of this research study.

Samples of your blood obtained for the purpose of this research project will be transferred to Dorevitch Pathology.

Once your blood samples are transferred to Dorevitch Pathology, Western Health will not be able to control whether Dorevitch Pathology transfer or sells your samples at some future date, however Western Health will not knowingly transfer your samples to anyone who has expressed intent to sell the samples.

11 What if new information arises during this research project?

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, your study doctor will tell you about it and discuss with you whether you want to continue in the research project. 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 project you will be asked to sign an updated consent form.

Also, on receiving new information, your study doctor might consider it to be in your best interests to withdraw you from the research project. If this happens, he/ she will explain the reasons and arrange for your regular health care to continue.

12 Can I have other treatments during this research project?

Whilst you are participating in this research project, you may not be able to take some or all of the medications or treatments you have been taking for your condition or for other reasons. It is important to tell your study doctor and the study staff about any treatments or medications you may be taking, including over-the-counter medications, vitamins or herbal remedies, acupuncture or other alternative treatments. You should also tell your study doctor about any changes to these during your participation in the research project. Your study doctor should also explain to you which treatments or medications need to be stopped for the time you are involved in the research project.

It may also be necessary for you to take medication during or after the research project to address side effects or symptoms that you may have. You may need to pay for these medications and so it is important that you ask your doctor about this possibility.

13 What if I withdraw from this research project?

If you decide to withdraw from the project, please notify a member of the research team before you withdraw. This notice will allow that person or the research supervisor to discuss any health risks or special requirements linked to withdrawing.

If you do withdraw your consent during the research project, the study doctor and relevant study staff 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 by the study team up to the time you withdraw will form part of the research project results. If you do not want them to do this, you must tell them before you join the research project.

14 Could this research project be stopped unexpectedly?

Although unlikely, it is possible that the research project could be stopped unexpectedly. This may happen if we find that either one of the two groups (inpatient or outpatient) is showing

significantly better or worse outcomes compared to the other group. We do not expect this to be the case however it is possible.

15 What happens when the research project ends?

After the research project ends, the results will be analysed and published in the form of a research manuscript in a peer-reviewed journal approximately 6 months after the final data has been collected. The publication will not contain any identifiable data and will contain summary data only. Depending on the results, it is possible that an outpatient based management pathway is implemented for the management of acute decompensated heart failure patients.

Part 2 How is the research project being conducted?

16 What will happen to information about me?

By signing the consent form you consent to the study doctor and relevant research staff 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. Your data will be coded with a unique patient identifier to protect your privacy. This will only be able to be re-identified by the principal investigators. All data will be kept on password protected computers at Western Health. 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.

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 permission. No individual data will be presented, only summary data and therefore there is no risk of re-identification.

Information about your participation in this research project may be recorded in your health records.

In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to request access to your information collected and stored by the research 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 document if you would like to access your information.
Any information obtained for the purpose of this research project and for the future research described in Section 16 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.

17 Complaints and compensation

If you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

In the event of loss or injury, no compensation will be provided by the parties involved in this research project. By consenting to participating in this study, you acknowledge and accept the risks associated with this study.

18 Who is organising and funding the research?

This research project is being conducted by Dr Mark Ranasinghe and Dr Benedict Costello

Western Health may benefit financially from this research project if, for example, the project assists Western Health obtain approval/funding for a new model of care.

By taking part in this research project you agree that samples of your blood (or data generated from analysis of these materials) may be provided Western Health may directly or indirectly benefit financially from your samples or from knowledge acquired through analysis of your samples.

You will not benefit financially from your involvement in this research project even if, for example, your samples (or knowledge acquired from analysis of your samples) prove to be of commercial value to Western Health.

In addition, if knowledge acquired through this research leads to discoveries that are of commercial value to Western Health, the study doctors or their institutions, there will be no financial benefit to you or your family from these discoveries.

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

Western Health or other health organisations may have an interest in the outcomes of this study in influencing the implementation of future models of care.

19 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 The Royal Melbourne Hospital.

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.

Approval has been provided by key stakeholders in relevant Western Health departments to carry out this research study.

20 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 medical problems which may be related to your involvement in the project (for example, any side effects), you can contact the principal study doctor on 0432 457 457 any of the following people. If this is a medical emergency, please contact 000 or attend the nearest emergency department.

Clinical contact person

Name	*Mark Ranasinghe*
Position	*Principal Study Coordinator*
Telephone	*0432 457 457*
Email	*Mark.Ranasinghe@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	*Mark Ranasinghe*
Position	*Principal Study Coordinator*
Telephone	*0432 457 457*
Email	*Mark.Ranasinghe@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:

Reviewing HREC approving this research and HREC Executive Officer details

Reviewing HREC name	*The Royal Melbourne Hospital HREC*
HREC Executive Officer	*Manager HREC*
Telephone	*(03) 9342 8530*
Email	*Research@mh.org.au*

Local HREC Office contact (Single Site - Research Governance Officer)

Name	*The Royal Melbourne Hospital HREC*
Position	*Manager HREC*
Telephone	*(03) 9342 8530*
Email	*Research@mh.org.au*

Consent Form - *Adult providing own consent*

Title	Early Discharge to Clinic-based Therapy of Patients Presenting with Decompensated Heart Failure: A Multi-Centre Randomised Controlled Trial
Short Title	*EDICT-HF Trial*
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Project Sponsor	Western Health
Coordinating Principal Investigator/ Principal Investigator	*Dr Mark Ranasinghe / Dr Ben Costello*
Location	*Sunshine Hospital / Footscray Hospital*

Consent Agreement

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 give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to Sunshine Hospital concerning my disease and treatment for the purposes of this project. I understand that such information will remain confidential.
I consent to the storage and use of blood and tissue samples taken from me for use, as described in the relevant section of the Participant Information Sheet, for:

- This specific research 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 study without affecting my future health care.

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

Declaration by Participant – for participants who have read the information

Name of Participant (please print) _____

Signature _____ Date _____

Declaration - for participants unable to read the information and consent form
See Note for Guidance on Good Clinical Practice CPMP/ICH/135/95 Section 4.8.9. A legally acceptable representative may be a witness*.
Witness to the informed consent process
Name (please print) _____

Signature _____ Date _____
* Witness is not to be the Investigator, a member of the study team or their delegate. 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 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 research project.
Note: All parties signing the consent section must date their own signature.

- ❒ Consent was obtained via telephone with _____ on [____/____/_____].
- ❒ Participant's signed consent form received by the Investigator on [____/____/_____]
- ❒ Consent was obtained using telehealth with _____ whose photographic identification was sighted by the Investigator who observed the Participant's signature being written
- ❒ Consent was obtained using telehealth with _____ whose photographic identification was sighted by the Participant who observed the Investigator's signature being written
- ❒ Discussed with _____ via telephone on [____/____/_____] and received signed consent form on [____/____/_____]. Signed by _____.

I understand that, if I decide to discontinue the study treatment, I may be asked to attend follow-up visits to allow collection of information regarding my health status. Alternatively, a member of the research 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 consent to the storage and use of blood and tissue samples taken from me for use, as described in the relevant section of the Participant Information Sheet, for:
- This specific research project

Name of Participant (please print) _____

Signature _____ Date _____

For participants unable to read the information and consent form
See Note for Guidance on Good Clinical Practice CPMP/ICH/135/95 Section 4.8.9. A legally acceptable representative may be a witness*.
Witness to the informed consent process
Name (please print) _____
Signature _____ Date _____
* Witness is not to be the Investigator, a member of the study team or their delegate. 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 - *Adult providing own consent*

Title	Early Discharge to Clinic-based Therapy of Patients Presenting with Decompensated Heart Failure: A Multi-Centre Randomised Controlled Trial
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Project Sponsor	Western Health
Coordinating Principal Investigator/ Principal Investigator	*Dr Mark Ranasinghe / Dr Ben Costello*
Location	Sunshine Hospital / Footscray 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 treatment, my relationship with those treating me or my relationship with Western Health.

Name of Participant (please print) _____

Signature _____ Date _____

In the event that the participant's decision to withdraw is communicated verbally, the Study Doctor/Senior Researcher will need to provide a description of the circumstances below.

Declaration by Study Doctor/Senior 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 Study Doctor/
Senior Researcher† (please print) _____

Signature _____ Date _____

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

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