Participant Information Sheet/Consent Form - Person Responsible/Medical treatment decision maker

Non-Interventional Study - *Person responsible/Medical treatment decision maker consenting on behalf of participant*

Eastern Health – Box Hill & Maroondah Hospitals

Title	Quality of Life in older Australians after Hip Fracture: a longitudinal study
Short Title	QoLAHF
Protocol Number	LR22-039-88189
Project Sponsor	Eastern Health
Coordinating Principal Investigator/ Principal Investigator	Dr Thomas Callaghan
Associate Investigator(s)	Dr Jack Dale, Dr Aihua Wu, Dr Basel El-Behesy
Location	Eastern Health – Box Hill & Maroondah Hospitals

Part 1 What does participation involve?

1 Introduction

The participant is invited to take part in this research project, Quality of Life after Hip Fracture (EQAHF) because they have fractured their hip and may require surgery. The research project is aiming to establish how quality of life, functional status and independence are affected following a hip fracture whether or not surgery is performed.

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

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

If you decide you want the participant 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 participant taking part in the research project
- Consent to the participant having the tests and research that are described
- Consent to the use of the participant's 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?

Osteoporosis is one of the most common conditions affecting older adults and can predispose to fragility fractures by far the most common of which is a hip fracture.

Hip fractures in older people are serious injuries and usually require a major operation. Surgery carries significant risks in this group of patients and the recovery process can be long and complicated leaving once independent patients now dependent on others for care. The aim of the study is to see what impact a hip fracture with or without an operation to fix it has on the quality of life, functional status and independence of people over the age of 65 in Australia.

Data from some other countries in the world has already been collected allowing us to estimate the risks of surgery and complications following a hip fracture. Collecting local data will allow us to provide more accurate risk assessment for people in Australia and to see the impact these injuries have on their quality of life and independence.

At the end of this study we will have enough information to identify what impact a hip fracture has on quality of life and which factors if any have the biggest impact on this. This information may help to guide health care professionals, patients and their families on decisions about their treatment options. It may also allow us to make appropriate plans for discharge from hospital and put into place suitable care and assistance in the community.

Researchers will also collect information on factors surrounding surgery, including gathering information on pre-existing medical conditions, treatment received before and after surgery, and the outcomes and complications of surgery. We will use this data to analyse secondary factors associated with hip fracture surgery. This secondary information is routinely available as part of standard medical care surrounding hip fractures.

This research has been initiated by the study doctor, Dr Thomas Callaghan.

This research is being conducted and funded by Eastern Health.

3 What does participation in this research involve?

This study is observational only. This means participation in this project will not lead to any alterations to patient care or have any impact on medical decisions made including those regarding any necessary surgery. Participants will receive the best care and monitoring according to the highest international standards, which may involve surgery and anaesthesia.

Alongside the routine medical assessment, a member of the research team will ask a series of short questions designed to assess functional status, level of independence and quality of life using a number of internationally validated questionnaires. As a result of the participant's memory problems, you as the medical treatment decision maker, will be asked these questions on their behalf. The answers to these questions will not influence their medical care.

We will record and store data about their medical care and hospital stay including test results. No additional tests or investigations will be conducted outside of the routine medical care.

After their discharge we will contact you by telephone at approximately 4 months and 12 months following their hospital admission. During these short telephone consultations you will again be asked the same series of question regarding their functional status, independence and quality of life to identify any changes that may have occurred following their hip fracture. Telephone calls will be expected to last less than 10 minutes in duration. No conversations or telephone calls will be recorded.

We will also review their medical record while they are in hospital and after they have gone home, to see if they have had any complications. If there are any concerns about complications, we will check with their local doctors and medical records for this information.

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

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

Please note no information will be collected or study assessments will be performed until we have established written consent from you by way of the attached consent form.

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 What does the participant have to do?

This study is observational. By participating in this study there will be no alterations to medical care, surgery, recovery or discharge. There will be no changes to medication and no lifestyle or dietary restrictions.

As the participant has some memory problems they will not be required to answer any questions by the research team at any point during the study. Instead, as the medical treatment decision maker, you will be asked to answer a series of short lifestyle questions about the participant at a series of time points after their injury. This will occur once during their initial hospital admission and at two further times via telephone at 4 months and 12 months post discharge. Telephone calls will be expected to last less than 10 minutes duration.

5 Other relevant information about the research project

In total there will be approximately 300 participants taking part in the study from hospitals across Eastern Health. Data collected from this study may be combined with data from other Australian hospitals in order to improve the quality of the results.

Data from this study will be stored securely and may be used in future related research concerning this topic. No information that will be able to identify you personally will be shared.

6 Does the participant have to take part in this research project?

Participation in any research project is voluntary. If you do not wish for the participant to take part, they do not have to. If you decide that they can take part and later change your mind, you are free to withdraw them from the project at any stage.

If you do decide that the participant can 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 the participant can or cannot take part, or take part and then be withdrawn, will not affect their routine treatment, relationship with those treating them or relationship with Eastern Health.

7 What are the alternatives to participation?

The participant does not have to take part in this research project to receive treatment at this hospital. Their treatment will be the same whether they take part or not.

You can also discuss this with another family member or the participant's local doctor before you decide to take part.

8 What are the possible benefits of taking part?

As the medical treatment decision maker you will receive telephone contact to enquire about the participant after their hospital stay for up to one year, which may allow us to detect any problems at an earlier stage, but we cannot guarantee or promise that you will receive any benefits from this project. There will be no clear benefit to the participant from their participation in this research. However, knowledge gained from this research may assist us in treating other patients in the future.

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

Since this research does not involve any interventional treatment the participant will receive the same care whether they part or not. The risks of taking part in the study are the same as those faced by any patient admitted to hospital after a hip fracture. There are no additional risks or side effects from taking part in this study.

You, as the Person responsible/Medical treatment decision maker will be contacted 2 further times by telephone over the next 12 months to, together with the participant, to answer questions on the participant's behalf.

If the participant becomes upset or distressed as a result of participation in the research, you should contact the study team as soon as possible. They will assist you in arranging appropriate treatment and support. Counselling services are available by qualified staff that are not members of the research team. This counselling will be provided free of charge.

10 What will happen to the participant's test samples?

No test samples need to be taken for the purpose of this study.

11 What if new information arises during this research project?

This study is just observational. The participant will receive routine care as per best medical practice.

12 Can the participant have other treatments during this research project?

This study is just observational. The participant may continue to receive care and therapies as needed during the research period.

13 What if the participant is withdrawn from this research project?

If you decide to withdraw the participant from this research project, please notify a member of the research team before withdrawal. A member of the research team will inform you if there are any special requirements linked to withdrawing.

If you do withdraw consent during the research project, the study doctor and relevant study staff will not collect additional personal information from the participant, 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 sponsor up to the time the participant withdraws will form part of the research project results. If you do not want them to do this, you must tell them before the participant joins the research project.

14 Could this research project be stopped unexpectedly?

It is unlikely that we will need to stop the project unexpectedly.

15 What happens when the research project ends?

We plan to make available a report of our results at the end of this study, which we can provide to you on request. You will also be offered the opportunity for extended follow-up for this project and participation in other research conducted by the Department of Anaesthetics at Eastern Health.

Part 2 How is the research project being conducted?

16 What will happen to information about the participant?

By signing the consent form you consent to the study doctor and relevant research staff collecting and using personal information about the participant for the research project. Any information obtained in connection with this research project that can identify the participant will remain confidential. Data will be collected and stored using the Eastern Health Research Electronic Data Capture (REDCap), a Health Insurance Portability and Accountability Act (HIPAA) compliant and highly secure research application. Access to this data will only be available to members of this research team. The participant's 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.

Information about the participant may be obtained from their health records held at this and other health services, 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 participation in this research project.

Information about the patient's participation in this research project may be recorded in their health record.

The participant's health records and any information obtained during the research project are subject to inspection for the purpose of verifying the procedures and the data. This review may be done by the relevant authorities and authorised representatives of the institution relevant to this Participant Information Sheet, Eastern Health, or as required by law. By signing the Consent Form, you authorise release of, or access to, this confidential information to the relevant research personnel and regulatory authorities as noted above.

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 the participants 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 collected and stored by the research team about the participant. You also have the right to request that any information with which you disagree be corrected. Please contact the research team member named at the end of this document if you would like to access the participant's information.

Any information obtained for the purpose of this research project that can identify the participant 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 the participant suffers 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 the participant is eligible for Medicare, they can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

18 Who is organising and funding the research?

This research project is being conducted by Dr Thomas Callaghan.

This research project is being conducted and funded by Eastern Health.

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 Eastern 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.

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 the participant has any medical problems which may be related to involvement in the project (for example, any side effects), you can contact the principal study doctor Thomas Callaghan on thomas.callaghan@easternhealth.org.au or 03 9871 3448, or any of the following people:

Clinical contact person

Name	Dr Thomas Callaghan
Position	Specialist Anaesthetist
Telephone	03 9871 3448
Email	Thomas.callaghan@easternhealth.org.au

For matters relating to research at the site at which the participant is taking part, the details of the local site complaints person are:

Complaints contact person

Name	Eastern Health Human Research Ethics Committee
Position	Manager
Telephone	03 9895 3398
Email	ethics@easternhealth.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	Eastern Health Human Research Ethics Committee
HREC Executive Officer	Chairperson
Telephone	03 9895 3398
Email	ethics@easternhealth.org.au

Consent Form – Person Responsible/Medical treatment decision maker

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

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

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

I give permission for the participant's doctors, other health professionals, hospitals or laboratories outside this hospital to release information to Eastern Health concerning the participant's condition and treatment for the purposes of this project. I understand that such information will remain confidential.

I understand that, if I decide to discontinue the research project 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.

Declaration by Person Responsible/Medical treatment decision maker – for Person Responsible/Medical treatment decision maker who has read the information

Name of Participant (please print) _____

Name of Person providing consent (please print) _____

Relationship of Person providing consent to Participant _____

Signature of Person providing consent _____ Date _____

Declaration - for Person Responsible/Medical treatment decision maker 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 person responsible/medical treatment decision maker for 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.

Form for Withdrawal of Participation – Person Responsible/Medical treatment decision maker

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Declaration by Person Responsible/Medical treatment decision maker

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

Name of Participant (please print) _____

Name of Person providing consent (please print) _____

Relationship of Person providing consent to Participant _____

Signature of Person providing consent _____ 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 person responsible/medical treatment decision maker for 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.