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**Participant Information Sheet/Consent Form**

**Non-Interventional Study** -*Adult providing own consent*

**Box Hill Hospital**

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| --- | --- |
| **Title** | Estimating Short-Term Indirect Cost and Physical Functioning Burden Associated with Osteoporotic Fractures |
| **Protocol Number** | 20190476 |
| **Project Sponsor** | Southern Star Research Pty Ltd |
| **Principal Investigator** | Professor Christopher Gilfillan |
| **Location** | Box Hill Hospital – Arnold Street, Box Hill VIC 3128, Australia |

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

**1 Introduction**

You are invited to take part in this research project, “Estimating Short-Term Indirect Cost and Physical Functioning Burden Associated with Osteoporotic Fractures”. This is because your healthcare team indicates you are suitable for this research. The research project is aiming to investigate the cost and impact of osteoporotic bone breaks on your physical ability as well as your use of medical equipment and support received.

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 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 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 the research that is 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 purpose of this study is to investigate the cost and impact of osteoporotic bone breaks on your physical ability. For example, the impact on your daily activities (e.g. preparing meals, housework), ability to maintain your physical self (e.g. wash and dress yourself), ability to work (e.g. hours per week worked). In addition, this study will investigate your use of medical equipment (e.g. use of walker) and support received (paid and unpaid help in your home).

For the purpose of this study, two groups will be investigated. The first group will be of women who have had an osteoporotic bone break that occurred in the past 12 months and the second group will be of women free of any osteoporotic bone breaks in the past 18 months.

Bone breaks are associated with significant burden both in formal care settings (e.g. hospitalisations, rehabilitative services, long-term care) and informal care settings (e.g. care provided by family and friends), in addition to lower quality of life. This study may help inform policy makers, clinicians, and patients about the impact of osteoporotic bone breaks on women across multiple countries and help understand the importance of reducing the risk of bone breaks. About 1,500 women from 5 countries (United States, Australia, Spain, Germany, South Korea) will participate in the study.

This research is being conducted by Adelphi Real World on behalf of the biopharmaceutical sponsor Amgen Inc. and UCB Inc. The study is being conducted in Australia by Southern Star Research on behalf of the sponsors.

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

If you agree to participate, you will be asked to sign this consent form stating that you have read and understood the information presented and have had all your questions answered. A copy of this consent form is yours to keep.

Next, the research team will provide you with a paper survey to complete. It will take about **15-20 minutes.** Please return it to the research team when you have finished.

The healthcare team will then review your medical records to copy information on your bone break (if you are part of the group with bone breaks), its treatment (if you are part of the group with bone breaks) and other relevant illness(es) that you may have experienced. The team will look at information collected from any time up to 30 months before you join the study until the research study is completed. You will not need to be present for this part of the study.

There will be no changes to your treatment or the care you receive from your doctor as part of this research.

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

There are no costs associated with participating in this research project. Upon completion of the survey, you will receive a Coles voucher for $50.00 AUDfor your time as a result of participating in this research project.

**4. 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 Eastern Health.

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

We cannot guarantee or promise that you will receive any benefits from this research. The information you provide will help us to strengthen the evidence around the burden of osteoporotic bone breaks. The findings of the study may be published in journals and presented at conferences. Please note that you will not be identifiable in any study reports or publications and you will not be provided with a summary of the study results.

There will be no clear benefit to you from your participation in this research.

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

No medical procedures will be performed and there will be no change to the medications already prescribed by your doctor; there is no risk of physical harm related to this study. We will collect information from you through a questionnaire and collect some additional health information from your medical records.

Every possible step is taken to ensure confidentiality, however there is always a minimal risk that someone who is not part of the research team may see your answers.

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

If you decide to withdraw from this research 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 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 sponsor 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.

**8 Could this research project be stopped unexpectedly?**

This research project may be stopped unexpectedly for a variety of reasons by the Sponsor. However, this will not impact you as once you complete the questionnaire your participation in the research project ends.

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

After you complete the questionnaire, there is no further follow-up for you to complete and your participation in the research project ends. When all participants’ questionnaires are collected globally, the research project will end and analysis of the information collected will be performed according to the research project objectives.

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

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

Your health records and questionnaire 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 Sponsor, Adelphi Real World, Amgen Inc., UCB and Southern Star Research, 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 you cannot be identified. All personally identifiable information collected during this study is confidential. Your health information will be assigned an ID number, to prevent research team members outside of your healthcare team from identifying you. Only re-identifiable/coded data will be sent to the sponsor and will be retained for 15 years post completion of the study.

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 the information collected and stored by the research team about you. 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 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.

Your rights under Data Privacy Laws

The European Union’s General Data Protection Regulation (GDPR) and other countries’ data privacy laws provide certain rights for data subjects. We follow both Australian and European data privacy laws. This consent form provides information on how we collect and use (process) your personal data. For additional information, the research team that invited you to participate in this study has a copy of Adelphi’s privacy policy for you to review which can also be found at http://www.adelphigroup.com/privacypolicy.pdf.

In many countries, you have a right to access, modify or request deletion of your personal data and to lodge a complaint with the appropriate data protection authority if you have concerns about how your personal data is processed. Please ask the research team that invited you to be in this study how to exercise these rights or contact us using the contact details shown in the Contacts section.

Adelphi Real World will not retain your personal data for longer than is necessary. At the end of the research project, Adelphi Real World will redact (remove) the personal data no longer required for the project. This means that most of the personal data collected during the research project is deleted and there is minimal personal data retained by Adelphi Real World.

**11 Who is organising and funding the research?**

This research project is being sponsored internationally by Amgen Inc. and UCB and sponsored and conducted in Australia by Southern Star Research Pty Ltd. The clinical research organisations responsible for the management of this research project overseas are Adelphi Real World and UBC Ltd.

Eastern Healthwill receive a payment from Southern Star Research Pty Ltd for undertaking this research project.

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

**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 medical problems which may be related to your involvement in the project you can contact the principal study doctor on (03) 9092 6753 or any of the following people:

**Clinical contact person**

|  |  |
| --- | --- |
| Name | Carolyn Harris |
| Position | Study Coordinator |
| Telephone | (03) 9094 9521 |
| Email | carolyn.harris@monash.edu |

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 | Eastern Health Office of Research & Ethics |
| 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**

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| --- | --- |
| Reviewing HREC name | Melbourne Health 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 | Eastern Health Office of Research & Ethics |
| Position | Manager |
| Telephone | (03) 9895 3398 |
| Email | ethics@easternhealth.org.au |

Overseas Sponsor Contact person:

Contact Adelphi Real World at: [arw-compliance@adelphigroup.com](mailto:arw-compliance@adelphigroup.com)

Find out more about Adelphi Real World at [www.adelphirealworld.com](http://www.adelphirealworld.com)

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

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| **Protocol Number** | 20190476 |
| **Project Sponsor** | Southern Star Research |
| **Principal Investigator** | Professor Christopher Gilfillan |
| **Location** | Box Hill Hospital – Arnold Street, Box Hill VIC 3128, Australia |

**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 healthcare.

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

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

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

Under certain circumstances (see Note for Guidance on Good Clinical Practice CPMP/ICH/135/95 at 4.8.9) a witness\* to informed consent is required.

|  |  |  |  |  |  |  |  |
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|  | | | | | | | |
|  | Name of Witness\* (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 participant has understood that explanation.

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|  | | | | | | |
|  | 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.