

## Participant Information Sheet/Consent Form-A

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

Monash Health

<b>Title</b>	Why Indigenous Australians Fall and Fracture: Study of Indigenous Muscle and Bone Ageing
<b>Short Title</b>	SIMBA
<b>Protocol Number</b>	Version 3 – 5 February 2020
<b>Project Sponsor</b>	Monash University
<b>Principal Investigator</b>	Prof Peter R Ebeling AO MBBS MD FRACP
<b>Associate Investigator(s)</b>	Dr Ayse Zengin Mx Catherine Shore-Lorenti Mr Christopher Fone
<b>Location</b>	Monash Medical Centre, Clayton VIC

## Part 1 What does my participation involve?

### 1. Introduction

You are invited to take part in this research project, which is called “Why Indigenous Australians Fall and Fracture: Study of Indigenous Muscle and Bone Ageing,” or “SIMBA” for short. You have been invited because your contact details were provided to us in one of the following ways:

- your contact details are registered with Bunurong Health Service who told you about this project, and you told them that you may be interested in participating and gave permission to forward your contact details to us;
- a member of the community or medical doctor told you about this project, and you told them that you may be interested in participating and gave permission to forward your contact details to us;
- you saw an advertisement for this project and then contacted us;
- you registered your contact details on our Bone & Muscle Research Group (BMRG) Registry.

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, local medical doctor, or Indigenous community leader.

Participation in this research project is voluntary. If you don’t wish to take part, you don’t have to.

If you do decide you want to take part in the research project, you will be asked to sign the consent form included at the end of this document. By signing it you are telling us that you:

- understand what you have read;
- consent to take part in this research project;
- consent to be involved in the research described; and
- 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?

Indigenous Australians have a substantially greater fracture risk than non-Indigenous Australians. For minimal trauma fractures, defined as fractures that result from trauma equal to or less than a fall from standing height, Indigenous men are 50% and Indigenous women 26% more likely to experience minimal trauma fractures than non-Indigenous men and women respectively.

The primary importance and value of this research study is that it will be the first to focus on bone and muscle ageing in Aboriginal and Torres Strait Islander Australians, which is also known as “musculoskeletal ageing”. Detailed musculoskeletal health assessments will be conducted for the first time, thereby considerably advancing our understanding of why fracture and fall risk are higher in Aboriginal and Torres Strait Islander adults. This will improve accuracy in fracture risk assessment, increase health literacy in the community, improve screening and diagnosis of osteoporosis, and formulate targeted culturally appropriate intervention strategies to reduce fall and fracture risk in Aboriginal and Torres Strait Islander adults. Together, the outcomes of this research aim to make a meaningful contribution to ensuring Indigenous Australians receive comparable quality of care to non-Indigenous Australians within our national healthcare system.

The aims of this research project are to:

- determine the prevalence of osteoporosis and sarcopenia across the ageing spectrum in Aboriginal and Torres Strait Islander adults;
- measure within-individual yearly change in skeletal and muscular characteristics that increase falls and fracture risk;
- identify lifestyle (dietary intake, physical activity) and co-morbidity (CVD, T2DM, CKD) determinants of bone and muscle strength loss during ageing; and
- improve health literacy in musculoskeletal health.

This research project has been initiated by researchers Professor Peter R Ebeling AO and Dr Ayse Zengin, and has been funded by a research grant from Osteoporosis Australia.

## 3. What does participation in this research involve?

If you decide to participate in this research project, you will first be contacted by the research team to complete a screening questionnaire over the phone, which will allow us to determine if you are eligible to participate. It will take approximately five minutes, and will involve answering a few questions about your age, weight, presence of any metal in your body, fluency in English, and the existence of any medical conditions that may affect bone and muscle imaging and/or your safety.

If you are eligible to participate, and you decide to participate, you will need to commit to attending approximately 12 hours of sessions over a three-year period as follows:

- 3 Imaging Sessions at Monash Medical Centre, for 2 hours each.  
The Imaging Sessions will be spread out over 2 years, with the first occurring within one month of joining, the second at 1 year and the third at 2 years after joining;
- 6 Community-based Health Education Seminars at an Indigenous community venue, for 1 hour each.  
The Seminars will start 1 year after joining the study, and will be held once a month for 6 months.

In the **Imaging Sessions**, we will complete the following with you:

- **Physical measurements:** weight, height, physical performance (such as balance, gait speed and jumping tests) and blood pressure;
- **Questionnaires:** covering name, contact details, medical history relating to bone and muscle health, reproductive history and menopausal status (women), family history of fractures, medications and nutritional supplements taken, physical exercise habits, diet, smoking and alcohol consumption, recent exposure to nuclear medicine, sarcopenia and quality of life, osteoporosis knowledge and beliefs;
- **Bone and body composition imaging:** a total of 14 scans will be performed at each Imaging Session, using DXA, pQCT and HR-pQCT machines.  
*During each scan, you will be required to remain perfectly still and silent for up to 7 minutes to ensure scans are free from motion error. You will be lying down fully clothed, for several scans (DXA), and seated for the rest (pQCT, HR-pQCT).*
- **Blood tests:** you will have a blood sample taken at the first and the last Imaging Session (but not at the 1-year timepoint).  
We will need you to fast from 10:00pm of the night before this blood test. Blood collection will be done early in the morning and we will provide you with some refreshments once the test is completed.  
The blood test will measure your kidney and liver function, sugar levels, cholesterol and other fats, as well as minerals and vitamin D.

For each of the Imaging Sessions, you will attend in person for 2 hours, on a day convenient for you between 7:00 am and 7:00 pm weekdays, at Monash Medical Centre, 246 Clayton Road, Clayton VIC. You can take a break for rest and bathroom for 15 minutes mid-way through the session if required.

In the **Community-based Health Educational Seminars**, you will learn about health topics such as:

- bone health, including health conditions such as osteoporosis where bone density and strength is low;
- muscle health, including health conditions such as sarcopenia where muscle function and strength is low;
- diseases that affect bone and muscle health;
- diet, nutrition, physical activity and exercise, and the role they play in bone and muscle health;

- bone and muscle health throughout our lifetime.

For each of the Educational Seminars, you will attend in person for 1 hour, on a set weekday between 7:00 am and 7:00 pm, at an Aboriginal community centre to be confirmed and communicated to you prior to your attendance.

Participant information collected will be treated as confidential and will be stored on a secure database accessible only to authorised researchers in our team until the completion of the project. Any paper documents will be stored in locked filing cabinets, and all data will be archived and stored securely for up to 15 years, following the earlier of research publication or archival.

You may choose not to provide certain personal information requested by researchers in relation to this project. If by choosing not to provide information you become ineligible to continue your participation in the project, researchers will notify you of this. You can then decide to either provide the information if you are comfortable to do so, or alternatively you may choose to withdraw from the project.

This project will be monitored by Professor Peter Ebeling AO MBBS MD FRACP. Prof Ebeling is a registered and experienced physician specialising in endocrinology and musculoskeletal health. He is Head of Department of Medicine at the School of Clinical Sciences, Monash University, and Chair of Division of Medicine at Monash Health.

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

#### 4. Other relevant information about the research project

This research is conducted at Monash Medical Centre in Clayton and Bunurong Health Service in Dandenong. A total of 298 participants will be recruited for this research project.

Participants are selected from the Aboriginal and Torres Strait Islander community here in Melbourne, with particular criteria including: adults aged 35 years or older, any gender, weigh not more than 160 kg, at least one side of the body free from any metal or other material that may interfere with imaging, fluent in written and spoken English with capacity to provide consent, no other existing medical conditions that may deem participation unsafe or inappropriate (e.g. inability to remain still and supine during scans), and women who are not pregnant or have breastfed in the last 6 months.

Researchers on this project are research staff at the Bone and Muscle Research Group, Department of Medicine, School of Clinical Sciences at Monash Health, Monash University.

#### 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.

If you decide to leave the research project at any time, 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.

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

**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:

- receiving copies of your DXA total hip and lumbar spine scans via your GP;
- satisfaction of knowing you are contributing to the quality of future research into musculoskeletal health in the community;
- learning about how medical research projects are conducted.

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

Potential risks of participating in this project include the following:

***Ionising radiation***

This research study involves exposure to a very small amount of radiation. As part of everyday living, everyone is exposed to naturally occurring background radiation and receives a dose of about 2 millisieverts (mSv) each year. The effective dose from this study is about 0.193 mSv per year for two years. At this dose level, no harmful effects of radiation have been demonstrated, as any effect is too small to measure. The effective radiation dose has been verified by a qualified Medical Physicist as likely to fall within annual dose constraints, as required by the Code of Practice for the Exposure of Humans to Ionizing Radiation for Research Purposes (2005), ARPANSA.

***Psychological distress***

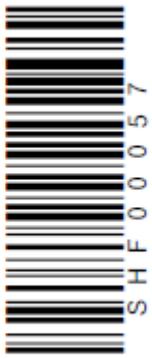
If you become upset or distressed as a result of your participation in the research project, the research team will be able to arrange for counselling or other appropriate support. Any counselling or support will be provided by qualified staff who are not members of the research team. In addition, you may prefer to suspend or end your participation in the project if distress occurs.

***Medical conditions***

If your participation results in identification of a medical condition of which you were unaware, we will inform your nominated doctor. For any medical conditions identified or injuries sustained as a result of participating in this research project, hospital care and treatment will be provided by the public health service at no extra cost to you if you elect to be treated as a public patient.

***Blood test***

Having a blood sample taken may cause some discomfort, bruising, minor infection or bleeding. If this happens, it can be easily treated.



**8. What will happen to my blood test samples?**

The blood samples collected at the first and last Imaging Session will be stored and frozen until all research volunteers have completed the study. Samples will be coded with a research ID number to protect your privacy. Only the research study staff with the codes will know which sample belongs to you. The samples will be stored at Monash Medical Centre and will be analysed by Monash Health Pathology once the study has been completed. Some of your samples may be stored for up to 15 years so that the researchers can measure other biomarkers of bone health, kidney function and heart health (once more research funding becomes available).

**9. 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 this research project, you must complete and sign the “Withdrawal of Consent” form provided at the end of this document, and return it to the researchers. Then, researchers will not collect any 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.

**10. 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 instrument malfunction, key staff being absent for an extended period of time, or any safety concerns. If this occurs, you will be notified by the researchers.

**11. What happens when the research project ends?**

Data will be analysed and findings presented at various Indigenous community centres and Bunurong Health Service. Additionally, scientific papers will be drafted and submitted to medical journals. A report will be submitted to the Victorian Aboriginal Community Controlled Health Organisation and to Osteoporosis Australia. If best practice requires modification, these reports will form the evidence required to begin changes in healthcare policy.

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

### 12. What will happen to information about me?

By signing the consent form at the end of this document, you consent to the research team collecting and using personal information about you for the research project. The personal information that the research team collects and uses will include details you provide on the consent form, questionnaires, and measurements taken during your sessions including imaging.



All data collected during this project will be individually identifiable to authorised researchers at the Bone and Muscle Research Group, and will be de-identified upon registration using a unique participant code. Your information will otherwise only be disclosed with your permission, or if required by law. Any information obtained in connection with this research project that can identify you will remain confidential, and accessible only where required by law, for ethics audit, or to researchers authorised by Monash Health Human Research Ethics Committee (HREC).

Hard copies of data will be stored in a locked cabinet at Monash Medical Centre. Electronic data will be stored on a secure Monash University network, and only authorised researchers will have access to the data. Computers used to operate the imaging instruments are password protected and located in the secure imaging room, where imaging data will be stored and backed up according to standard procedures. All data will be stored in this manner for a period of 15 years, following the earlier of research publication or archival, and then will be destroyed.

The results of this research project may 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. All presented data will be aggregated, and no individual results will be published. We may use your data for future research projects providing it is de-identified (name, date of birth and contact details removed).

In accordance with relevant Australian and 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.

### 13. Complaints and compensation

If you suffer any injuries or complications as a result of this research project, you should contact the research team as soon as possible (see contact details in section 15 below), and you will be assisted with arrangement of appropriate medical treatment. Only Medicare-eligible individuals can participate in human clinical trials research, and can receive any medical treatment required to treat injury or complication, free of charge, as a public patient in any Australian public hospital.

If you have any complaints about any aspect of the project, you may contact the Monash Health HREC Office. See complaints contact details in section 15 below.

In the event of loss or injury, you may be able to seek compensation through the courts.

### 14. Who is organising and funding the research?

This research project is being conducted and sponsored by the School of Clinical Sciences at Monash Health, Monash University. It is being funded by a research grant from Osteoporosis Australia.

You will not benefit financially from your involvement in this research project, even if, for example, knowledge acquired from your information proves to be of commercial value to Monash University.

In addition, if knowledge acquired through this research leads to discoveries that are of commercial value to Monash University, the researchers 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).

**15. 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 Monash Health.

This project will be carried out according to *Good Clinical Practice (GCP)* guidelines and the *National Statement on Ethical Conduct in Human Research (NHMRC 2018)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

**16. Further information and who to contact**

The person you may need to contact will depend on the nature of your query.

For enquiries relating to this research project, or if you have any problems which may be related to your involvement in the project, please contact the **Research contact person** below.

If you have any medical problems which may be related to your involvement in this project, i.e. possible side effects, you can contact the **Clinical contact person** below, or any of the other people listed below. In case of a medical emergency please call 000 for immediate attention.

If you have any complaints about any aspect of this research project, the way it is being conducted, or any questions about being a research participant in general, please contact the **Complaints contact person** below.

**Research contact person**

Name	Dr Ayse Zengin
Position	Research Fellow, Bone & Muscle Research Group
Telephone	03 8572 2918
Email	med-bmrg@monash.edu

**Clinical contact person**

Name	Professor Peter Ebeling AO MBBS MD FRACP
Position	Head of Medicine, School of Clinical Sciences at Monash Health
Telephone	03 8572 2570
Email	peter.ebeling@monash.edu

**Complaints contact person**

Name	Deborah Dell
Position	Manager, Human Research Ethics Committee, Monash Health
Telephone	03 9594 4605
Email	deborah.dell@monashhealth.org

**Consent Form-A** (Adult providing own consent)

<b>Title</b>	Why Indigenous Australians Fall and Fracture: Study of Indigenous Muscle and Bone Ageing
<b>Short Title</b>	SIMBA
<b>Protocol Number</b>	Version 3 – 5 February 2020
<b>Project Sponsor</b>	Monash University
<b>Principal Investigator</b>	Prof Peter R Ebeling AO MBBS MD FRACP
<b>Associate Investigator(s)</b>	Dr Ayse Zengin Mx Catherine Shore-Lorenti Mr Christopher Fone
<b>Location</b>	Monash Medical Centre, Clayton VIC

**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 I understand that I am free to withdraw my participation at any time during the project without affecting my future care or relationship with Monash Health or Monash University.

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

I consent to my de-identified data being used for future related research studies.

Name of Participant (please print) _____ Signature _____ Date _____
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**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 given.

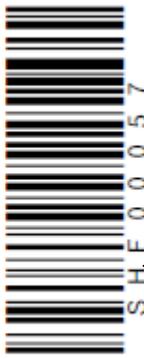
Name of Researcher† (please print) _____ Signature _____ Date _____
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† An appropriately qualified member of the research team must provide the explanation of, and information concerning, the research project.

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

## Withdrawal of Participation Form-A *(Adult providing own consent)*

<b>Title</b>	Why Indigenous Australians Fall and Fracture: Study of Indigenous Muscle and Bone Ageing
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<b>Location</b>	Monash Medical Centre, Clayton VIC



**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, Monash University, or Monash 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 declaration must date their own signature.