Participant Information Sheet/Consent Form

Interventional Study - *Adult providing own consent*

Title	Combining osteoanabolic pharmacotherapy with osteogenic exercise in women with postmenopausal osteoporosis/osteopenia
Short Title	Romosozumab with osteogenic exercise in postmenopausal osteoporosis
Protocol Number	1
Coordinating Principal Investigator/ Principal Investigator	Dr Shejil Kumar
Associate Investigator(s)	A/Prof Christian Girgis, Prof Roderick Clifton-Bligh, Prof Belinda Beck, Ms Liza Nery

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this research project. This is because you are a woman aged between 50 and 80 years who has gone through menopause and have been identified as having evidence of thin/fragile bones placing you at increased risk of bone fractures but not at such high risk that it would be unsafe for you to participate in the study. You are able to participate in assessments to deem whether it is safe for you to participate in exercise as part of the study and you are not already participating in an exercise program with resistance or high-impact exercises. The research project is testing a combination of two existing treatments for postmenopausal osteoporosis. The new treatment is combining romosozumab (a drug already used for osteoporosis) or placebo with different forms of exercise.

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 use of your personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

Kumar S, *et al. BMJ Open* 2024; 14:e086708. doi: 10.1136/bmjopen-2024-086708

2 What is the purpose of this research?

The study involves combining a bone-building medication (romosozumab) or placebo with one of two different exercise programs. The purpose is to determine which exercise program, when combined with romosozumab, produces greater improvements in bone mass over 8-months in women with osteoporosis who have gone through menopause. This study is important because the research might show what type of exercise combined with romosozumab is the most effective treatment for osteoporosis. The study will also assess whether the same bone-building medication (romosozumab), compared with placebo, can improve muscle mass, muscle strength and overall physical function, quality of life and risk of falls which is important because vast majority of bone fractures occur after people fall over. Romosozumab is currently approved for use in osteoporosis in Australia.

Medications, drugs and devices have to be approved for use by the Therapeutic Goods Administration (TGA). Romosozumab is approved in Australia to treat osteoporosis.

The results of this research will be used by the study doctor Shejil Kumar towards obtaining a PhD degree.

This research has been initiated by the study doctor, Dr Shejil Kumar.

This research has been funded by the departments of Diabetes, Endocrinology & Metabolism at study sites and grants provided by Amgen/Healthy Bones Australia/Australia and New Zealand Bone and Mineral Society (ANZBMS), Avant Mutual and the NORTH foundation.

3 What does participation in this research involve?

If you agree to participate in this study, you will be asked to sign this Participant Consent Form. The consent form will need to be signed before any study assessments are done.

This study will be conducted over 8-months. Your involvement in the study will first involve 'screening procedures' to determine whether you are suitable to participate in this study including a medical history and physical assessment by a doctor, blood tests, a trace of your heart (ECG), X-ray of your lower back/spine, specialised X-ray assessing the thickness of bone in your lower spine, hip and wrist (bone density scan) and a specialised scan assessing your body composition (fat and muscle).

If you are deemed eligible to participate in the study, you will then be randomly allocated into a study group based on whether or not you will receive the active study drug or salt water/placebo, and whether or not you will be in a supervised exercise program in an exercise facility or a home-based unsupervised exercise program. This is what we call a randomised trial. The drug/placebo will be given to you once every month for 8-months through an injection under the skin (subcutaneous). The exercise sessions will occur twice per week for approximately 45 minutes per session. You will not know whether you are receiving the active study drug or the placebo – this is called 'blinding' and is important in this study because otherwise your knowledge of the treatment you are receiving may affect some of your results.

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. We put people into groups and give each group a different treatment. The results are compared to see if one is better. To try to make sure the groups are the same, each participant is put into a group by chance (random). There will be a two in three chance of you receiving romosozumab and a one in three chance of you receiving placebo. All participants will be commenced on an exercise program.

You will be participating in a double-blind study. This means that neither you nor your study doctor will know which treatment you are receiving. However, in certain circumstances your study doctor can find out which treatment you are receiving.

A placebo is a medication with no active ingredients. It looks like the real thing but is not.

The study drug being given to you has been shown in large trials of postmenopausal women to be very effective in improving bone strength and reducing risk of fractures and has been shown to be overall safe. This drug is approved for use in Australia for osteoporosis.
The exercise programs have also been used in other trials of postmenopausal women and have been shown to be safe.
The combination of these two treatments (drug and exercise) is what is specifically being assessed in this study.

If you agree to participate in this trial and are deemed suitable to participate and after you are allocated to a study group, you will then be asked to have monthly clinic visits over an 8-month period with each visit including a physical assessment by a doctor, blood tests, an ECG, and providing you with an injection under the skin (subcutaneous injection), which will either be the active study drug romosozumab (210mg) or placebo. Romosozumab is given as two injections (2 x 105mg) and so placebo will also be administered as two injections. Every 4-months you will also have tests of your physical function, and every 4-months you will have an X-ray of your lower back, a bone density scan, a body composition scan and a survey regarding your quality of life and any menopause-related symptoms.

We would also require you to participate in one of two exercise programs depending on which program you are randomised into.

One exercise program will require attendance at two approximately 45-minute sessions per week for 8-months which will be at licenced exercise facilities in Sydney and conducted in a safe manner under expert supervision. The first month will involve a safe transition period focussing on learning the correct posture and form for the exercises. Exercises will include deadlift, overhead press, back squat and jumping from a chin-up bar. The intensity of the exercises will be slowly and safely upgraded depending on your capacity. This exercise program will be delivered by physiotherapists and accredited exercise physiologists who have completed comprehensive training to become providers of the program.

The other exercise program will involve two approximately 45-minute sessions per week for 8-months unsupervised at home and we will show you which exercises to do beforehand. This exercise includes walking for warm-up and cool-down and free weight exercises (sit to stands, stepping, walking heel to toe and sideways).

We expect at least 75% attendance overall throughout the year at these exercise sessions. You will be required to record your exercise attendance and habits into a logbook provided by the study team. If you decide to change your exercise habits outside of the exercise program you are placed in, then we will take this into account when reviewing the results of the study. The cost of the exercise programs will be covered by specific funding for this research study.

Definition of blood sampling: Samples of blood taken from a vein will be required. The amount of blood taken will be equivalent to ten-twenty millilitres (two to four teaspoons) taken monthly for the first 4-months and then at 6-months and 8-months. Depending on which exercise program you are randomised into, we may also like to collect a blood sample immediately before, immediately after and 4-hours after one exercise session near the start and one exercise session near the end of the 8-month study.

Participating in the trial will mean you are only able to receive the treatment we provide you for your bone health.

In addition, the researchers would like to have access to your medical record to obtain information relevant to the study. The information collected includes your age, sex, ethnicity, height, weight, smoking history, alcohol intake, and results of all the above tests.

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

There are no 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.

You will be reimbursed for any reasonable travel, parking, meals and other expenses associated with the research project visit, including hospital parking vouchers, public transport travel costs if requested, and a meal voucher if you need to be fasted for your study visit.

It is desirable that your local doctor be advised of your decision to participate in this research project. Your local doctor will be informed of your participation in this research project by the study team unless you request that this does not occur.

Timeline of your involvement in the study:

STEP	**TASK**
Consent	Written signed informed consent provided by you
Screening procedures	To ensure you are suitable for inclusion in the study - medical and medication history - basic observations (e.g. heart rate, blood pressure), height and weight - physical exam - electrocardiogram (ECG) i.e. heart trace - spine X-ray - bone density scan and body composition scan - blood test
Randomisation	You will be randomised into drug treatment (drug vs placebo) and one of two different exercise programs
Baseline study visit	- medical update, observations, physical exam, ECG, muscle strength assessment, physical performance assessments, exercise questionnaire, calcium intake questionnaire, quality of life survey, menopause survey, blood test - administration of either drug or placebo (depending on your group)
1-month study visit	- medical update, observations, physical exam, ECG, blood test - administration of drug or placebo
2-month study visit	- medical update, observations, physical exam, ECG, blood test - administration of drug or placebo
3-month study visit	- medical update, observations, physical exam, ECG, blood test - administration of drug or placebo
4-month study visit	- medical update, observations, physical exam, ECG, spine X-ray, bone density scan, body composition scan, muscle strength assessment, physical performance assessments, quality of life survey, menopause survey, blood test - administration of drug or placebo
5-month study visit	- medical update, observations, physical exam, ECG - administration of drug or placebo
6-month study visit	- medical update, observations, physical exam, ECG, blood test

	- administration of drug or placebo
7-month study visit	- medical update, observations, physical exam, ECG - administration of drug or placebo
8-month study visit	- medical update, observations, physical exam, ECG, spine X-ray, bone density scan, body composition scan, muscle strength assessment, physical performance assessments, exercise questionnaire, calcium intake questionnaire, quality of life survey, menopause survey, blood test
Post-study visit 1	- medical update, observations, physical exam, ECG
Post-study visit 2	- medical update, observations, physical exam, ECG

A study visit requires you to attend the health facility where you are having your assessments and treatments provided as part of the study.

The above timeline does not include the exercise interventions. During the active 8-months of the study (starting from the baseline study visit to the 8-month study visit), you will also be engaged in one of two different exercise programs consisting of two 45-minute sessions weekly.

4 What do I have to do?

During your involvement in the study, you may be expected take vitamin D tablets if required to maintain a normal vitamin D level. If your vitamin D levels are normal at the start of the study without the need for vitamin D tablets, then we generally wouldn't recommend vitamin D tablets. Vitamin D, if required, would be considered usual care and hence would not be funded by the study sponsor. Other than the exercise delivered as part of the study, you should not be involved in any other resistance or high-impact exercise training. If you do engage in exercise outside of this, then please document this in the exercise logbook provided by the study team. You will be able to take your regular medications however you won't be able to take any medications specifically used to treat osteoporosis during the study (other than the drug provided to you in the study) or medications known to have negative effects on bone health (steroid medications, anti-hormone therapies for breast cancer).

5 Other relevant information about the research project

Overall, the study will involve approximately 102 participants. Each participant will be randomised to either receiving romosozumab or placebo and also randomised to one of two different exercise programs. Researchers will be based at study sites and we are also collaborating with a bone/exercise researcher based in Brisbane who is an expert on the exercises being used in this study and she will help ensure it is being done in an effective and safe way.

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 the hospital at which your osteoporosis is managed.

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 having standard approved medication for osteoporosis including oral and intravenous bisphosphonate medications, subcutaneous denosumab injections and menopausal hormone replacement therapy. People who otherwise would have qualified for government PBS-reimbursed treatments for osteoporosis will not be included in our study for ethical reasons given you have a one in three chance of being randomised to placebo. 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 overall from this study may include furthering medical knowledge and improving future treatment options for osteoporosis and bone health in postmenopausal women.

There may not be any clear benefit to you from your participation in this research. However depending on which group/treatment you are assigned to, you may experience benefits including improvements in the bone density/strength of your lower spine and hip, and increased muscle strength and physical function.

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

All medical procedures involve some risk of injury. In addition, there may be risks associated with this study that are presently unknown or unforeseeable. In spite of all reasonable precautions, you might develop medical complications from participating in this study. The known risks of this study are:

- Inconvenience of being involved in the study and completing clinic/study visits monthly for 8-months
- Risks related to the use of the study drug (see table below)
- Risks related to the exercise program
  - falls (although none occurred in recent studies)
  - bone fractures (although none occurred in recent studies)
- Risks related to having blood tests taken such as pain, bruising and infection
- Radiation exposure from X-ray scans
  - considered very low
  - the study has been approved by a radiation safety officer

Medical treatments often cause side effects. You may have none, some or all of the effects listed below, and they may be mild, moderate or severe. If you have any of these side effects, or are worried about them, talk with your study doctor. Your study doctor will also be looking out for side effects.

There may be side effects that the researchers do not expect or do not know about and that may be serious. Tell your study doctor immediately about any new or unusual symptoms that you get.

Many side effects go away shortly after treatment ends. However, sometimes side effects can be serious, long lasting or permanent. If a severe side effect or reaction occurs, your study

doctor may need to stop your treatment. Your study doctor will discuss the best way of managing any side effects with you.

Side Effect of Study Drug	How often is it likely to occur?	How severe might it be?	How long might it last?
Joint pains/aches	1 in 10 people	Mild	1-2 days
Runny nose	1 in 10 people	Mild	1-2 days
Back pain	1 in 10 people	Mild	1-2 days
Low blood calcium level	Less than 1 in 1000 people	Mild	1-2 days
Allergic reaction to the drug	3 in 100 people	Mild	1-2 days
Pain/swelling/redness at injection site	1 in 20 people	Mild	1-2 days
Jaw/teeth issues	Less than 1 in 1000 people	Mild-moderate	1-3 months
Fracture related to taking the drug	Less than 1 in 1000 people	Moderate-severe	1-3 months

In one large trial comparing romosozumab with placebo in women with postmenopausal osteoporosis, there was no increased risk of heart disease or stroke. In another large trial comparing romosozumab with a tablet treatment for osteoporosis, there was a small increased risk of heart disease or stroke in the romosozumab group (although this was rare in both groups and may have been due to chance). Hence, we are screening you for your risk of heart disease at the start of the study and if you are considered high risk for heart disease then you may be excluded from the study. We are also performing heart traces (ECGs) every month to screen for this.

The study investigators including Dr Shejil Kumar will assess you for these side effects regularly and if any arise, will assess you appropriately to determine the cause and severity of the side effect and whether any further tests or treatments are required to manage the side effect.

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.

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

The scans we are taking are for research purposes. They are not intended to be used like scans taken for a full clinical examination. The scans will not be used to help diagnose, treat or manage a particular condition. A specialist will look at your scans for features relevant to the research project. On rare occasions, the specialist may find an unusual feature that could have a significant risk to your health. If this happens, we will contact you to talk about the findings. We cannot guarantee that we will find any/all unusual features.

This research project 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 research project is about <1 mSv. The dose from this research project is comparable to that received from many diagnostic medical x-ray and nuclear medicine procedures. At this dose level, no harmful effects of radiation have been demonstrated, as any effect is too small to measure. This risk is believed to be low.

10 What will happen to my test samples?

The blood samples will be analysed for safety measures such as your calcium levels in the blood and kidney function, but also exploratory bone-related markers as part of the study. We will store your blood samples in the laboratory at the study site so that if novel bone- or muscle-related markers become available in the future, we can test your sample further. Blood samples will be stored for at least 5 years and possibly longer. There may be, in the future, bone and other relevant biomarker tests, not yet developed, that may be relevant to this study. The stored blood samples may be used and tested using any future such related assays. We will provide you with the option to learn about these studies if they arise in the future and you are free to withdraw at any time from the use of the stored blood sample.

Some of these blood samples will be taken as part of routine care of your bone health however majority of the blood tests are being taken specifically for research purposes. The samples taken from you will be re-identifiable meaning that the laboratory staff can identify who the blood sample belongs to using a specific code.

Samples of your blood obtained for the purpose of this research project will be stored in the NSW Health Pathology laboratory.

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. The study team will cover the cost of any treatments you require for conditions deemed to be side effects from participation in the study.

13 What if I withdraw from this research project?

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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 researchers as part of the study 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?

This research project may be stopped unexpectedly for a variety of reasons. These may include reasons such as:
• Unacceptable side effects
• The drug/treatment/device being shown not to be effective
• The drug/treatment/device being shown to work and not need further testing

15 What happens when the research project ends?

At completion of the project, we will conduct two more monthly follow up visits to make sure you haven't developed any side effects. At completion of the study, you can access the free home-based unsupervised exercises. You can also access the supervised exercise program however you would need to pay for this exercise at the usual rate quoted by the exercise providers. If you receive the study drug romosozumab during the study, then this may still be available to you for a further 4-months after the study finishes (as the current approved lifetime exposure is 12 months in Australia), although you would need to pay for this treatment. If you received placebo during the study, then the drug romosozumab may be available to you for a total 12-months after the study finishes, although you would need to pay for this treatment. At the end of the 8-month study, we will provide you with information on how to continue to manage your bone health. Once the data from the study is analysed and prepared for dissemination/publication at associated medical/scientific conferences and in peer-reviewed medical/scientific journals, the investigators will share a summary of the results with you if you would like to see it.

Part 2 How is the research project being conducted?

16 What will happen to information about me?

Any data collected about you will be restricted to data relevant to the conduct of this study. The data will initially be collected in a way which is coded (i.e. you can be re-identified based on a specific code) and the data will be kept on an official database in a password-protected computer in the Diabetes, Endocrinology & Metabolism department at the study site with data access controlled by Dr Shejil Kumar and only made available to other study investigators. The data will be stored for a minimum of 15 years and will be stored in a way which is non-identifiable (in other words, you wouldn't be able to be re-identified).

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 information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law. The information collected about you will be kept in an official database on a password-protected computer in the Endocrinology, Diabetes & Metabolism department at study sites with access to the data controlled by Dr Shejil Kumar and only provided to other study investigators to maintain your privacy and confidentiality.

Information about you may be obtained from your health records held at this and other health services for the purpose of this research. By signing the consent form you agree to the study team accessing health records if they are relevant to your participation in this research project.

Your health records and any information obtained during the research project are subject to inspection (for the purpose of verifying the procedures and the data) by the relevant authorities and authorised representatives of the Sponsor and Institution or as required by law. By signing the Consent Form, you authorise release of, or access to, this confidential information to the relevant study 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, except with your permission.

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

In accordance with relevant Australian and/or New South Wales 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 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. You may be eligible for compensation in the event of harm occurring to you as a result of the study.

18 Who is organising and funding the research?

This research project is being conducted by Dr Shejil Kumar under the supervision of A/Prof Christian Girgis and Prof Roderick Clifton-Bligh. Funding of the research is being provided by a combined research grant from Amgen/Healthy Bones Australia/Australia and New Zealand Bone and Mineral Society (ANZBMS), grants from Avant Mutual and NORTH foundation, as

well as research funding provided by the Department of Diabetes, Endocrinology & Metabolism at study sites.

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

The study doctors and sponsors and institutions have no declarations of interest.

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 sponsor.

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 before you decide whether to participate, you can contact the principal study doctor on 0493881354. If you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can contact any of the following people:

Clinical contact person

Name	Professor Roderick Clifton-Bligh
Position	Endocrinology Staff Specialist, Royal North Shore Hospital
Telephone	94631680
Email	Roderick.cliftonbligh@health.nsw.gov.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	NSLHD Research Office
Position	Research Office Manager
Telephone	99264590
Email	NSLHD-Research@health.nsw.gov.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 the following and quote the study reference number 2022/ETH01794:

Reviewing HREC approving this research and HREC Executive Officer details

Reviewing HREC name	NSLHD
HREC Executive Officer	NSLHD Ethics Officer
Telephone	99264590
Email	NSLHD-Research@health.nsw.gov.au

Consent Form - *Adult providing own consent*

Title	Combining osteoanabolic pharmacotherapy with osteogenic exercise in women with postmenopausal osteoporosis/osteopenia
Short Title	Romosozumab with osteogenic exercise in postmenopausal osteoporosis
Protocol Number	1
Coordinating Principal Investigator/ Principal Investigator	Dr Shejil Kumar
Associate Investigator(s)	A/Prof Christian Girgis, Prof Roderick Clifton-Bligh, Prof Belinda Beck, Ms Liza Nery

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 consent to my stored blood samples being used in future research related to this study:

YES ☐ NO ☐

Depending on which exercise program I am randomised into, I consent to my blood sample being taken immediately before, immediately after and 4-hours after one exercise session near the start and one exercise session near the end of the 8-month study period:

YES ☐ NO ☐

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

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.

Name of Participant (please print) _____

Signature _____ Date _____

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.

I understand that, if I decide to discontinue the study treatment, I may be asked to attend follow-up visits to allow ongoing collection of information regarding my health status. If I decide not to attend further follow-up visits then I am free to do so. 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 samples taken from me for use, as described in the relevant section of the Participant Information Sheet, for:

- This specific research project
- Other research that is closely related to this research project
- Any future research.

Name of Participant (please print) _____

Signature _____ Date _____

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	Combining osteoanabolic pharmacotherapy with osteogenic exercise in women with postmenopausal osteoporosis/osteopenia
Short Title	Romosozumab with osteogenic exercise in postmenopausal osteoporosis
Protocol Number	1
Coordinating Principal Investigator/ Principal Investigator	Dr Shejil Kumar
Associate Investigator(s)	A/Prof Christian Girgis, Prof Roderick Clifton-Bligh, Prof Belinda Beck, Ms Liza Nery

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 the study site.

Name of Participant (please print) _____

Signature _____ Date _____

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.