Permission to Take Part in a Human Research Study

Title of Research Study: Effects of Romosozumab on Bone Health in Women with Spinal Cord Injury and Osteoporosis (ISS# 20197268)

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Supported By: This research is supported by Amgen, Inc. and by the Department of Physical Medicine and Rehabilitation at Northwestern University

Key Information:
The first few pages of this document include a summary of this study to help you decide whether or not to participate. Detailed information is provided after the summary.

Why am I being asked to take part in this research study?
We are asking you to take part in this research study because you are a female and have a history of spinal cord injury (SCI) and may be at risk for osteoporosis, or weak bones.

What should I know about a research study?
- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?
SCI can cause rapid bone loss, especially in the lower extremities. This bone loss may continue up to 5 years after SCI and lead to the development of osteoporosis (OP). OP is a condition where there is bone loss and an increased risk for fractures (broken bones).

This research is being done because we want to find out if a drug treatment will increase bone mass in females with SCI. This is a two-year study and will involve receiving two different drugs that are known to treat OP, taking daily supplements (calcium and vitamin D), and returning to the research site for study visits.

Year 1: During the first year, you will be given a drug called romosozumab (Evenity®). This drug works by increasing bone formation and is FDA-approved for treating OP in post-menopausal women at high risk of fracture or those who did not benefit from using other available OP treatments. In this study, romosozumab is considered to be investigational because it is not specifically approved for use in women with SCI. Romosozumab is not a daily pill but is given as two injections once a month. The drug will be injected just under your skin in your abdomen, thigh, or arm by a trained professional. In this study you will receive 12 months treatment of romosozumab for a total of 24 injections.

Year 2: After completing 12 months with romosozumab, you will be given a drug called alendronate (Fosamax®) to take at home. Alendronate is FDA-approved to treat osteopenia (being at risk for OP), OP in men and post-menopausal women, and for the prevention and treatment of glucocorticoid-induced OP. This drug is a pill taken once a week by mouth and works by maintaining and sometimes increasing bone mass.

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In this study, we will collect information about your bone health, including imaging or pictures of your bones, and blood and urine.

How long will the research last and what will I need to do?
If you qualify, we expect that you will be in this research study for 25 months. You will be given bone health medications and asked to come for 17 study visits at Northwestern Medicine and nearby buildings.

More detailed information about the study procedures can be found under the section **What happens if I say "Yes, I want to be in this research"?**

Is there any way being in this study could be bad for me?
It is possible that you may experience side effects from taking the study drugs. You will also be exposed to radiation during the bone scans. More detailed information about the risks of this study can be found under **"Is there any way being in this study could be bad for me? (Detailed Risks)"**

Will being in this study help me in any way?
We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits to you include that you may experience increased bone formation, which might help treat your OP and reduce the risk of future bone fractures. Taking part in this study may also help scientists to better understand bone formation and inform future research studies about building stronger bones in people with SCI.

What happens if I do not want to be in this research?
Participation in research is completely voluntary. You decide whether or not to participate. If you choose to not participate, there will be no penalty to you or loss of benefit to which you are entitled.

Alternative approaches to possibly treat bone loss include taking an FDA-approved medication for osteoporosis and vitamin D and calcium. Physical Therapy may be of additional benefit. Your physician can tell you about what medications might be available to you.

Detailed Information:
The rest of this document includes detailed information about this study (in addition to the information listed above).

Whom can I talk to?
If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team. Dr. Thomas Schnitzer is the person in charge of this research study. You can call him at telephone #312-503-2315 (Monday through Friday, from 9am to 5pm). You can also call the Study Coordinator at telephone #312-503-5780 (Monday through Friday, 9am to 5pm) with questions about this research study. For problems arising evenings or weekends, you may call telephone #312-649-2964 and ask for Dr. Schnitzer to be paged.

This research has been reviewed and approved by an Institutional Review Board (IRB). You may talk to them at (312) 503-9338 or irb@northwestern.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.

- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

How many people will be studied?
We expect about 12 people will be in this research study.

What happens if I say "Yes, I want to be in this research"?
As a subject in this study, you will be asked to come to 710 N. Lake Shore Drive, Chicago, IL 60611. Some of the study procedures may take place in nearby buildings and the study coordinator will take you to those locations. At study visits, we will measure you bone mass density (BMD), take images of your hip and knee, and draw blood to see how your bones are responding to the study treatment. There will be an independent medical monitor for the study to ensure safety.

Your part in this study will last for about 25 months. There will be 1 or 2 Screening Visits. If you meet all study criteria, you will have a Baseline Visit to begin study treatment.

> Year 1 - Treatment with Romosozumab: You will have 12 monthly visits during this year because this study drug needs to be given by a trained professional every 30 days.
>
> Year 2 - Treatment with Alendronate: You will have up to 3 visits (Month 15, Month 18, and Month 24) during this year. If, due to distance and transportation needs, you are unable to attend the visit at Month 15, this visit can be done over the phone and your study drug and supplements will be mailed to you.

DXA Scan: We will measure BMD by a DXA scan (dual-energy x-ray absorptiometry scan), which is done like an x-ray. The scan will take images of your hips and lower spine. Your body will be positioned on an exam table and pictures will be taken of your bones. The DXA scan takes about 20 minutes, although you should plan to spend about an hour at the DXA appointment. You will be asked to wear or bring clothes to change into that do not have metal parts.

CT Scan: We will also study Computed Tomography (CT) pictures of your knee and hip. CT pictures are taken like an x-ray, but they create a more detailed picture. For the CT scan, you will be positioned on a table and you may be secured to the table so that you are able to remain completely still during the scan. The table will slide into the CT machine and an x-ray tube within the CT unit will rotate around you, taking x-ray pictures of your legs from different angles. CT scans can take up to 20 minutes, although you should plan to spend about an hour at the CT appointment. The research CT scans collected for this study will be stripped of all your personal information (such as your name or any other identifying information) and shipped to the University of Calgary where the images will be analyzed.

Lab Tests: Some of the blood that will be collected for the study will tell us more about your overall health, including complete blood count, kidney and liver functions, calcium levels, vitamin D levels, and thyroid hormone levels. We will also collect blood for bone makers, which tell us more information about how your bone cells are functioning and your bone formation. The bone marker tests will be stripped of all your personal information (such as your name or any other identifying information) and shipped to another facility where the samples will be processed. If you are a female without childbearing potential, urine pregnancy tests will not be done after the screening visit.

Electrocardiogram (ECG): ECG is a quick and noninvasive test used to record electrical activity of your heart. While you are laying on an exam table, sensors (electrodes) that can detect your heart rhythm are attached (with a sticker) to your chest and your arms and legs. These sensors are usually left on for just a few minutes.

The following is a timeline of the 17 scheduled study visits.

Screening (Visit 1)
This visit may take up to 4 hours. If needed, it can be done over multiple visits.

- The study staff will review this study with you and answer all your questions before asking you to sign this consent form.
- You will be asked about your medical history (including emotional and psychiatric history), your SCI, and your current abilities.
- You will be asked about your use of alcohol, tobacco, recreational (where legal) or medical use of marijuana and use of any illegal drugs.
- You will be asked about all medications (prescription and non-prescription), herbal medications and vitamins you are currently taking.
- Urine sample to check your general health and for pregnancy.
- DXA scan of your hips and spine
- Vital signs (heart rate, blood pressure, body temperature), height and weight will be recorded.
- ECG will be done.
- A walking test will be done, if you are able.
- A physical examination will be performed.
- Blood will be collected to check your general health as well as to perform labs for this research study that include hormone testing, thyroid, vitamin D and to see how well your blood clots. About 16 mL (1 tablespoon) of blood will be collected.
    - **Vitamin D**: If your vitamin D levels obtained during the Screening visit are below normal, you will be given vitamin D (50,000 IU). You will be asked to take this by mouth once a week for up to 8 weeks and return for a blood draw to check your Vitamin D levels again.

Unscheduled Vitamin D Visit
If your vitamin D levels during the screening visit were below normal and you were given a supply of vitamin D (50,000 IU), you will have about 2 mL (1/2 teaspoon) of your blood drawn.

Baseline (Visit 2)
This visit may take about 2 hours, and include:

- Vital signs
- Review of any changes in your health and medications
- Blood draw (about 20 mL or 4 teaspoons)
- Urine pregnancy test, if applicable
- CT scan of one hip and one knee
- A walking test will be done, if you are able.
- You will be provided calcium and vitamin D supplements to take at home. The study doctor will tell you how much to take based upon your medical needs. The amount of calcium prescribed will be between 500 and 1000 mg/day and the vitamin D amount prescribed will be about 1000 IU/day, or as directed by your doctor.
- Romosozumab - The study staff will give you your first two study drug injections.

Month 1 (Visit 3)
This visit may take up to 2 hours, and include:
- Vital signs
- Review of any changes in your health and medications
- Blood will be drawn (about 24 mL or 5 teaspoons) to check your calcium and vitamin D levels.
- Urine pregnancy test, if applicable
- Romosozumab: The study staff will give you two study drug injections.

Month 2 (Visit 4)
This visit may take up to 1 hour, and include:
- Vital signs
- Review of any changes in your health and medications
- Urine pregnancy test, if applicable
- Injections of study drug by our research staff

Month 3 (Visit 5)
This visit may take up to 3 hours, and include:
- Vital signs
- Review of any changes in your health and medications
- Blood will be drawn (about 20 mL or 4 teaspoons). Depending on your Month 1 lab results, you may have a repeat calcium and/or vitamin D test (up to 4 mL or 1 teaspoon more of blood).
- Urine pregnancy test, if applicable
- DXA scan
- CT scan of knee
- A walking test, if you are able
- Injections of study drug by our research staff
- You will be provided calcium and vitamin D supplements.

Months 4 and 5 (Visits 6 and 7)
Same procedures as Month 2 (Visit 4).

Month 6 (Visit 8)
Same procedures as Month 3 (Visit 5), plus:
- CT scan of the hip

Month 7, 8, 9, 10, and 11 (Visits 9-13)
Same procedures as Month 2 (Visit 4), plus:
- At Month 9, you will be provided calcium and vitamin D supplements.

Month 12 (Visit 14)
This visit may take up to 4 hours and include:
- Vital signs
- Review of any changes in your health and medications
- Blood draw (about 26 mL or 5 teaspoons)
- Urine pregnancy test, if applicable
- DXA and CT scans

- A walking test, if you are able
- Alendronate: The study staff will review with you how to take alendronate and will give a Medication Guide with instructions for taking the drug at home. Briefly:
  - Take this drug only on an empty stomach, after you get up for the day and before taking your first food, drink, or other medicine or supplements.
  - Take this drug while you are sitting upright.
  - Do not chew or suck on the tablet.
  - Swallow tablet with a full glass (6-8 oz) of plain water only. Do not take it with mineral water, coffee, tea, soda, or juice.
- You will be given enough study drug to take at home until your next study visit.
- You will be provided calcium and vitamin D supplements to take until the next study visit.

Month 15 (Visit 15)
This visit may be done at the study site (60 mins) or as a phone call (30 mins).

- Phone Call:
  - Review of any changes in your health and medications.
  - You will be mailed a new supply of study drug and calcium and vitamin D.
- Clinic Visit:
  - Vital signs
  - Review of any changes in your health and medications.
  - Urine pregnancy test, if applicable
  - You will be given enough study drug and supplements to take until the next visit.

Month 18 (Visit 16)
This visit may take about 1 hour and include:

- Vital signs
- Review of any changes in your health and medications
- Blood draw (about 20 mL or 4 teaspoons)
- Urine pregnancy test, if applicable
- You will be given enough study drug and supplements to take at home until your next study visit.

Month 24 (Visit 17)
This visit may take up to 3 hours and include:

- Vital signs
- Review of any changes in your health and medications
- Blood draw (about 20 mL or 4 teaspoons)
- Urine pregnancy test, if applicable
- DXA and CT scans
- A walking test, if you are able
- Study staff will collect from you any remaining study drug (alendronate).

What are my responsibilities if I take part in this research?
If you take part in this research, you will be responsible to:

- Show up for all study visits and following study instructions.
- Tell the study doctor or the study staff about any drugs you are taking, have recently taken, or are planning to take, including herbal remedies, supplements, and drugs you take without a prescription.
- Bring all your study supplements and study drug (used and unused) with you to each study visit. Do not throw away any study drug or supplements.

What happens if I say "Yes", but I change my mind later?
You can leave the research at any time; it will not be held against you.

If you decide to leave the research or stop taking the study drug for any reason, you must notify your study doctor immediately so that a plan can be made for your continued medical care. At that time, you should have the final tests, procedures and evaluations performed as described above under Month 12 (Visit 14) or Month 24 (Visit 17).

Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefit to which you are entitled. Specifically, your choice not to be in this study will not negatively affect your right to any present or future medical treatment.

If you stop being in the research, already collected data may not be removed from the study database. You will be asked whether the investigator can collect data from your routine medical care. If you agree, this data will be handled the same as research data.

Detailed Risks: Is there any way being in this study could be bad for me?
This research may hurt you in the following ways:

ROMOSOZUMAB RISKS

Romosozumab may cause all, some, or none of the side effects listed below. These side effects can be mild but could also be serious, life-threatening, or even result in death. You may also experience an allergic reaction that has not been seen before.

As of 07January 2020, approximately 8,550 people have received romosozumab in research studies. Since it was first approved for sale in January 2019, there have been approximately 45,997 patient-years of exposure to romosozumab.

Side effects that other people have had in research studies that are thought to have been caused by romosozumab are:

- Very Common side effects (which may affect more than 1 person in 10): common cold and joint pain
- Common side effects (which may affect between 1 and 10 people in every 100): allergic reaction (drug hypersensitivity), injection site reactions, headache, muscle spasms, cough, swelling of limbs, neck pain, and tingling
- Uncommon side effects (which may affect between 1 and 10 people in every 1000): low calcium levels in the blood

Allergic Reaction (Drug Hypersensitivity): Serious allergic reactions can happen with use of romosozumab. Call your study doctor or get emergency medical help right away if you have any symptoms of an allergic reaction, such as rash, hives, and swelling usually of the face, lips, mouth, tongue, or throat which may cause difficulty in swallowing or breathing.

Injection Site Reactions: Reactions at or near the area of the injection have been seen in people receiving romosozumab. Symptoms may include tenderness or pain, redness, bruising, and itching at the injection site. If you have any of these symptoms, you should contact the

study doctor or his/her study staff immediately. Other symptoms may include warmth, swelling, and/or infection at the injection site.

Decrease in Blood Calcium (Hypocalcemia): Romosozumab may cause low levels of calcium in blood. Symptoms of low blood calcium may include spasms, twitches or muscle cramps and numbness or tingling in fingers, toes or around the mouth. Tell your study doctor if you notice any of these symptoms. Your study doctor will prescribe calcium and vitamin D to help prevent low calcium levels in your blood while you take romosozumab. Take calcium and vitamin D as your study doctor tells you to.

Serious Cardiovascular (Heart and Blood Vessels) Events: Heart attacks have occurred during treatment with romosozumab in research studies. It is not known whether romosozumab caused these heart attacks. Call your study doctor or get emergency medical help right away if you have symptoms of heart attack, such as chest pain or pressure, shortness of breath, or lightheadedness or dizziness.

Strokes have occurred during treatment with romosozumab in research studies. It is not known whether romosozumab caused these strokes. Call your study doctor or get emergency medical help right away if you have symptoms of stroke, such as headache, numbness or weakness in face, arm, or legs, difficulty talking, changes in vision, or loss of balance.

Osteonecrosis of the Jaw (ONJ): Severe jaw bone problems have occurred during treatment with romosozumab in research studies. It is not known whether romosozumab caused these jaw bone problems. Your study doctor may advise you to see your dentist before you start romosozumab. Ask your study doctor or dentist about good mouth care. Contact your study doctor and dentist right away if you experience any problems with your mouth or teeth such as loose teeth, pain or swelling, or non-healing of sores or discharge, as these could be signs of jaw bone problems.

Unusual Thigh Bone Fractures (Atypical Femoral Fractures): Unusual fractures in the thigh bone have been reported in people receiving romosozumab in research studies. It is not known whether romosozumab caused these unusual fractures. Symptoms of this type of fracture include new or unusual pain in your hip, groin, or thigh. Tell your study doctor if you notice any of these symptoms.

ALENDRONATE RISKS

Esophagus problems: Some people who take this drug may develop problems in the esophagus (the tube that connects the mouth and the stomach). These problems include irritation, inflammation, or ulcers of the esophagus which may sometimes bleed.

It is important that you take this drug exactly as prescribed to help lower your chance of getting esophagus problems. Call your doctor right away if you get chest pain, new or worsening heartburn, or have trouble or pain when you swallow.

Decrease in Blood Calcium (Hypocalcemia): This study drug may lower the calcium levels in your blood. Call your study doctor if you have symptoms of low blood calcium such as: spasms, twitches, or cramps in your muscles; numbness or tingling in your fingers, toes or around your mouth.

Bone, joint, or muscle pain: Some people who take this drug develop severe bone, joint, or muscle pain. The time to onset of symptoms varied from one day to several months after starting the drug. Most patients had relief of symptoms after stopping the medication.

Osteonecrosis of the Jaw (ONJ) may occur. This problem can occur spontaneously, but is usually related to having a tooth extraction and/or local infection with delayed healing. Your study doctor will examine your mouth before you start the study drug and may tell you to see your dentist. Ask your healthcare provider or dentist about good mouth care. Contact your study doctor and dentist right away if you experience any problems with your mouth or teeth such as loose teeth, pain or swelling, or non-healing of sores or discharge, as these could be signs of jaw bone problems.

Unusual Thigh Bone Fractures (Atypical Femoral Fractures) have occurred in unusual locations in people taking alendronate, most often after long-term treatment with these drugs (more than 3 years). Symptoms of this type of fracture include new or unusual pain in your hip, groin, or thigh. Tell your study doctor if you notice any of these symptoms.

OTHER RISKS

Radiation Exposure: Background radiation is present on Earth (soil, air, water, food) and also includes cosmic radiation. Exposure to radiation from natural sources is a feature of everyday life. Your participation in this study will involve additional exposure to radiation. The radiation dose received for one DXA scan is approximately equal to 4.5 days of background radiation. The radiation dose received for one Hip CT scan is approximately equal to 1.6 years of background radiation. The radiation dose received for one Knee CT scan is approximately equal to 20 days of background radiation. The cumulative radiation exposure from these tests is considered small and is not likely to adversely affect you or your disease. However, the effects of radiation add up over a lifetime. When deciding to enter this study, think about your past and future contact with radiation.

Constipation: Side effects associated with calcium supplements include constipation, stomach bloating, intestinal gas, nausea, or change in the calcium or phosphate levels in the blood. There may be some added risk of developing kidney stones if you have had calcium kidney stones in the past.

ECG: Skin irritation is rare, but could occur from the electrodes (patches) or gel that is placed on your skin.

Blood Draw: The risks of taking blood include pain, a bruise at the point where the blood is taken, redness and swelling of the vein and infection, and a rare risk of fainting.

Allergic Reaction: Be sure to seek emergency help and contact the study doctor as soon as possible if you have an allergic reaction to the study drug. Signs of an allergic reaction include hives; difficulty breathing; swelling of your face, lips, tongue, or throat.

Questionnaires: Some of the questions asked may be upsetting, or you may feel uncomfortable answering them. If you do not wish to answer a question, you may skip it and go to the next question.

Unforeseen Risks: In addition to these risks, this research may hurt you in ways that are unknown. These may be a minor inconvenience or may be so severe as to cause death.

This study involves the use of your identifiable, personal information and there is a chance that a loss of confidentiality could occur. The researchers have procedures in place to lessen the possibility of this happening. See the section below titled: **"What happens to the information collected for the research?".**

What do I need to know about reproductive health and/or sexual activity if I am in this study?

The study drug romosozumab is known to harm an unborn baby. It can also pass into breast milk and may harm a nursing baby. The effect of the study drug alendronate on human eggs has not been studied. The effects on an unborn baby while using alendronate during pregnancy and the risk of birth defects are also unknown. Therefore, women should not attempt pregnancy or should not be pregnant or breast-feeding while taking part in this study. After you finish the study drug, you should wait an additional 90 days to become pregnant.

If you are sexually active, you should use at least one effective means of birth control while participating in this research study. According to the World Health Organization and the United States Center for Disease Control and Prevention, the most effective forms of birth control include complete abstinence, surgical sterilization (both male and female), intrauterine devices (IUDs), and the contraceptive implant. The next most effective forms of birth control include injectables, oral contraceptive pills, the contraceptive ring, or the contraceptive patch. Acceptable but least effective methods of birth control include male condoms (with or without spermicide) and female condoms.

If you are considered to be postmenopausal, you are not required to use contraception while participating in this research study. Postmenopausal women rarely become pregnant.

If you become pregnant while participating in this research study or for 90 days after you complete the study, it is important that you tell the study doctor or other research team member immediately. You may be required to stop participation in this study; however, other treatment options will be discussed with you at that time if necessary.

Will it cost me anything to participate in this research study?

Taking part in this research study will not lead to any costs to you.

You and your insurance company will be charged for the health care services that you would ordinarily be responsible to pay. In some cases, insurance will not pay for services ordinarily covered because these services were performed in a research study. You should check with your insurance to see what services will be covered by your insurance and what you will be responsible to pay.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this institution.

Your study chart and data and specimens collected as part of this study will be retained for up 25 years after the study for future research related to bone health in people with SCI. Only members of the study doctor's team will have access to this information. The study charts will be stored in a locked location at Northwestern University or at a secure off-site location. CT

scan data without any identifying information will also be stored at the University of Calgary in Canada where CT scan data will be analyzed.

The sponsor, monitors, auditors, the IRB, the Northwestern University Office for Research Integrity, the US Office of Research Integrity (ORI), the US Office for the Protection of Human Research Protections (OHRP), and the US Food and Drug Administration (FDA) may be granted direct access to your medical records to conduct and oversee the research. By signing this document, you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Data Sharing
De-identified data from this study may be shared with the research community at large to advance science and health. We will remove or code any personal information that could identify you before files are shared with other researchers to ensure that, by current scientific standards and known methods, no one will be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

Can I be removed from the research without my OK?
The person in charge of the research study can remove you from the research study without your approval. Possible reasons for removal include:

- You develop side effects that are considered dangerous
- You do not follow the study instructions given to you by the Investigator
- Your treating physician determines that it is not in your best interest to continue in the study
- Administrative or regulatory decision

We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

What else do I need to know?
If you become ill or are injured as a result of this study (medications, devices or procedures), you should seek medical treatment through your doctor or treatment center of choice. You should promptly tell the study doctor about any illness or injury.

The hospital [university, researchers] will not pay for medical care required because of a bad outcome resulting from your participation in this research study. Payment for this treatment will be your responsibility. No compensation is available for research-related injuries. You are not waiving any legal rights. If you have sustained a research-related injury of if you have questions about this medical care, talk to the principal investigator for this study, Dr. Thomas Schnitzer at telephone number (312) 503-2315.

If you agree to take part in this research study, we will pay you $25 for each scheduled clinic visit you complete. You will receive $50 for Month 3 and Month 6 visits with imaging (DXA, CT) and $100 for Month 12 and 24 visits with imaging. All payments will be in cash other than the $100, which will be by check or debit card.

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A travel stipend of $25 will be given at each completed study visit on site. This travel stipend is meant to cover general expenses of travel to and from site. When necessary, we can arrange and/or pay for reasonable travel expenses (such as taxis and car mileage) to come to the study site for visits. Please keep your travel receipts. (*)If we pay for your travel to and from the site, you will not receive the additional travel stipend of $25.

Visits	Amount of Stipend	Travel Stipend*	Payment Type
Screening (Visit 1) and Baseline (Visit 2)	$25	$25	Cash
Follow Visits: Months 1, 2, 4, 5, 7, 8, 9, 10, 11, 15, and 18	$25	$25	Cash
Month 3 (Visit 5)	$50	$25	Cash
Month 6 (Visit 8)	$50	$25	Cash
Month 12 (Visit 14)	$100	$25	Check or Debit Card
Month 24 (Visit 17)	$100	$25	Check or Debit Card
Unscheduled Visits (including Vitamin D)	$0	$25	Cash
TOTAL	**$625**	**Up to $425**	

The Accounting Services at Northwestern University will be given your name, address, and Social Security Number in order to issue a check for your study participation. Study payments are considered taxable income and reportable to the IRS. A Form 1099 will be sent to you if your total payments are $600 or more in a calendar year.

You may be issued the Stored Value Card (VISA), which is a type of bank debit card with a specific dollar value programmed into it. Once a visit that qualifies for compensation is completed, funds will be approved and loaded onto your card.

You will need to set a PIN to use the card at an ATM. Using the PNC automated service number and Account Access Code provided on the card, follow the prompts to establish a PIN. You may also call this number to obtain the current balance on the card and to verify your activity. A fee will be charged to speak to a live operator. This information can also be checked online at pncprepaidcard.com. Please note that neither PNC nor Northwestern can obtain the PIN if forgotten.

If the card is used at a PNC ATM, there is no fee; however, there will be a $2.50 charge for non-PNC ATM withdrawals. One card will be issued for the duration of your participation. If your card is lost or stolen, please call the study team on the contact information provided on this consent document.

Please be advised: You will incur a fee if the card is not used in 6 months and a monthly fee for each additional month of non-use. However, as long as there is activity (funds are added or card is used), on the card within 6 months the month period will reset and no monthly fee will be assessed. If the card is used at a restaurant, there will be a 20% "hold" above the tab amount. The card will be declined if used at a gas pump. Rather, the card must be physically presented to the gas station attendant.

You may be given access to new inventions that are being developed by the investigator, the study sponsor, or other people involved in the study. Certain laws can make it harder to obtain legal protection for a new invention shared with a study participant, unless the study participant agrees to keep information about the invention confidential. You agree to keep confidential information you may receive about new inventions, such as new drugs, new devices, or new methods.

HIPAA Authorization

We are committed to respect your privacy and to keep your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information that includes health information in your medical records and information that can identify you. For example, personal health information may include your name, address, phone number or social security number. Your health information we may collect and use for this research includes:

- Results of physical examinations
- Medical history, including mental health information, history of HIV, and substance use information (use of recreational and legal drugs)
- DXA and CT scan results
- Lab tests, or certain health information indicating or relating to a particular condition as well as questionnaires
- Records about study medication or drugs
- Billing information

This consent expires on April 4, 2045. After this date, Northwestern University may not gather new information about you, use or disclose your personal health information collected in this study for any purpose other than the research study described in this consent unless Northwestern University obtains permission to do so from you. Illinois State Law permits use and disclosure of your mental health information only to the extent specified in this document.

The following clinical providers may give the researchers information about you: all current and previous health care providers, including but not limited to the Shirley Ryan AbilityLab (SRALAB), Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), and Northwestern Lake Forest Hospital (NLFH).

Once we have the health information listed above, we may share some of this information with the following offices or entities outside of Northwestern University and its clinical partners (or affiliates): the Northwestern University Institutional Review Board Office and Office for Research Integrity; the US Office of Research Integrity; the US Office for Human Research Protections; the US Food and Drug Administration.

Any research information shared with outside entities will not contain your name, address, telephone or social security number or any other personal identifier unless disclosure of the

identifier is necessary for review by such parties or is required by law or University policy [except that such information may be viewed by the Study sponsor and its partners or contractors at the Principal Investigator's office].

The following entities may receive your health information:

- Authorized members of the Northwestern University and the Shirley Ryan AbilityLab workforce, who may need to see your information, such as administrative staff members from the Office for Research, Office for Research Integrity and members of the Institutional Review Board.
- Clinical affiliates, including but not limited to the Shirley Ryan AbilityLab (SRALAB), Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), Northwestern Lake Forest Hospital (NLFH), and the Ann & Robert H. Lurie Children's Hospital of Chicago (Lurie Children's). Your participation in this clinical trial may be tracked in an electronic database and may be seen by investigators running other trials that you are enrolled in and by your healthcare providers.
- Other University research centers and University contractors who are also working on the study,
- Study monitors and auditors who make sure that the study is being done properly,
- Amgen, Inc., who is funding the study, and that company's contractors and partners.
- Government agencies and public health authorities, such as the Food and Drug Administration (FDA) and the Department of Health and Human Services (DHHS).
- Registries or other research-related databases: The study doctor maintains a registry of anyone who is interested in participating in pain and bone health studies in the future, and who has already participated in a study. The following registries: Physical Medicine and Rehabilitation Registry, Bone Health Registry.

Those persons who get your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it. Some of those persons may be able to share your information with others without your separate permission. Also, Federal law/42 CFR Part 2 prohibits unauthorized disclosure of these records.

The results of this study may also be used for teaching, publications, or for presentation at scientific meetings.

Unless you revoke your consent, it will expire April 4, 2045.

Although you may revoke consent to participation in this research at any time and in any format, you must revoke authorization for use or disclosure of your health information in writing. To revoke your authorization, write to:

Dr. Thomas J. Schnitzer
Northwestern University Feinberg School of Medicine
Department of Physical Medicine and Rehabilitation
710 N. Lake Shore Drive, Abbott Hall Room 1020
Chicago, IL 60611

You do not have to authorize the use or disclosure of your health information; however, you will not be allowed to take part in this research study. If you do not authorize the use or disclosure of

your health information, it will not affect your treatment by health care providers, or the payment or enrollment in any health plans, or affect your eligibility for benefits.

A copy of this signed consent document, information about this study, and the results of any test or procedure done may be included in your medical records and may be seen by your insurance company.

Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

_____ _____

Signature of Participant Date

_____

Printed Name of Participant

_____ _____

Signature of Person Obtaining Consent Date

_____

Printed Name of Person Obtaining Consent

My signature below documents that the information in the consent document and assent process and any other written and verbal information was accurately explained to, and apparently understood by, the participant, and that consent was freely given by the participant.

_____ _____

Signature of Witness to Consent/Assent Process Date

_____

Printed Name of Person Witnessing Consent/Assent Process