Study Title: Romosozumab to Improve Bone Mineral Density and Architecture in Chronic SCI

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INTRODUCTION

You are being asked to participate in a research study that is supported by the James J. Peters Veterans Affairs Medical Center (JJPVAMC). This research study is being performed at JJPVAMC and at Kessler Institute for Rehabilitation (KIR). JJPVAMC and Kessler are separate Institutions and independent of one another. Before you decide to take part, it is important for you to know why the research is being done and what it will involve. This includes any potential risks to you, as well as any potential benefits you might receive.

You will read the information below closely, and you will discuss it with your family and friends if you wish. You can also ask one of the study staff members if there is anything that is not clear to you or if you would like more details. You will take your time to decide. If you do decide to take part in this study, your signature on this consent form will show that you received all of the information below, and that you were able to discuss any questions and concerns you had with a member of the study team.

1. Purpose of study and how long it will last:

You are being asked to participate in a research study because you are a male between the ages of 18 and 65 years old or female between the ages of 18 and 55 years old with a chronic (≥3 years) spinal cord injury (SCI). The purpose of this study is to determine the usefulness of a drug, romosozumab, to prevent bone loss in your legs due to SCI. Romosozumab is an FDA-approved bone anabolic (promotes bone growth) used to treat osteoporosis (thinning and weakening of bone) in women after menopause who have an increased risk for fractures. This drug is considered experimental for the purpose of this study. If you decide to take part in this research, your study participation will last for approximately 24 months (17 total study visits, including a screening visit, of those 17 visits 7 will include bloodwork and/or DXA). Visits will range from 1- 4.5 hours depending on the number of tests that need to be completed. A copy of this form will be given to you and a copy will be kept by the JJPVAMC research team. There may be words in this consent form that you do not understand. If you do not understand a word or sentence, please ask the person who is reviewing this document with you to explain. This study is funded by the Department of Veterans Affairs Rehabilitation Research and Development Service award (# I01RX003415).

Participants:
You will be one of up to 100 subjects who are screened to identify 39 participants with a chronic, motor-complete or incomplete SCI (3 years or more). The study is a double-blind placebo-controlled trial in which you will be randomly assigned (like the flip of a coin) to one of two groups: romosozumab injections (26 subjects) or Placebo – inactive salt solution injections (13 subjects) for 12 months. Following romosozumab or placebo administration, both groups will receive a denosumab injection once every 6 months for 12 months.

Inclusion Criteria
1. Motor-complete or incomplete SCI (every level of injury); International Standards for Neurological Classification of Spinal Cord Injury (ISNCSCI) grade A-C non-ambulatory (defined as wheelchair dependent >75% of the time);
2. Duration of SCI ≥3 years
3. Males between the ages of 18 and 65 years old or females (e.g., premenopausal) between the ages of 18 and 55 years old;
4. BMD at the distal femur ≤1.0 g/cm^2 (as determined at screening by DXA scan).
5. Agreement to use a highly effective contraceptive method for women of reproductive potential.

Exclusion Criteria
1. Active and/or history of coronary heart disease, myocardial infarction, or stroke;
2. Osteosarcoma (bone cancer);
3. Long-bone fracture of the leg within the past year;
4. History of prior bone disease (Paget's hyperparathyroidism, etc.);
5. Postmenopausal women;
6. Men with known hypogonadism prior to SCI;
7. Anabolic therapy longer than six months duration after SCI;
8. Glucocorticoid administration longer than three months duration within the last year;
9. Endocrinopathies (hyperthyroidism, Cushing's disease or syndrome, etc.);
10. Severe underlying chronic disease (e.g., COPD, end-stage heart disease, chronic renal failure);
11. Heterotopic ossification (HO) of the distal femur (the distal femur is the primary outcome variable; HO to any other boney region will not prevent study participation);
12. History of chronic alcohol abuse;
13. Diagnosis of hypercalcemia;
14. Diagnosis of hypocalcemia (if corrected, subject may still be eligible for study participation);

15. Pregnancy, or plans to become pregnant within 6 months after the end of study treatment;
16. Lactation;
17. Prescribed a bisphosphonate for heterotopic ossification (HO), or prescribed any other agent to treat osteoporosis other than calcium and vitamin D;
18. Current diagnosis of cancer or history of cancer within the last 5 years;
19. Prescribed moderate or high dose corticosteroids (>40 mg/d prednisone or an equivalent dose of other corticosteroid medication) for longer than one week, not including drug administered to preserve neurological function at the time of acute SCI;
20. Life expectancy less than 5 years;
21. History of hypersensitivity reaction (including allergic reaction, facial swelling and hives) to any Prolia (denosumab) or Evenity (romosozumab) component;
22. Current immunosuppression or infection;
23. Acute fracture or extensive bone trauma;
24. Osteonecrosis of the jaw (ONJ) or risk for ONJ, such as invasive dental procedures (including tooth extraction, dental implants, oral surgery in the past 6 months), poor oral hygiene, periodontal and/or pre-existing dental disease; and
25. Planned invasive dental procedure over the next two years.

2. Description of the Study Including Procedures to be Used:

You are aware that if you agree to participate in this study, you will be asked to visit the JJP VAMC for 8 study visits (Screening and months 0, 1, 3, 6, 12, 18, 24). You understand that the BMD of your knees and hips (distal femur) will be determined by DXA scan during your screening visit. You are aware that this study is double-blinded. This means that neither you nor the study team members will have knowledge of the treatment group you are assigned to. You will also be asked to visit the JJP VAMC to receive injections of your study drug at the following intervals:

Romosozumab + denosumab group:

If you are randomly selected to receive romosozumab treatment followed by denosumab treatment, you understand that you will be asked to visit JJP VAMC once a month for 12 months to receive injections of romosozumab. After those first 12 months of romosozumab treatment, you will be asked to visit JJP VAMC twice (once every 6 months for 12 months) to receive injections of denosumab.

Placebo + denosumab group:
If you are randomly selected to receive placebo followed by denosumab treatment, you understand that you will be asked to visit JJP VAMC once a month for 12 months to receive injections of placebo (normal saline solution). After those first 12 months, you will be asked to visit JJP VAMC twice (once every 6 months for 12 months) to receive injections of denosumab.

Vitamin D levels will be measured at baseline to exclude a vitamin D deficiency state (below 30 ng/mL). A deficiency of vitamin D will not disqualify a patient from study participation. If a deficiency in vitamin D is diagnosed, supplemental vitamin D (4000 IU/day) will be administered until vitamin D levels are within normal range, after which you will continue taking supplemental vitamin D (2000 IU/day) for the remainder of the study. You understand that if you are not vitamin D deficient, you will receive supplemental vitamin D (2000 IU/day) over the course of the study. In addition to vitamin D you will also receive 1000 mg of elemental calcium (calcium absorbed by the body) daily to ensure your calcium levels are sufficient. You understand you will be studied for measurements of chemical markers of calcium and bone metabolism, bone mineral density (BMD), which will be performed by a method called dual energy x-ray absorptiometry (DXA), and bone structure, performed by a method called peripheral quantitative computed tomography (pQCT), as indicated in the work schedule below. You understand that any rehabilitation care that is prescribed to you by your physician may be continued for the duration of this study.

Study Timeline:

Table of Procedures Studies/Tests	Screening	Baseline (Month 0)	Month 1	Month 3	Month 6	Month 12	Month 18	Month 24
DXA	X	X			X	X	X	X
pQCT		X			X	X	X	X
Markers of Bone Formation/Resorption		X	X	X	X	X	X	X
Calcium Metabolism		X	X	X	X	X	X	X
General Laboratories		X	X	X	X	X	X	X
Endocrine Laboratories		X				X		X
Pregnancy Test (if applicable)	X	X	X	X	X	X	X	X

Study Drug Injection Timeline															
Month		Baseline (0)	1	2	3	4	5	6	7	8	9	10	11	12	18	24
Treatment group	Romo (*) + Deno (X)	*	*	*	*	*	*	*	*	*	*	*	*	X	X	
	Placebo (^) + Deno (X)	^	^	^	^	^	^	^	^	^	^	^	^	X	X	

*= Romosozumab
^= Placebo
X= Denosumab

Romosozumab 210mg SQ will be administered each month subcutaneously for 12 months. Denosumab 60 mg SQ will be administered once every six months for 12 months after 12 months of romosozumab or placebo administration. Bone Biomarkers: serum C-telopeptide, serum osteocalcin, bone alkaline phosphatase, and carboxyterminal propeptide of type 1 procollagen. Calcium Metabolism: serum total and ionized calcium concentrations, 24-hour urine calcium, 25 OH-vitamin D (performed monthly during supplementation therapy), 1,25 (OH)2-vitamin D, and intact PTH. Endocrine Labs: serum thyroid function tests (T3, T4, & TSH), cortisol, total testosterone, calculated free testosterone, estradiol, growth hormone, insulin-like growth factor-1.

Vitamin D and Calcium Administration: (For entire study duration):
Your baseline vitamin D status will be assessed. If your vitamin D levels are found to be in the normal range, you will receive 2000 IU of vitamin D/day by mouth. If your blood levels of vitamin D are below the normal level (30 ng/mL), you will be given 4,000 IU/day vitamin D for 4 weeks, before reducing the dose to 2000 IU/day. Regardless of group assignment, you will receive 1000 mg of elemental calcium (calcium absorbed by the body) daily to ensure your calcium intake is sufficient.

Dual Energy x-ray Absorptiometry (DXA): (Visit months: 0, 6, 12, 18, 24):
You will be asked to lie on a semi-padded, fixed table-top to complete a bone density measurement with a DXA scanner. Two machines, one above and one below, will move together passing over and

under you. You will complete a total body DXA scan as well as separate scans of both hips and knees. You understand that a DXA scan will be performed during your screening visit to measure the bone mineral density (BMD) of your knees and hips (BMD at the distal femur ≤1.0 g/cm2 determined at screening).

Peripheral Quantitative Computed Tomography (pQCT): (Visit months: 0, 6, 12, 18, 24):
You understand scans will be performed using a Stratec XCT 3000 scanner pQCT (STIM designs, Carmel, CA). This is a specialized bone imaging device that can obtain measurement of bone density and shape at both the knee and ankle. The pQCT scanner is on a specialized lift enabling it to be used for measurements of the bones of your knee and ankle regions. This will be done by placing your legs into the chamber of the machine. This machine will use a low dose of radiation, which will determine the amount of bone in your legs and takes approximately 60 minutes to complete. The pQCT scanner is accessible to people with SCI and has a wider gantry than other pQCT instruments, which makes it uniquely suited to measure the knee region in persons with SCI.

Chemical Markers for Bone Formation and Breakdown, Calcium Metabolism, and General Laboratories (Visit months: 0, 1, 3, 6, 12, 18, 24):
A routine blood sample will be drawn from a vein as outlined above in the work schedule. Approximately 75 ml of blood (5 tablespoons) will be drawn from a vein in your arm. You understand the investigators are obtaining chemical markers of bone formation and breakdown, calcium metabolism and vitamin D levels, and a complete chemistry panel. Additional calcium metabolism markers will be obtained by 24-hour urine collection.

Endocrine Laboratories (Visit months 0, 12, 24)
A routine blood sample will be drawn from a vein as outlined above in the work schedule at baseline (month 0), month 12 and month 24. An additional 12 mL of blood (2 teaspoons) will be drawn from a vein in your arm. You understand the investigators are obtaining levels of certain circulating hormones to ensure levels are not different between the medication group and placebo group.

24-hour Urine Collection (Visit months: 0, 1, 3, 6, 12, 18, 24):
You will complete a 24-hour urinary calcium collection into a container provided by the investigators. This collection will be used to measure the calcium in your urine as well as other chemical markers of bone health.

Romosozumab or placebo Injection (Once a month for the first 12 months):
You understand that a subcutaneous (under the skin) injection of the 210mg of the drug romosozumab (EVENITY®) or placebo (normal saline) will be administered in the upper arm by a designated unblinded clinical personnel. You will only receive romosozumab injections if you are randomly assigned to this treatment group.

Denosumab Injection (Months 12 & 18):
You understand that a subcutaneous (under the skin) injection of the 60 mg of the drug denosumab (Prolia®) will be administered in the upper arm by the study physician. You will receive denosumab once every 6 months for 12 months following the 12 months of romosozumab or placebo administration.

Pregnancy Test - (all study visits):
If you are female with child-bearing potential, you will be asked to complete a pregnancy test to ensure that you are not pregnant. You will have the choice to provide urine sample or a blood sample to complete this test. If you choose to give urine you will be asked to fill a urine sample cup which will be used to assess pregnancy. If you choose to give a blood sample, you will have a total of 5 mL (1 teaspoon) blood drawn from a vein inside your elbow to confirm that you are not pregnant. If the test shows that you are pregnant then you will be withdrawn from the study.

All specimens obtained during this study will be stored in the Basic Science Laboratory at The Center of Excellence on the Medical Consequences of Spinal Cord Injury located at the JJPVAMC, Bronx, NY. All samples will be labeled with a number randomly assigned to you, along with the date and information regarding the study. Samples will be stored for analysis specifically related to this study. Samples will be stored until all data related to this study has been analyzed and at the end of this period specimens will be destroyed.

3. Description of any Procedures that may Result in Discomfort or Inconvenience:
Vitamin D and Calcium Supplementation: You may feel that taking Vitamin D supplementation (4,000 IU/day for 4 weeks, if you're vitamin D deficient, followed by 2000 IU/day for approximately 23 months; or 2000 IU/day for approximately 24 months if you're not vitamin D deficient) is a burden and inconvenient to take on a daily basis while participating in this study.

Bone Density Studies: You may feel discomfort when you are asked to transfer or when you are transferred by appropriate staff from your wheelchair to the DXA and pQCT tables. You might find the padded DXA table uncomfortable for the hour it takes to complete the DXA scanning. Each DXA scan will expose you to a small amount of radiation (approximately ½ of the radiation from a routine chest x-ray).

Blood Collection: You understand you may feel discomfort, pain, lightheadedness, dizziness, blurred vision, nausea, and in rare cases, temporary loss of consciousness (syncope) during the needle insertion. There is also the potential risk of developing a bruise or infection at the site of skin puncture

Study Drug Administration: You may feel inconvenienced by the administration of the study medications. You understand that you will receive either romosozumab or placebo injections monthly for 12 months, and denosumab every 6 months for 12 months. You understand that you will need to visit the JJP VAMC once a month for 12 months to receive your romosozumab or placebo injection, which you may feel inconvenienced by. You are aware that there may be some slight discomfort at the site of injection.

Since this research may have unknown effects on an unborn child and should not be done during pregnancy, it is necessary for a pregnancy test to be done first. To your knowledge you are not pregnant at the present time. If you agree to avoid becoming pregnant (use highly effective contraceptives e.g. hormonal contraception or an intrauterine device) throughout the treatment period until 6 months after the final injection. Specific risks to the fetus may include increased perinatal mortality, and impaired development of bones, teeth and or lymph nodes.

4. Expected Risks of the Study:

***Blood Draws*:** You may feel discomfort, pain, lightheadedness, dizziness, blurred vision, nausea, and in rare cases, temporary loss of consciousness (syncope) during the needle insertion. There is also the potential risk of developing a bruise or infection at the site of skin puncture.

DXA and pQCT Scans: The DXA and pQCT scans carry a small risk associated with low levels of radiation used in the scan. You understand that the DXA and pQCT measurements combined will be approximately 50% of the radiation received from a routine chest x-ray. The DXA and pQCT

measurements in total will be ~0.03 to 0.05 mSv of radiation exposure, which equates to ~4 to 6 times the amount of daily natural background radiation (approximately 0.008 mSv).

***Vitamin D and Calcium Supplementation*:** Even though the amount of vitamin D that you will receive daily for this study is clinically safe (2,000 IU or 4,000 IU per day), it is important that you understand high doses of vitamin D (greater than or equal to 40,000 IU per day) is considered to be potentially toxic. Vitamin D toxicity can cause non-specific symptoms such as weight loss, polyuria (excessive urine production), and irregular heartbeat. You also understand that vitamin D toxicity can be associated with an increase in calcium levels in the blood, which may lead to vascular and tissue calcification (deposits of calcium in the vessels and body's organs), with resultant damage to the heart, blood vessels, and kidneys. You also understand the risk of an elevated calcium level (hypercalcemia) in the blood and urine are minimal with dosage of vitamin D and calcium given during this study. The main complication of an elevated calcium level (hypercalcemia) is weakness, headache, extreme tiredness, vomiting, diarrhea, constipation, bone pain or irregular heartbeat. To monitor this, a blood test to measure your calcium and 24-hour urine calcium levels will be monitored at each visit. You may also experience constipation from the calcium supplementation. If the calcium supplementation causes you moderate to severe constipation, the investigators will ask you to discontinue calcium supplementation. If you experience mild constipation, the principal investigators will contact you on how to adjust your bowel program or reduce the dose of calcium supplementation, if you wish to remain on calcium supplementation for the duration of the study.

Study Drug (Romosozumab) Side Effects: You understand that the most common side effects of romosozumab (EVENITY®) are joint pain (8.1-13.1%) and headaches (5.2-6.6%). Other possible side effects include injection site reaction (4.9%), abnormal physical weakness (asthenia; 2.3-2.5%), pins-and-needles in hands/feet (paresthesia; 1.4-2%), hives (0.4%), rash (1.1%), skin redness (erythema; 1.4%), insomnia (1.7-2%) You also understand that rare but possible adverse events include: swelling of legs (peripheral edema; 1.7-2.4%), hypocalcemia (low calcium levels; 0-1%), serious allergic reactions (<0.1%), low calcium levels in your blood (hypocalcemia; 0-1%), severe jaw bone problems (osteonecrosis; 0-1%), unusual thigh bone fractures (0-1%). Symptoms of a serious allergic reaction may include rash, hives, swelling of the face, lips, mouth, tongue, or throat which may case difficulty swallowing or breathing. Symptoms of low blood calcium levels (hypocalcemia) include spasms, twitches, cramps in your muscles; and numbness or tingling in your fingers, toes or around your mouth. Symptoms of unusual thigh bone fracture include new or unusual pain in your hip, groin, or thigh. The most serious side effects of romosozumab are increased risk of heart attack (0.3-0.8%) or stroke (0.2-

0.6%). Symptoms of heart attack may include chest pain or pressure, shortness of breath, feeling light-headed or dizzy. Symptoms of stroke may include headache, numbness or weakness in arm or legs, difficulty talking, or changes in vision or loss of balance. If you have had a heart attack or stroke, especially if it happened in the past year, please inform the research team.

***Study Drug (Denosumab) Side Effects*:** You understand the most common adverse events are back pain (10-34.7%), pain in the extremities (4.6%), musculoskeletal pain (3.7-19%), high cholesterol (7.2%), and cystitis (bacterial infection of the bladder and/or urinary tract; 5.9%). You also understand that rare but possible adverse events include: pancreatitis (inflammation of the pancreas; 0.2%), dermatologic reactions [dermatitis (inflammation of the skin), eczema and rashes; 10.8%], serious infections (4-6%), infections leading to hospitalization [skin infections (0.4%), infections of the abdomen (0.9%), urinary tract (0.7%) and ear infections (0.1), and endocarditis (inflammation of the inside lining of the heart layers; (<0.1%)]. Osteonecrosis of the jaw (ONJ) is an extremely rare condition (0.7-7.1%) that occurs after giving the medication to be used in this study (e.g., denosumab). ONJ is a condition where part of the bone of the jaw rapidly deteriorates after receiving this medication. When ONJ occurs, it most often happens in persons who have a history of or are identified as having severe dental problems or who are also on drugs that adversely influence their immune system, such as steroids or other such medications.

You understand that in the general able-bodied population, those who have received denosumab therapy for extended periods of time (much longer than that proposed to be administered in this study) may infrequently have fractures of the leg below the hip region. This is an uncommon condition that has been reported in women receiving denosumab for postmenopausal osteoporosis and cancer patients. Prior to the occurrence of the leg fracture, this condition may be associated with new or unusual hip or groin pain. Causality with the administration of this medication often is not definitively established because these fractures also have occurred in osteoporotic patients who have not received this drug. In addition to these hip fractures in the general able-bodied population, the risk of multiple vertebral fractures has been shown to increase to that of the pre-treatment level approximately 19 months after discontinuing treatment with denosumab.

There also may be risks and discomforts that cannot be foreseen.

5. Expected Benefits of the Study:

There may be no direct benefit to you from this study, but any information that the researchers get from this study may help others. The study medication has the potential to prevent the loss of bone in your

legs and elsewhere in your body. If an abnormality that may be clinically treated is identified during the study, it will be brought to your and/or your physician's attention.

6. Other Treatments Available:

Participation in the study is voluntary and the alternative to this study is to not participate and seek clinical advice from your doctor.

7. Use of Research Results:

The researchers will let you and your physician know of any significant new findings made during this study which may affect your willingness to participate in this study. All research material generated from the study will remain in the possession of Dr. Christopher P. Cardozo and his study team at the JJP VAMC.

Your research records will be maintained according to the requirements of the JJPVAMC as follows:

Data Collection, Storage, and Transfer:

- Your coded electronic data will be collected on VA computers that are not connected to the internet.
- Your coded electronic data without your name, or other identifying information, will be stored on secured networks, behind electronic security systems, in access-restricted folders.
- Hard copies of your data will be stored in a locked file cabinet behind 2 locked doors.

Access to the research materials generated from the study will be restricted to Dr. Christopher Cardozo and his study team. Records will be retained according to National Archives and Records Administration, in accordance with Records Schedule RCS-10-1. If results of this study are reported in medical journals or at meetings, you will not be identified by name, by recognizable photograph, or by any other means without your specific consent. No information by which you can be identified will be released or published unless required by law. In order to comply with federal regulations, research records identifying you may be reviewed by the following:

Authorized representatives of the JJPVAMC (e.g., Institutional Review Board, Research Compliance Officer) and VA, including the Office of Research Oversight (ORO), Federal Agencies such as the Government Accounting Office (GAO), VA Office of Inspector General (OIG), and Office for Human Research Protections (OHRP) may have access to your research records. If this research involves

articles regulated by the FDA, the FDA may choose to inspect and copy research records that identify individual research subjects.

Clinical Trials:
Because this research involves articles regulated by the FDA, the FDA may choose to inspect and copy medical or research records that identify individual research subjects. If this study was initiated on or after March 7, 2012, a description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. You can search this website at any time.

8. Special Circumstances:
If you are a patient, a copy of this consent form will be placed in your medical record.

9. Compensation and/or Treatment in the Event of Injury:
The VA must provide necessary medical treatment to a research subject injured by participation in a research project approved by a VA R&D Committee and conducted under the supervision of one or more VA employees. Further information about compensation and medical treatment may be obtained from the medical administration service at this VA medical center.

10. Voluntary Participation:
You are not required to take part in this study; your participation is entirely voluntary you can refuse to participate in this study or withdraw your participation in this study after you consent without penalty or loss of VA or other benefits to which you are entitled.

11. Termination of Participation:
You can refuse to participate now or you can withdraw from the study at any time after giving your consent. This will not interfere with your regular medical treatment, if you are a patient. The investigator also has the right to withdraw you from the study at any time for reasons including, but not limited to, medical concerns (your health and safety are in jeopardy with continued participation in the study), non-compliance (you miss several scheduled appointments without notification) and protocol deviations (exclusion/inclusion criteria change and you are no longer eligible to participate). As romosozumab and denosumab have the potential to cause fetal harm, pregnancy is a stopping criterion if it occurs after study initiation, and women who become pregnant will be withdrawn from the study.

12. Costs and Reimbursements:

As a veteran or non-veteran, you will not be charged for any treatments or procedures that are part of this study. For veterans who are required to pay co-payments for medical care and services provided by VA, these co-payments will continue to apply for medical care and services provided by VA that are not part of this study. You have been told that you will receive $500 for your participation in the 24 month main study: $75 for the baseline and month 6 study visits, $100 each for the study visits in months 12 and 18, and $50 each for study visits in months 1, 3, 24. Payment will be in the form of an electronic fund transfer (EFT) sent directly to your bank. You will be required to provide the research staff with information that includes the name of your bank, routing number and account number to complete the EFT. Reimbursement typically takes 6-8 weeks after completing the visit due to the administrative processing time.

Payment Schedule:

Baseline: $75
Month 1: $50
Month 3: $50
Month 6: $75
Month 12: $100
Month 18: $100
Month 24: $50
Total: $500

13. Contact Person(s):

To obtain answers to questions about the research, report or seek treatment for a research-related injury, or to voice concerns or complaints about the research contact the following:

- **During the Day: [Dr. Christopher Cardozo at (718) 584-9000 ext.1828]**
- **After Hours: [Dr. Christopher Cardozo** [redacted]

I understand that should I wish to discuss my participation in this study with any other doctor or layperson, I can contact Mary Sano, Ph.D., Associate Chief of Staff (ACOS) R&D Program at the JJP VAMC by requesting an appointment at (718)741-4228 hospital extension 4228, first floor in the research building, Room 1F-01. If I have questions, concerns, and/or complaints or to offer input.

RESEARCH SUBJECTS' RIGHTS: I have read or have had read to me all of the above. Dr. Christopher Cardozo or his delegate has explained the study to me and answered all of my questions. I have been told of the risks or discomforts and possible benefits of the study. I have been told of other choices of treatment available to me.

I understand that I do not have to take part in this study, and my refusal to participate will involve no penalty or loss of rights to which I am entitled. I may withdraw from this study at any time without penalty or loss of VA or other benefits to which I am entitled.

The results of this study may be published, but my records will not be revealed unless required by law. This study has been explained to me. I have had a chance to ask questions. I voluntarily consent to participate in this study. I will receive a signed copy of this consent form.

Subject Signature	Date	Time
Person Obtaining Informed Consent (Print Name) (Investigator or Delegate as indicated on Assurance Page)	Signature of Person Obtaining Informed Consent	Date

VERBAL CONSENT IF THE PARTICIPANT LACKS UPPER LIMB FUNCTION TO COMFORTABLY WRITE

_____ is unable to sign the consent form due to impaired arm function. I certify that I have carefully explained the purpose and nature of this research to him/her in appropriate language and he/she has had an opportunity to discuss it with me in detail. I have answered all of his/her questions and he/she has consented to participate in this research. I, therefore, am signing the consent form to document that he/she has given his/her consent to participate in this research study.

Person Obtaining Consent:

Name: _____

Signature: _____

Date: _____

Witness Name: _____

Signature: _____

Date: _____