Department of Veterans Affairs

RESEARCH CONSENT FORM

Washington DC VA Medical Center

Participant Name: _____ Date: _____

Title of Study: Impact of Semaglutide (Long-Acting GLP1 Agonist) on peripheral blood-derived CD34+ Endothelial progenitor cells (EPCS) and Subcutaneous fat derived mesenchymal stromal cells (MSCS) in Type 2 Diabetes Subjects.

Principal Investigator: Sabyasachi Sen, MD, PhD VA Facility: 688

Key Information

You are being asked to take part in a research study about a special sort of cells called Endothelial Cells. This page will give you key information to help you decide whether or not you want to participate in this study. More detailed information can be found on the next pages. Ask the research team questions during the consent process and use the contact information on this form to ask questions later.

WHAT IS THE PURPOSE, PROCEDURES, AND DURATION OF THIS STUDY? By doing this study, we hope to learn whether the drug semaglutide will improve your overall cardiovascular health by increasing the number of a special cells in your body called Endothelial progenitor Cells. Endothelial cells protect the inner lining of your blood vessel and this medication might help them survive in the high sugar environment of diabetes. Your participation in this research will last about 8 months.

WHAT ARE THE REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY? By being in this study your diabetes might improve, you might lose some weight and the overall health of your blood vessels might get better. For a complete description of benefits please refer to the Detailed Consent.

WHAT ARE THE REASONS YOU MIGHT NOT CHOOSE TO VOLUNTEER FOR THIS STUDY? There are few medication side effects such as nausea, vomiting, diarrhea, constipation and abdominal pain. You might also not be comfortable with a required collection of fat tissue sample from your belly area. This study also involves blood draw. For a complete description of risks please refer to the details below.

DO YOU HAVE TO TAKE PART IN THIS STUDY? You do not have to take part in this research. It is your choice whether or not you want to take part. You can agree to take part and later change your mind. If you choose not to take part or choose to stop taking part at any time, there will be no penalty to you or loss of benefits to which you are otherwise entitled.

WHAT IF YOU HAVE QUESTIONS OR CONCERNS? The person in charge of this study is Dr. Sabyasachi Sen. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study you can contact Dr. Sen at 301-461-6676.

If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the DC VAMC IRB OFFICE at 202-745-2338 . This is the Board that is responsible for overseeing the safety of human participants in this study. You may call the DCVAMC Research and Development Office at 202-745-8122 if you have questions, complaints or concerns about the study or if you would like to obtain information or offer input.

Title of Study: Impact of Semaglutide (Long-Acting GLP1 Agonist) on peripheral blood-derived CD34+ Endothelial progenitor cells (EPCS) and Subcutaneous fat derived mesenchymal stromal cells (MSCS) in Type 2 Diabetes Subjects.

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DETAILED CONSENT

WHY AM I BEING INVITED TO TAKE PART IN A RESEARCH STUDY?

You have been invited to participate in a research study. You are being asked to take part in this study because you: 1) have type 2 diabetes, 2) are currently taking metformin and/or insulin and/or other anti-diabetic therapy, or lifestyle modification alone 3) your diabetes is not under control**,** and, 4) you do not have any disease of the heart vessels but you do have some risk factors for it. We will be enrolling male and female subjects who are 20-90 years of age.

WHAT IS THE STUDY ABOUT AND WHY ARE WE DOING IT?

Type 2 diabetes is a national epidemic. Diabetes has undesirable effects on blood vessels which may contribute to heart disease. The inner lining of your blood vessels are protected by a type of special cells called Endothelial Cells. They form a barrier, so your blood doesn't touch the inner part of the body. Those endothelial cells form from another type of cells called endothelial progenitor cells. Endothelial Progenitor Cells (EPCs) are found in the blood. These cells die when they are exposed to high sugar environment. Research has shown that improving the survival of these special cells, by reducing sugar in the body, may decrease the harmful effects of diabetes on blood vessels and reduce or reverse heart disease. Semaglutide is an FDA (Food and Drug Administration) approved prescription medicine used along with oral medications to lower blood sugar in people with Type 2 diabetes. Other than improving the survivability of the special EPC cells it might also reduce inflammation in the fat cells of your body which would mean weight loss something this medication is already known to do.

The medication we will be using in this research is called, Semaglutide, it is already FDA approved for diabetes and we will be using it to control your diabetes as well. It is **once a week injection**, which comes in a pen form like some of the commercially available insulin. This drug is not insulin.

This is a placebo-controlled study, which means there is a 50% chance you will get a placebo, which will also be like the pen injection, but without the actual medication in it. The placebo will contain saline only. If you are taking the placebo medications, it is as if you are taking no medication at all. That's why we will not take you off your metformin because we want your blood sugar to be under control. This study will have 4 visits total. The screening visit, Visit 1 at week 0, Visit 2 at Week 8 and Visit 3 at week 24.

If you decide to take part in this study, your diabetes might get better if you are in the treatment group of this study, also you might lose some weight. It is also possible you will get no direct

benefit from this study, but the data we will collect will be used to further our understanding of science. If you decide that you will not be taking part in this study, no more procedures will be performed as you withdrew consent.

There will be 4 phone calls made to you to inquire about your wellbeing, as part of this study.

This research study is expected to take approximately 3 years. Your individual participation in the project will take about 32 weeks. There will be 4 visits in total where you will need to travel to the DC VAMC, including the screening visit (today). Details of the visit schedule are below.

We expect about 40 people will take part in the entire study.

Dr. Sen, a full-time member of the DC VAMC staff is the Principal Investigator for this study. He has no other relationship with NovoNordisk, the sponsor of this project. This is a study that will combine VA data with non-VA data collected previously. The data gathered from your participation will remain located at the VA where the data will be combined and analyzed. The non-VA data is data already gathered by Dr. Sen at another institution. The VA is the only site active for enrollment for this study.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

WHAT WILL HAPPEN AND WHAT CAN I EXPECT IF I TAKE PART IN THIS STUDY?

If you consent to participate in this research study the first visit of this trial will be a screening visit, where we will determine if you are fully eligible to be part of this research study.
What will be done in the Screening Visit?

- A medical history and physical exam will be performed, to make sure it is safe for you to participate.
- Your heart rate, blood pressure, temperature, weight, height and BMI (Body Mass Index) will be measured
- If no recent tests (Last 3 months) available, lab tests including urine and a blood draw of **22ml (1.5 tablespoons)** will be done to check the following:
  - Complete Blood Count (CBC) and Sedimentation Rate (Infection, anemia, and others)
  - Hemoglobin A1C (HbA1C) (Blood sugar)
  - ALT/AST (Liver function)
  - Lipid Panel (Cholesterol)
  - Blood Urea Nitrogen (BUN) (Kidney function)
  - Electrolytes (Kidney function)

- Fasting Glucose (Blood sugar)
- Thyroid Stimulating Hormone (TSH) (Thyroid Function)
- Urine Sample**:**
  - To get a Pregnancy test (if applicable)
  - Micro-albumin / Creatinine Function (Kidney function)

Also, you will be asked to not change your current eating habits, including alcohol intakes because we want to see if any weight loss that might happen was caused by the study medication.

If the results of the screening tests show that you are eligible for this study, you will be randomly assigned (randomized) into one of the two study groups by chance. There is a 50% chance you will receive the study medication. We will be doing this because we want to compare the group that would have received the study medications to the ones who will not. The treatment you get will be chosen by chance, like flipping a coin. Neither you nor the study doctor will choose what treatment you get.

Based on everything we gather from the screening visit; you may not be eligible for the study. This may be due to your medical history, current list of medications, laboratory results, vitals, or another reason that, at the discretion of the study doctor, makes you not suitable for the study.

If Eligible, What Will Be Done in Visits 1, 2, and 3?

- Lab tests involving a urine sample and a fasting blood draw of approximately **95 milliliters, (6.5 tablespoons**, less then when giving blood**)** will be done at study Visits 1, 2, and 3. We will use these samples, send out to LabCorp, to check for your diabetes status (sugar levels), kidney function, lipid levels, and more. Some of the blood will be given to our research laboratory staff at the VA for processing of EPCs. If necessary, a secondary site at George Washington University will be used by the VA researchers after processing, in which non-cellular, non-DNA containing, unidentifiable/unlinked samples may be analyzed.
- Vitals: your heart rate, blood pressure, weight and height will be measured
- Your waist and hip circumference measurements will be done.
- Your weight and body composition will be measured with bare feet on the body composition scale. This scale sends a mild electrical current through your body when you step on it. The electrical current is so small that you will not feel it. This is a research related procedure only and is not usually done as part of a physical exam.
- Arterial Stiffness measurements (like a mini ultrasound) of the blood vessels (pulse) in your wrist, neck, and groin area. This is a research related procedure, not routinely done in clinical setting. This procedure will tell us if your blood vessels are elastic or not as elasticity of the vessels are correlated with their health, as hardened vessels are not healthy.
- Fat Biopsy (only in Visit 1 and 3): In order to detect any inflammation in your fatty tissue we will need about 2-3 grams sample of your belly fat. You will lie down on an exam table. Physician performing the biopsy will do a quick abdominal exam followed by application of topical anesthetics. A small incision will be made (less than half an inch), and a biopsy needle will be inserted. Once the needle is in the fatty layer of your belly, a fat sample will be extracted using suction. Then a larger needle will be used to get some more fatty tissue. After this procedure, the incision will be closed

using either suture or sterile tape. If suture was used to close the incision, you will need to be back in a week for suture removal.

The following will happen to everyone in the study (in all groups):

When (approx.)	**What happens**
Screening (Week -2)	Today's visit • Consent form, list of current medications, and review of inclusion/exclusion criteria • Screening lab tests: Urine and Blood Draw • Medical history and physical exam • Vital signs (Blood Pressure, Heart Rate, and Temperature)
	• Height, weight, BMI
Study Visit 1: Beginning Treatment (Week 0)	• Randomization: *Get randomly assigned to one of 2 groups* • *Determine if you are experiencing any side effects.* • Vital signs (Blood Pressure, Heart Rate, and Temperature) • Weight/body composition (Tanita Scale), and hip and waist measurements • Fasting Lab work: Urine and Blood • Arterial Stiffness measurements • Subcutaneous Fat Biopsy • Dispense Study medication or placebo. ***Begin taking study medication or placebo at home next day. Week 0 to week 4, take 0.25 mg/week. Week 4 to week 8, take 0.5mg/week.***
Follow Up Phone Call (Week4)	• Adverse Event Assessment

Study Visit 2 (Week 8)	• Vital signs (Blood Pressure, Heart Rate, and Temperature) • *Determine if you are experiencing any side effects.* • Weight/body composition (Tanita Scale), and hip and waist measurements • Fasting Lab work: Urine and Blood • Arterial Stiffness measurements • Return unused study drug and packaging from visit 1 • Compliance Check • Dispense study medication or placebo • ***Continue taking study medication or placebo at home. From Week 8 to week 24, take 1 mg/week.***
Follow Up Phone Call (Week16)	• Adverse Event Assessment
Study Visit 3: End of Treatment (Week 24)	• Vital signs (Blood Pressure, Heart Rate, and Temperature) • *Determine if you are experiencing any side effects.* • Height, weight/body composition (Tanita Scale), and hip and waist measurements • Fasting Lab work: Urine and Blood • Arterial Stiffness measurements • Subcutaneous Fat Biopsy • Return unused study drug and packaging from visit 2 • Compliance Check
Follow up telephone call (Week 28)	• Determine if you are experiencing any side effects after stopping the study medication

You might not find out what treatment you received during this study until the whole study has been completed. Which might be a few years from when you complete the study.

Your individually identifiable health information is information about you that contains your health information and information that would identify you such as your name, date of birth, or other individual identifiers. The VA Principal investigator (PI) and/or the VA research team members are asking to access and use your past or present health information in addition to new health information they may collect for the study named above.

The investigators of this study are committed to protecting your privacy and the confidentiality of information related to your health care. Your individually identifiable health information used for this VA study includes the information below:

- Name
- Medical Record Number

- Telephone Number
- Social Security Number
- Date of Birth

If you take part in this research, you will be responsible to take all the study medications on time and listen to the study staff regarding any instructions. You also have to make sure the study medications are refrigerated and that the study drug is kept away from children.

While participating in this research study, do not take part in any other research project without approval from the investigators. This is to protect you from possible injury from things such as extra blood drawing, extra X-rays, or potential drug interactions. Taking part in other research studies without first discussing it with the investigators of this study may invalidate the results of this study, as well as that of the other studies.

Your participation in this study may be stopped if the study doctor thinks 1) it is in your best interest to stop, 2) if you do not follow the study requirements, or 3) if the study is stopped for any reason. The study doctor will tell you about new information that might affect your health or could change your decision to be in this study If this occurs, you may be asked to sign a new consent form.

WHAT POSSIBLE RISKS OR DISCOMFORTS MIGHT I HAVE IF I TAKE PART IN THIS STUDY?

Any procedure has possible risks and discomforts. The procedures in this study may cause all, some, or none of the risks or side effects listed.

General Risks: You may experience risks or discomfort as a result of being in this study. As with any research study there may be risks to you that are not known at this time. The known risks are described below.

Blood Draw: This may result in discomfort at the site of the needle entry or bruising at the site. There is also a remote risk of fainting or local infection associated with drawing blood.

Urine collection: You will be asked at some visits to give a urine sample. Some people do not like the idea of providing a urine sample and may experience difficultly with the collection as a result.

Medical Information: You will be asked to provide a medical history. Some participants may find this uncomfortable or embarrassing. We have minimized this risk by making sure people could not have access to your identity other than the research team members. Your information will be locked safe with us, but there is always a chance of data loss.

Tanita Body Composition Scale may cause interference with electrical devices inside your body such as a pacemaker to malfunction.

Subcutaneous fat biopsies: Collection of subcutaneous adipose tissue biopsies may result in pain, bruising, blood pooling inside, infection, and scarring. The procedure will be performed under sterile

technique to minimize the chances of infection. Local anesthetic will be used to minimize pain. Ice will be applied to the site immediately after the procedure to limit bruising, swelling and tenderness. After each biopsy, you will be monitored by the study physician. Post-biopsy the incision site will be cleaned and closed with adhesive wound closures and covered with gauze and dressing tape. You will be instructed to report to the study physician any changes at the biopsy site including bleeding, redness, pain, puss formation etc.

Study Medication: semaglutide. The following warnings and precautions are listed:

- The most common adverse reactions, reported in ≥ 5% of patients treated with semaglutide, are: Nausea, Vomiting, Diarrhea, Abdominal pain and Constipation.
- Pancreatitis has been reported in clinical trials. If pancreatitis is suspected, study medication will be discontinued immediately.
- Diabetic Retinopathy Complications have been reported in a clinical trial. We will monitor patients with a history of diabetic retinopathy.
- Thyroid C-cell tumors were found in mouse. It is unknown if semaglutide causes C-cell tumors in humans (including MTC).
- Acute Kidney Injury: There have been some reports kidney injury in patients treated with medication similar to this. Kidney function will be checked throughout the study, especially in patients reporting severe abdominal reaction.
- You should not become pregnant while taking Semaglutide as it is not known if Semaglutide can harm your unborn baby. You should stop using Semaglutide 2 months before you plan to become pregnant. If you become pregnant, the Semaglutide might involve risks to the embryo or fetus, which are currently unforeseeable. Tell the investigator or research staff if you believe you might be pregnant.

There is always a chance that any procedure can harm you. The procedures in this study are no different. In addition to the risks described above, you may experience a previously unknown risk or side effect.

Risks of the usual care you receive are not risks of this study. Those risks are not included in this consent form. You should talk with your health care providers if you have any questions about the risks of usual care.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

We do not know if you will get any benefits from taking part in this research study. However, possible benefits may include

- Improvement in diabetes condition
- Improved cardiovascular health and possible decrease in body weight.
- Continual monitoring of your diabetes progression and overall health through standard of care labs.
- Information gained form this research study may help other people with diabetes in the future.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT WANT TO JOIN THIS STUDY?

Instead of being in this research study, your choices may include: 1) You could take part in another study, 2) you could choose no treatment, 3) you could take semaglutide on your own, not as part of the research, if prescribed by your physician.

You may discuss these options with your doctor.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

To the extent allowed by law, we limit your personal information to people who have to review it. We cannot promise complete secrecy. Federal agencies including, but not limited to, the FDA, OHRP, ORO, and the VA Office of the Inspector General (OIG) may have access to the records. The FDA may choose to inspect research records that include the subject's individual medical records.

VHA will maintain the confidentiality of your records if information is shared with others, the VHA will require that your records will be kept confidential. Federal and local regulations may require review of our medical and research records by representatives of Food and Drug Administration (FDA), Government Accountability Office (GAO), the VA, Office of Human Research Protection (OHRP), Office of Research Oversight (ORO), VA Office of the Inspector General (OIG), the Institutional Review Board (IRB) and the Research Compliance Officer (RCO) of this medical center.

Your information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

We will include information about your study participation in your medical record.

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

While this study is being conducted, you will not have access to your research related health records. This will not affect your VA healthcare including your doctor's ability to see your records as part of your normal care and will not affect your right to have access to the research records after the study is completed.

HEALTH INFORMATION PORTABILITY AND ACCOUNTABILITY ACT (HIPAA)

There are rules to protect your private health information. Federal and state laws and the federal medical law, known as the HIPAA Privacy Rule, also protect your privacy. By signing this form, you provide your permission called your 'authorization,' for the use and disclosure of information protected by the HIPAA Privacy Rule.

Your individually identifiable health information is information about you that contains your health

information and information that would identify you such as your name, date of birth, or other individual identifiers. VHA is asking you to allow the VA Principal Investigator (PI) and/or the VA research team members to access and use your past or present health information in addition to new health information they may collect for the study named above. The investigators of this study are committed to protecting your privacy and the confidentiality of information related to your health care.

Your treatment, payment, enrollment, or eligibility for VA benefits will not be affected, whether or not you sign this consent form.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form, in addition to :

- Your VA health records such as diagnoses, progress notes, medications, lab or radiology findings, medical history, allergies,
- sickle cell anemia, HIV status, drug, alcohol or STD treatment, genetic test results or mental health treatment;
- demographic Information such as name, age, race;
- digital Images and questionnaires/surveys

The research team may also need to disclose your health information and the information it collects to others as part of the study progress, including:

- The Study Sponsor/Funding Source – Novo NorDisk:
- VA or non-VA person or entity who takes responsibility for; initiates, or funds this study – Institute for Clinical Research, Inc.
- Academic Affiliate (institution/name/employee/department): - George Washington University
- Compliance and Safety Monitors
- Other: bill.com, a third party vendor responsible for issuing participant reimbursements.

Other Federal agencies required to monitor or oversee research (such as FDA, OHRP, GAO): Food and Drug Administration, Office (FDA), Office of Human Research Protections (OHRP), the VA Office of Research Oversight (ORO), Government Accountability (GAO); VA Office of the Inspector General (OIG); the Institutional Review Board (IRB) and Research Compliance Officer(s) (RCO) at this medical center.

Your health information disclosed pursuant to this authorization may no longer be protected by Federal laws or regulations and may be subject to re-disclosure by the recipient.

You can revoke this authorization, in writing, at any time. To revoke your authorization, you must write to the Release of Information Office at this facility or you can ask a member of the research team to give you a form to revoke the authorization. Your request will be valid when the Release of Information Office receives it. If you revoke this authorization, you will not be able to continue to participate in the study. This will not affect your rights as a VHA patient to treatment or benefit outside of the study.

If you revoke this authorization, Dr. Sen and his research team can continue to use information about you

that was collected before receipt of the revocation. The research team will not collect information about you after you revoke the authorization.

Treatment, payment or enrollment/eligibility for benefits cannot be conditioned on you signing this authorization. This authorization will expire at the end of the research study unless revoked prior to that time. If study information that has been placed into a repository to be used for future research will not expire, or expire on the following date or event, or not expire}.

HOW WILL RESEARCH RESULTS BE USED?

We will let you and your physician know of any important discoveries made during this study, which may affect you, your condition, or your willingness to participate in this study.

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.

We will maintain your privacy and the confidentiality of the research record and no information by which you can be identified will be released or published without your authorization unless required by law. Dr. Sen will have possession of all data including questionnaires. Other research staff members will have access to them, but they will be stored in a secure location in accordance with the record control schedule. At that time, they will be destroyed. There is a possibility that the Food and Drug Administration (FDA) or Novo NorDisk may inspect the records.

WHAT WILL HAPPEN IF I AM INJURED BECAUSE OF MY BEING IN THE STUDY?

If you are injured as a result of taking part in this study, the VAMC will provide necessary medical treatment at no cost to you. However, the VAMC has the right not to provide treatment for injuries resulting from your noncompliance with study procedures.

Additional compensation may or may not be payable in the event of physical injury arising from this study under applicable federal law. Further information about compensation may be obtained from the Office of the Patient Experience & Advocacy at this VA Medical Center**.** The contact number is 202-745-8588.

You do not waive any legal rights by signing this Consent Form.

WILL I BE PAID FOR MY PARTICIPATION IN A RESEARCH STUDY?

If you agree to participate in this research study, we will pay you for your time and effort. You will receive $50 for the screening visit, $150 for Visit 1, $50 for Visit 2, and $150 for Visit 3, totaling $400 for the whole trial.

You will be issued payment as a check delivered from bill.com which will arrive 4-6 weeks after visit 1 and 3. In rare cases, a debit card can be issued that your funds are loaded onto after each completed study visit. If you are issued a debit card, it can be used at your discretion. When a visit is completed,

funds will be approved and loaded onto your card. The funds will be available within 1 business day and can be used at your discretion. In order to assign a ClinCard (debit card) to you and load funds onto the ClinCard Greenphire will need your Subject ID, Name, Address, and Date of Birth.

WHAT OTHER SPECIAL INFORMATION SHOULD I KNOW?

1. You are not required to take part in this study: your participation is entirely voluntary.
2. 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.
3. There will be no costs to you for any of the treatment or testing done as part of this research study. Eligibility for medical care is based upon the usual VA eligibility policy and is not guaranteed by participation in a research study.
4. For Non-Veterans enrolled in this study you will receive a copy of the VA Privacy Practice Notice. The Privacy Practice Notice describes how medical information about you may be used or disclosed and how you can get access to this information. The Department of Veteran Affairs is required by law to maintain the privacy of your information. The VHA must provide a copy of Notice of Privacy Practice (NoPP) to all non-Veterans enrolled in approved VHA research studies. The non-Veteran patient will be required to acknowledge receipt of the Notice of Privacy Practice by signing VA form 10-0483.
5. By signing this document below, you voluntarily consent to participate in this study and authorize the use and disclosure of your health information for this study. You also confirm that you have read this consent, or it has been read to you. You will receive a copy of this consent after you sign it.
6. If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the *DC VAMC IRB OFFICE at 202-745-2338* . This is the Board that is responsible for overseeing the safety of human participants in this study. You may call the *DCVAMC Research and Development Office at 202-745-8122* if you have questions, complaints or concerns about the study or if you would like to obtain information or offer input.

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Principal Investigator: Sabyasachi Sen, MD, PhD VA Facility: 688

AFFIRMATION FROM SUBJECT

Dr. Sen or a member of his research team has explained the study to me and answered all of my questions. I have been told of 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 identity will not be revealed unless required by law.

In case there are medical problems or questions, I have been told I can call Dr. Sen at (202-994-8560) during the day and Dr. Sen at 301-461-6676 after hours. If any medical problems occur in connection with this study the VA will provide emergency care.

I understand the explanation of my rights as a research subject, and I voluntarily consent to participate in this study. I understand the explanation of what the study is about and how and why it is being done. I will receive a signed and dated copy of this consent form.

_____ ____/____/____

Participant's Signature Date

_____

Print Name (Participant)

I have informed the participant of the intent, nature benefits and risks of the research project. I judge that he/she understood my explanation and that his/her consent was given freely.

_____ _____ ____/____/____

Consent Informant Signature Print Name Date

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