U.S. Department of Veterans Affairs
Atlanta VA Health Care System

Informed Consent Template Version 7-1-20

Consent to be a Research Subject

You Are Being Asked to Be in a Research Study

Concise presentation of key concepts

You are being asked to be in a research study. A research study is designed to answer a scientific question. If you agree to be in the study, you will be one of 126 people who are being studied at the Atlanta VA Health Care System.

Why is this study being done?

This study is being done to answer the question: Is maintaining normal blood glucose levels by accelerated treatment more effective than usual care in preventing the typical worsening of diabetes in patients with early type 2 diabetes? You are being asked to be in this study because your HbA1c is between 6.0 and 7.4%, and you may have
(i) undiagnosed type 2 diabetes, or
(ii) diagnosed type 2 diabetes which is not treated with any drugs, or
(iii) diagnosed type 2 diabetes which is treated only with metformin.

Do you have to be in the study?

It is your decision to be part of this study. You do not have to be in it. Your choice will not affect your access to medical care for your condition. Before you make your decision, you should take time to learn about the study.

What do I have to do if I choose to participate in this study?

If you are eligible and want to be part of the study, you will participate for 33 months. Once they are determined to be eligible, participants will come for 12 study visits. There may also be additional visits if needed, such as for assistance with changes to study medications. The researchers will ask you to do the following: attend the VA's diet and exercise program, take drugs to treat your diabetes if needed, have blood and urine tests, maybe test your blood glucose (sugar) with fingersticks, have photos of the back of your eyes, have continuous glucose monitoring (CGM) tests, and fill out questionnaires.

How is this study going to help you?

If you are in the study, you will be helping the researchers answer the study questions. Your diabetes care will be directed by a senior diabetes specialist. You may benefit by learning more about managing your diabetes. Or, you may not benefit from taking part in the study.

What are the risks or discomforts I should know about before making a decision?

The study will take time. Accelerated treatment may not work any better than regular care, and may even cause harm. All studies have some risks. Some risks are relatively small, like being bored or losing time, along with possible loss of privacy, and breach of confidentiality. Others are potential side effects typical of diabetes drugs – for this study, these could include upset stomach, fluid retention, and yeast infection. A full list of possible risks, and their frequency and severity, is in the RISKS section of this document.

Alternatives to Joining This Study

The alternative is not participating – to continue your usual management with your health care provider.

What Should I Do Next?

Read this form, or have it read to you. Make sure the study doctor or study staff explains the study to you. Ask questions (e.g., about exact time commitment, about unfamiliar words, more details on specific procedures, etc.) Make sure you understand which parts of the study are research and which are standard care that you would have even if you did not join the study. Take time to consider this and talk about it with your family and friends.

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TITLE: Changing the Natural History of Type 2 Diabetes – CHANGE Study

PRINCIPAL INVESTIGATOR: Lawrence S Phillips, M.D.

SPONSOR'S NAME: National Institutes of Health - NIDDK

PURPOSE:

You are being asked to volunteer in a research study. This form is designed to tell you everything you need to think about before you decide if you want to be a part of the study. It is entirely your choice. If you decide to take part, you can change your mind later and withdraw from the research study. The decision to join or not join the study will not cause you to lose any benefits. If you decide not to take part in this study, your health care providers will continue to treat you.

Before making your decision:
- Please carefully read this form or have it read to you
- Please listen to the study doctor or study staff explain the study to you
- Please ask questions about anything that is not clear

You can take a copy of this consent form, to keep. Feel free to take your time thinking about whether you would like to participate. You may wish to discuss your decision with family or friends. Do not sign this consent form unless you have had a chance to ask questions and get answers that make sense to you. By signing this form, you will not give up any legal rights.

The purpose of this study is to determine, in patients with early diabetes, if accelerated treatment aimed to reach normal blood glucose levels, is any better than usual care, at preventing the typical worsening of type 2 diabetes. You are being asked to participate because you have moderately elevated HbA1c (6.0-7.4%) levels, either without any use of diabetes drugs or with using only metformin. If needed, the study will use a plan to intensify treatment, by adding metformin (if not already taking it), and other diabetes drugs. All the diabetes drugs in the plan are approved to treat diabetes by the US Food and Drug Aministration (FDA). There are no experimental or “research” drugs in this study.

WHAT IS DIFFERENT FROM USUAL CARE?

Diabetes is a disorder of high blood glucose (sugar). It is caused by the body’s insulin-producing cells not making enough insulin. Over time, diabetes tends to get worse – blood glucose levels rise, so more treatment is needed. We treat diabetes with diet, exercise, and/or drugs to lower blood glucose. The goal is to prevent or delay development of diabetes

complications. With usual care, management is often guided by a blood test to measure hemoglobin A1c (HbA1c) every 3 months. If the test is high, another drug can be added.

This study will compare usual care with management guided by blood glucose levels, in fingersticks done an average of once a day. Normal glucose is below 100 mg/dl before meals, and below 130 after meals. If blood glucose is still high for 2 weeks in a row after at least 4 weeks of diet, exercise, and/or the highest tolerated dosage of diabetes drugs, another drug will be added. If needed, the sequence of drugs will be: metformin (if not already taking metformin), pioglitazone, semaglutide, empagliflozin, then glargine insulin.

This sequence is not itself unusual. However, compared to usual care, this management is accelerated and more intensive. The study will evaluate if the intensive approach based on glucose levels, is better than usual care in keeping diabetes from getting worse. The study will compare accelerated intensive management based on blood glucose levels (an average of one test a day) to usual care based on HbA1c measured every 3 months.

Intensive management aimed to keep blood glucose normal, is more complicated than usual care – simply having a HbA1c test every 3 months. We don't know if intensive management is better than usual care in helping to preserve the function of the body's insulin-producing cells. This study will compare intensive management with usual care.

Your participation in the study will last about 33 months, with at least 12 visits to the study clinic. You may need to come for extra visits if a new drug is added to your treatment. We expect to enroll 126 participants at the Atlanta VA Health Care System.

WHAT WILL I BE ASKED TO DO?:

You will be asked to come to the study clinic for the visits described below. The study visits will take place at the Clinical Studies Center (CSC) on the 11th floor of the main hospital tower. These visits will take about 1-1.5 hours for simple visits, and about 3-4 hours if there is an oral glucose tolerance test (OGTT) at the visit.

Your responsibilities as a participant include:

- Coming to the study clinic for each scheduled visit during the study
- Participating in the VA's *MOVE!* lifestyle change program (help with diet and exercise)
- If you are randomized to the intensive treatment group, doing fingersticks of your blood glucose an average of once a day (this is self-monitored blood glucose, SMBG)
- Doing CGM monitoring (with a device about the size of a quarter that sticks to the back of your arm), every 3 months, and also after 3 weeks of the *MOVE!* program and 3 weeks after you have reached the maximum tolerated dose of each new drug added to your treatment
- Taking your study medications, if needed, as indicated by the study team

- Having blood and urine tests, and photos of the back of your eyes (retina)
- Communicating any questions or concerns to the study team if you are not sure about your medications or something else that could be related to your being in the study
- Bringing in your study supplies as requested by the study team

SCREENING VISIT 1

At this visit, you will read the consent form and discuss any questions that you may have with the study team. If you agree to participate the following will take place:

- Blood sample for HbA1c (1 teaspoon)
- Blood sample for Lipids (1 teaspoon)
- Blood sample for Comprehensive Metabolic Panel (1 teaspoon)

- A 2-hour OGTT visit will be scheduled for 1-2 weeks later.

SCREENING VISIT 2

This is the visit to determine if you are eligible for the study. You will "fast" overnight (no food for at least 8 hours after dinner the night before; you may drink water) before the day of your visit. Please take your usual morning medications (including your metformin) with water.

- 2-hour oral glucose tolerance test (OGTT), to measure your blood glucose levels in response to a sugary drink. This measures your body's ability to make insulin. We will ask you to drink a flavored sweet drink. There will be blood samples at baseline, 1 hour, and 2 hours (3 tests) over a period of 2 hours. At the start of the test, we will place an IV (intravenous catheter) in a vein in your arm or hand. An IV is a small plastic catheter inserted into a vein that will stay in your vein during the 2-hour test. The IV is inserted so that we can draw several blood samples without doing a needle stick each time. When the test is done, we will remove the IV from your vein. The total amount of blood will be about 6 teaspoons.

- A Run-In visit will be scheduled for 1-2 weeks later.

RUN-IN VISIT

- If you qualify to participate based on your HbA1c and your 2-hour OGTT at baseline, you will come in for the Run-In visit.
- We will teach you to check your blood glucose by a fingerstick (if you don't know this already). This is called self-monitoring of blood glucose (SMBG). We will give you a glucose meter and glucose test strips. You will do SMBG an average of once a day,

for two weeks, and record your glucose levels – like participants in the intensive treatment group will do.
- We will teach you to take the most commonly used diabetes drug, metformin (if you don't take this already). This will be the extended-release form, one pill, twice a day with meals. If you already take metformin, we will see if you can tolerate the usual maximum dose (1000 mg twice a day),
- The study staff will review the *MOVE!* lifestyle change program with you.
- We will also teach you how to do continuous glucose monitoring (CGM).
- During the OGTT, we will also teach you how to inject yourself (so that you will know, if it turns out that you need to use an injectable diabetes medication)
- If your Run-in is successful (you tolerate metformin if you haven't been taking it already, and you are comfortable with doing SMBG), you will be randomized (like the flip of a coin) to either the intensive treatment or the usual care group.
- If you are in the intensive treatment group, you will continue to do SMBG. If you are in the usual care group, you will do SMBG only if it turns out that you need to use insulin.

BASELINE VISIT (MONTH 0)

At this visit, the following will occur:

- Blood draw for HbA1c, kidney function (estimated glomerular filtration rate, eGFR) (3 teaspoons)
- Urine sample for microalbumin / creatinine ratio to detect diabetic kidney disease if present at baseline
- 3-hour OGTT with blood samples at -10, -5, 10, 20, 30, 60, 90, 120, 150 and 180 minutes (to evaluate how well your body produces insulin, from cells in your pancreas)
- Fundus photos to detect diabetic eye disease at baseline if present
- CGM monitoring for 14 days.
- Dispensing of ForaCare blood glucose meters and test strips (if we do not use the ForaCare meters, will use regular glucose meters and test strips from the VA).
- Quality of Life Questionnaires: Diabetes Distress Scale and EuroQoL-5D

MONTH 3-9-15-21-27 VISITS

At 3 months of follow-up (and every 6 months after this visit), the following study activities will occur:

- Blood draw for HbA1c (1 teaspoon)
- CGM monitoring for 14 days.
- Resupply of test strips for SMBG (for participants in the intensive treatment group).

MONTH 6-12-18-24 VISITS

At the 6-month visit (and every 6 months after this visit), the following will occur:

- Blood draw for HbA1c (1 teaspoon)
- Urine sample for microalbumin / creatinine ratio
- CGM monitoring for 14 days.
- Resupply of test strips for SMBG (for participants in the intensive treatment group).
- A blood draw to measure vitamin B12 will be collected at the 12 month visit (1 teaspoon)

MONTH 30 VISIT

This is the final study visit before the "washout" period. At this visit, the following will occur:

- Blood draw for HbA1c, kidney function (3 teaspoons)
- Urine sample for microalbumin / creatinine ratio
- 3-hour OGTT with extra blood draws as at baseline (to evaluate how well your body produces insulin)
- Fundus photos to detect diabetic eye disease if present
- CGM monitoring for 14 days.
- Quality of Life Questionnaires: Diabetes Distress Scale and EuroQoL-5D
- Return the ForaCare meters

After the Month 30 visit, you will be instructed to stop all diabetes drugs (except for metformin if you were already taking it at randomization) for a 3-month "washout" period. You will be scheduled to return for a post washout visit 3 months after the Month 30 visit.

POST WASHOUT VISIT

At this visit, the following will occur:

- Blood draw for HbA1c, kidney function (3 teaspoons)
- Urine sample for microalbumin / creatinine ratio
- 3-hour OGTT with extra blood draws as at baseline (to evaluate how well your body produces insulin)
- CGM monitoring for 14 days.

The study team will communicate with your regular care provider to inform them of your current diabetes medications and that your participation in the study has ended. We will also give you an individualized, personalized recommendation for managing your diabetes.

RISKS:

There may be side effects from the study drugs or procedures that are not known at this time.

The most common risks and discomforts expected in this study are:

Risk from study activities:

- In some cases, a person may faint or become sick to the stomach at the sight of a needle or when blood is drawn.
- In about 1 in 4 people, there may be some discomfort or bruising at the site of the needle stick.
- Some people may get slightly nauseated or get an upset stomach from the glucose (sugar) drink given during the OGTT. These symptoms are infrequent and usually disappear within 15 to 30 minutes.
- Eye drops used for dilation during the fundus eye photos can rarely cause angle closure glaucoma.
- There is a slight amount of pain associated with checking blood glucose levels using fingersticks.
- There can also be a small amount of pain associated with the injections of the study medications (semaglutide and insulin, if these drugs are needed to keep your glucose levels normal). These are injected into the fatty tissue in the abdomen, arms or legs.
- The risks of wearing the CGM sensor are minimal. These may include mild symptoms from the sensor application, or the adhesive tape used to keep the sensor in place. Although rare, the possible side effects of applying and wearing the sensor include swelling, rash, itching, bruising, pain, and hardening of the skin at the site of the sensor insertion. Infection, inflammation, or bleeding at the sensor insertion site are also possible, but they are all very rare risks of applying a sensor to the skin.
- Filling out quality of life questionnaires could potentially cause distress to some participants.

Risk from drugs used (if participants need these drugs to keep glucose levels normal):

Any time that a diabetes medication is started, stopped, or changed, there is a risk of having high blood sugar levels (hyperglycemia) or low blood sugar levels (hypoglycemia). The symptoms of high blood sugar levels can include: drowsiness, thirst, excessive urination, loss of appetite. The symptoms of low blood sugar levels can include: sweating, fatigue, nervousness, shakiness, rapid heartbeat, nausea, confusion, personality changes.

Metformin:
The most common side effects of metformin include nausea, headaches, diarrhea, vomiting, bloating, excessive gas, loss of appetite, and an unpleasant taste in the mouth. These are more common when the medication is first started and usually lessen or disappear over time. About 10 out of 100 people using metformin may experience these symptoms to some degree. These side effects are rarely severe enough to result in needing to stop the medication. Other side effects include lower-than-normal levels of vitamin B12 in the blood.

Pioglitazone:
Common side effects of pioglitazone include ankle swelling, and weight gain. Shortness of breath is rare.

Semaglutide:
Common side effects of semaglutide and other drugs in the same family can include nausea, diarrhea, vomiting, abdominal pain, decreased appetite, fatigue, and low blood glucose. An increased risk of pancreatitis and gallbladder inflammation (cholecystitis) and/or gallstones in the gallbladder (cholelithiasis) has also been reported with some of the drugs in this family. An increased risk of medullary thyroid cancer has been found in animal studies with some of the drugs in this family, but there has been no evidence of this in humans.

Empagliflozin:
Common side effects of empagliflozin are dehydration, dizziness, genital yeast infections, urinary tract infection, low blood pressure. Most of these side effects can be prevented by adequate hydration while taking this medicine.

Glargine insulin:
Side effects of glargine include low blood glucose (hypoglycemia) and weight gain. Other side effects may include itching, redness, or swelling at the injection site.

Rare but possible risks include: allergic reactions to any of the diabetes drugs.

It is possible that the researchers will learn something new during the study about the risks of being in it. If this happens, they will tell you about it. Then you can decide if you want to

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continue to be in this study or not. You may be asked to sign a new consent form that includes the new information if you decide to stay in the study.

BENEFITS:

There may be no benefit to you personally from taking part in this study. During the study, your diabetes management will be supervised by a senior, experienced diabetes expert. If you are in either the intensive or the "usual care" treatment group, your glucose and HbA1c levels may improve compared to those levels in people with early diabetes who are not in this study. If you are in the intensive treatment group, your blood glucose levels may improve compared to "usual care". You may also improve your own understanding of how to manage your diabetes. Doctors, researchers and scientists may learn new things that will help others.

COMPENSATION:

You will receive compensation for time and travel. You will receive $40.00 for study clinic visits (regularly scheduled and any unscheduled visits that are necessary). Payment will be made using a ClinCard, which works like a debit card. It is provided by Greenphire. When visits are completed, funds will be loaded onto your card. You will be able to use the funds in approximately 1 business day. We anticipate that you will have up to 12 clinic visits over the period of the study (total that you can receive for these visits is $480.00). If more than 12 visits are needed, they will also be compensated at $40.00 each.

Greenphire and its Customer Support members will have access to your name, address, and date of birth. This information will help them provide customer service in case you have questions or need support while using the ClinCard.

COSTS:

You will not be charged for any treatments or procedures that are part of this study. However, some Veterans are required to pay co-payments for medical care and services provided by the VA. These co-payment requirements will continue to apply to medical care and services that are not part of this study.

The VA will provide the necessary medical treatment if you get injured from being in this study. This requirement does not apply to:
(1) Treatment for injuries due to non-compliance by a subject with study procedures; or,
(2) Research conducted for VA under a contract with an individual or a non-VA institution.

If you believe you have been injured by this research, you should contact Dr. Lawrence Phillips at 404-728-7608.

ALTERNATIVES:

You do not have to be in this study to receive treatment for your diabetes. Thousands of patients with diabetes have management at the Atlanta VA.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

We will keep information about you, including any research records we create, strictly confidential to the extent required by law.

We may be required to release your record if we receive a subpoena or a court order. The study staff will keep your study files locked in a file cabinet in a private office. We will use [a study number*] rather than your name on study records when we can. Your name and other facts that might point to you will not appear when we present this study or publish its results. People other than those doing this research study may have access to your medical and study records including:

- The Office for Human Research Protections (OHRP)
- The Government Accountability Office (GAO)
- The Food and Drug Administration (FDA)
- The Inspector General
- Emory University
- The Foundation for Atlanta Veterans Education and Research (FAVER)
- ForaCare (FORA® Health View System for SMBG data)
- Diasyst (SMBG data)
- Abbott (Abbott Libre CGM data)
- Greenphire (administers ClinCard compensation)
- Any appropriate state or federal government agencies that make rules and policy about how research is done that are not listed above

All research records and/or identifiers will be destroyed at the end of the study in accordance with the VA record retention schedule.

If you are a Veteran who is a patient at the Atlanta VA Health Care System, a copy of your signed and dated consent and HIPAA forms may be placed in your medical record(s). If you are a non-Veteran receiving clinical services (i.e., use of the laboratory, radiology, audiology, etc.) as part of this study, you will have an electronic medical record created for you. You will also be given a VA Notice of Privacy Practices (NOPP) and we will ask you to sign a form saying that you have received this notice.

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.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, and information from your medical records such as medical history, allergies, lab results.

The research team may also need to disclose your health information and the information it collects to others as part of the study progress. Others may include the Office of Human Research Protections (OHRP), the Inspector General, and the Government Accountability Office (GAO), the Food and Drug Administration (FDA), ForaCare, Abbott, Greenphire.

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. Lawrence Phillips, Room 11C-110A, Atlanta VA Health Care System, 1670 Clairmont Road, Decatur GA 30033 and his or her 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.

RESULTS:

The study team will give you your individual results from your participation in this study. At the end of the study, the study doctor (Dr. Phillips) will also give you a personal recommendation about the best way to manage your diabetes after the study is over.

The study will also be registered and the study results reported on a U.S. Government website, https://clinicaltrials.gov/, but any information which could possibly identify you or any other study participant will not be included. As described on the Web site, "ClinicalTrials.gov is a Web-based resource that provides patients, their family members, health care professionals, researchers, and the public with easy access to information on publicly and privately supported clinical studies on a wide range of diseases and conditions. The Web site is maintained by the National Library of Medicine (NLM) at the National Institutes of Health (NIH). Information on ClinicalTrials.gov is provided and updated by the sponsor or principal investigator of the clinical study. Studies are generally submitted to the Web site (that is, registered) when they begin, and the information on the site is updated throughout the study."

IDENTIFIABLE PRIVATE INFORMATION OR IDENTIFIABLE SPECIMENS:

Blood and urine specimens collected at study visits in the Clinical Studies Center will be identified so that they can be analyzed in the VA Clinical Laboratory and the results attributed to the correct patient. Samples will not be banked by the study team and the VA Clinical Laboratory will dispose of the samples once they have been analyzed.

Other blood samples will be sent to the University of Minnesota for assays, and these and other study results will be sent to Emory University and the University of Washington for data analysis. Those samples will have no identifiable private information – they will have only your study identification number (ID), and your study date (your baseline visit will be day 0).

The photos of your retina will also be sent to the University of Wisconsin Fundus Photo Reading Center (FPRC) for analysis, but they will have no identifiable private information – only your study ID, and study date.

If you are in the intensive treatment group, your fingerstick glucose levels will go into the ForaCare database, and study staff will review them using software made by Diasyst, but the data will be linked to the glucose meter ID, not to you. Neither ForaCare nor Diasyst will know which participants have different glucose meters, and you will not be identifiable.

POTENTIAL CONFLICT OF INTEREST:

The study doctor (Dr. Phillips) does research which is supported by the National Institutes of Health (NIH), the VA, and pharmaceutical companies including Novo Nordisk, Abbvie, Pfizer, GlaxoSmithKline, Kowa, Abbott, and Janssen. Dr. Phillips is also a co-founder, officer, and stockholder of a startup company, Diasyst, which develops and markets software aimed to help improve diabetes management. If you are in the intensive treatment group, Diasyst may be used to help study staff see patterns in your SMBG glucose levels. Abbott makes and markets the devices that will be used for continuous glucose monitoring (CGM) in the study. ForaCare makes and markets the glucose meters and strips that will be used for SMBG in this study.

Dr. Phillips will not receive any personal income from any of these companies that is directly related to your being in this study. If the use of Diasyst helps to improve the diabetes care of participants in this study, it is possible that such information could help Diasyst, and that could raise the value of the stock that Dr. Phillips holds. If the use of CGM in this study also helps to improve diabetes care, it is possible that such information could also help Abbott. If the use of ForaCare meters and strips in this study also helps to improve diabetes care, it is possible that such information could also help ForaCare.

CONTACT PERSONS:

If you have any questions, concerns, or complaints about this study you can call a member of the study staff: Lawrence S Phillips, M.D. at 404-728-7608 or Stephanie Raines at 404-321-6111 ext. 206932.

If you think that you have been harmed from being in this study call: Lawrence S Phillips, M.D. at 404-728-7608.

If you want to speak to someone who is not a member of the study to discuss problems, ask questions or voice concerns, you can call:

The Research Compliance Officer at (404) 321-6111 ext. 206964 or the Clinical Studies Center Manager at (404) 321-6111 ext. 206933.

If you have any questions about your rights as a participant in this research study, call the Emory University Institutional Review Board at (404) 712-0720 or toll free at 1-877-503-9797.

VOLUNTARY PARTICIPATION AND WITHDRAWAL:

The study doctors have the right to end your participation in this study for any of the following reasons: If it would be dangerous for you to continue, if you do not follow study procedures as directed by the study doctors, or if Dr. Phillips decides to end the study.

Your participation is voluntary, and you have the right to refuse to be in this study. You can stop at any time after giving your consent. This decision will not affect in any way your current or future medical care or any other benefits to which you are otherwise entitled. For your safety, however, you should consider the study doctor's advice about how to go off the study treatment.

The study doctors may stop you from taking part in this study at any time if they decide it is in your best interest or if you do not follow study instructions.

We will give you a copy of this consent form to keep. If you are willing to volunteer for this research, please sign below.

RESEARCH PARTICIPANT'S SIGNATURE AND DATE:

_____

Research Participant's name **Date**

_____ _____

Research Participant's Signature Date

SURVEILLANCE OF DIABETES MANAGEMENT AFTER THE PRIMARY STUDY ENDS:

We ask your permission to allow us to continue to collect information about your diabetes management from your VA medical records for up to 10 years after the end of your participation in the primary study.

There will be no further visits or phone calls to you during this time, but this data will allow us to understand how your diabetes is managed after the study. This post-study surveillance would allow us to determine the diabetes drugs used by former participants, glucose monitoring used, and glycemic control achieved. This information may be useful to understand the long- term impact of the intensive diabetes management that we are studying.

We will not provide this information to anyone else. The data will be collected and stored with a code number only, and your personal health information will not be revealed in any scientific publications resulting from this study.

Please indicate whether you are willing to allow the study team to review your VA medical record for up to 10 years to collect information about your diabetes management after the primary study ends.

You can still be in the primary study even if you decide not to allow this chart review.

☐ Yes, I am willing to allow review of my medical records after the primary study.
____ Initials

☐ No, I am not willing to allow review of my medical records after the primary study.
____ Initials