COMPOUND AUTHORIZATION AND CONSENT FOR PARTICIPATION IN A RESEARCH STUDY

YALE UNIVERSITY SCHOOL OF MEDICINE
YALE-NEW HAVEN HOSPITAL

Study Title: Reversibility of brain glucose transport and metabolism in T2DM: an intervention study
Principal Investigator: Dr Elizabeth Sanchez Rangel. 300 Cedar Street, New Haven CT 06519
Phone Number: (475) 355-4539

Research Study Summary:

- We are asking you to join a research study.
- The purpose of this research study is to look at the effects of high blood glucose levels in the brain and assess if there is any difference in brain glucose in poorly controlled T2DM individuals with short duration and long duration of diabetes.
- Study procedures will include: A screening visit, placement of a continuous glucose monitor (CGM) 2 weeks before the first magnetic resonance spectroscopy (MRS) at week 0, Additional visits/phone calls for intensification of diabetes management and nutrition visits.
- At least **4** in-person visits are required and at least 4 scheduled telephone visits to monitor progress.
- These visits will take approximately 10 hours in total.
- There are some risks from participating in this study. There are potential risks associated with blood testing, risks associated with glucose clamp experiments, risk associated with Magnetic resonance exposure and continuous glucose monitor placement. See below for further details.
- By participating in this study, you might benefit from the continuous glucose monitor free supplies and increased frequency of medical attention to lower your blood glucose into target ranges.
- Taking part in this study is your choice. You can choose to take part, or you can choose not to take part in this study. You can also change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.
- If you are interested in learning more about the study, please continue reading, or have someone read to you, the rest of this document. Take as much time as you need before you make your decision. Ask the study staff questions about anything you do not understand. Once you understand the study, we will ask you if you wish to participate; if so, you will have to sign this form.

Why is this study being offered to me?
We are asking you to take part in a research study because you are an individual with uncontrolled type 2 diabetes between the ages 18 and 60 years old. We are looking for 15 individuals with T2DM of less than 5 years of diagnosis and 15 with more than 5 years of diagnosis.

Who is paying for the study?
National Institute of health

What is the study about?
The purpose of this research study is to look at the effects of high blood glucose levels in the brain and assess if there is any difference in brain glucose in poorly controlled T2DM individuals with short duration and long duration of diabetes. We will also assess if these changes are

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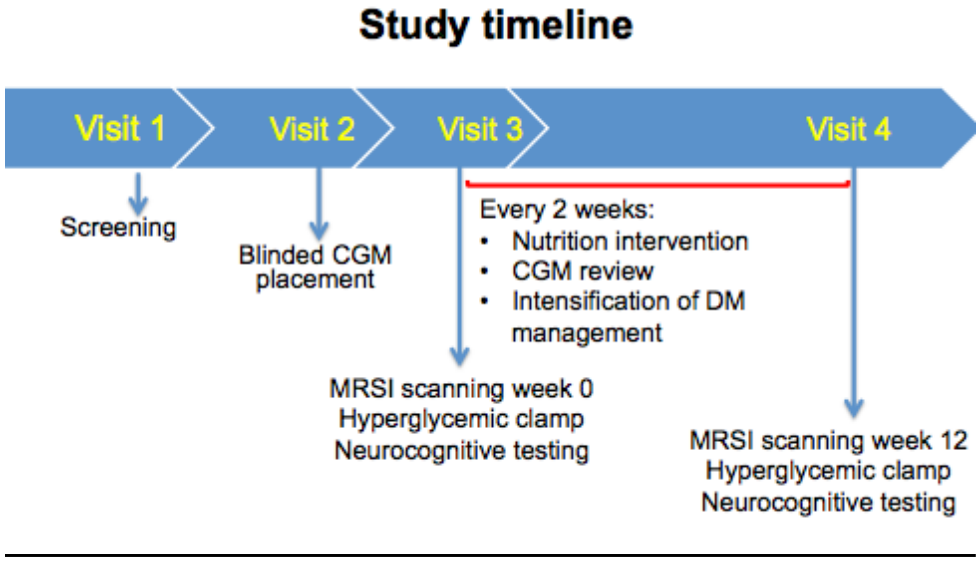
reversible with improved glucose control. A better understanding of the impact of duration of diabetes on brain glucose may have important implications for understanding the pathophysiology of brain complications in T2DM

What are you asking me to do and how long will it take?
If you agree to take part in this study, this is what will happen:



Visit #1: Screening visit: you will have a screening visit at the Yale New Haven Hospital (YNHH) Hospital Research Unit (HRU with a medical history and physical exam. Blood work will be collected to ensure that you do not have any major medical problems, which would exclude you from the study. Female subjects will also have a urine pregnancy test prior to study participation. This visit will take approximately 1 hour. If you are eligible after the screen visit, you will be asked to return for at least 4 more visits as follows:

Visit # 2 Placement of Continuous Glucose Monitor (CGM) Placement

On the visit for CGM placement:

A study clinician will explain to you how to use the blinded CGM (FreeStyle Libre Pro).

- The CGM will be placed on your upper arm.
- You will be asked to complete neurocognitive questionnaires.
- This visit will take approximately 30 minutes at HRU.

CGM:
CGM allows us to measure your glucose levels continuously throughout the day. The results will be blinded (you will not be able to see your glucose levels). As such, it is not a replacement for self-monitoring of blood glucose. You should continue your normal testing routine while wearing

the sensor. If you are already using a CGM, you must continue to use your CGM, however, you will also be asked to wear this second blinded study sensor. We will ask you to wear the CGM for ~14 days prior to your first brain scan (MRS). We will ask you to wear the CGM again for ~14 days prior to your second brain scan (MRS). It will be placed on your upper arm and attached with an adhesive patch by a trained study staff member. The sensor includes a wire-like tip which will be under your skin in your fat tissue. You will be taught how to use the CGM. The sensor is water-resistant and can be worn while bathing, showering, or swimming as long as you do not take it deeper than 3 feet (1 meter) and do not keep it under water for longer than 30 minutes at a time. Intense exercise may cause the sensor to loosen due to sweat or movement of the sensor. If the CGM sensor falls off while you are wearing it, we will ask you to return to the HRU or CSRU so that a new sensor can be re-inserted. Please contact us at 203-737-4777 or diabetes.research@yale.edu if you have any questions, concerns or issues related to the CGM. The sensor will be removed on the day of the scan.

Neurocognitive questionnaires: You will be asked to complete some questionnaires and tests on a computer or on paper to assess your cognitive function.

Visit # 3 and 4: MRS (magnetic resonance spectroscopy) scanning with hyperglycemic clamp: MRS is a specialized technique associated with magnetic resonance imaging (MRI) and is a non-invasive scan that will be used to take pictures that tell us about structures and chemicals in your brain.

You will arrive on the morning of the scan at ~7AM following an 8 hour overnight fast. One intravenous catheter will be placed in a vein in one arm to sample blood at different time points. A second IV will be placed in the other arm for infusion of 2H labeled dextrose (a glucose solution) and insulin. Following IV placements and baseline blood samples, at ~8 AM you will receive an insulin infusion to keep glucose levels at ~100-110 mg/dl for baseline scanning while avoiding hypoglycemia (glucose <70 mg/dL). Then, your blood glucose level will be increased to ~220 mg/dl using for ~2 hours. Throughout the visit, blood samples will be taken to measure glucose levels and hormones that play a role in regulating your blood sugar levels. A nurse experienced with working in a MRS environment will be with you at all times. A study physician will be outside the scanner during the entire study.

Intensification of Diabetes regimens over the course of 12 weeks: You may undergo intensification of your diabetes regimen. This process will be managed by Dr. Sanchez, a fully trained attending endocrinologist or a study clinician, and will follow the general strategies outlined in the Position Statement of the American Diabetes Association and the European Association for the Study of Diabetes. Continuous glucose monitoring records will be sent to Dr. Sanchez or a study clinician weekly for review to guide adjustment of diabetes regimens. You will be in contact with Dr. Sanchez via phone, email and consultation visits.

Nutrition Consultations: You will be in communication with a nutritionist regularly over the course of the 12-week study. The nutritionist will provide you with dietary counseling.

Continuous Glucose Monitoring (CGM): You will be provided with an unblinded CGM, a Freestyle Libre personal continuous glucose monitoring (FSL-CGM) during the 12-week intervention. Freestyle Libre 14 Day Sensor is an FDA-approved continuous glucose monitoring system that consists of a handheld reader and a sensor that is worn on your upper arm. It is used as a replacement for the fingerstick and blood glucose meter method of monitoring blood sugar levels in diabetic patients.

This Flash Glucose Monitoring System is a 14-day reader, involves a sensor being applied to the back of the arm. The sensor uses a flexible, thin filament inserted just under your skin to measure glucose levels every minute. The sensor is water-resistant and can be worn while bathing, showering, or swimming as long as you do not take it deeper than 3 feet (1 meter) and do not keep it under water for longer than 30 minutes at a time. Intense exercise may cause the sensor to loosen due to sweat or movement of the sensor. A handheld reader is then used to scan the sensor which provides a blood glucose reading. It is also possible to use your mobile phone to read your blood sugar levels and store glucose data instead of a handheld. You just need to install the Freestyle Librelink app on a phone that is NFC-enabled and running either Android OS 5.0 and higher or iPhone 7 or later.

Training sessions will be conducted as needed to ensure familiarity and comfort with system operation. There is no need for calibrations. It replaces fingerstick blood glucose testing for diabetes treatment decisions.

You will be instructed to share data remotely to the study team through libre view, a continuous glucose monitor management application run by Free style libre (Abbott). A member of the study team (physician and/or advanced practice register nurse) will review the information on a weekly basis and will make changes to your diabetes management as needed. Study participants will have in-person check-in visits for history, exam, and review of any potential adverse clinical or device-related events, if needed.

What are the risks and discomforts of participating?

While in this study, you may have side effects. Expected side effects are listed here. In addition to the risks listed below, there may be risks that are currently unknown. If we know significant new information during the time you are on the study, we will tell you so you can decide if you should stay in the study. Possible side effects that you may experience during this study will be fully explained to you by the study staff. Please ask as many questions as you want so that you can understand the possible side effects before you decide whether you want to be in this study. Please ask the study clinicians or the study staff to explain any information or words that are not clear to you.

MRS:
Magnetic resonance (MR) is a technique that uses magnetism and radio waves, not x rays, to take pictures and measure chemicals of different parts of the body. The United States Food and Drug Administration (FDA) has set guidelines for magnet strength and exposure to radio waves, and we carefully observe those guidelines.

You will be watched closely throughout the MR study. Some people may feel uncomfortable or anxious. If this happens to you, you may ask to stop the study at any time and we will take you out of the MR scanner. On rare occasions, some people might feel dizzy, get an upset stomach, have a metallic taste or feel tingling sensations or muscle twitches. These sensations usually go away quickly but please tell the research staff if you have them.

There are some risks with an MR study for certain people. If you have a pacemaker or some metal objects inside your body, you may not be in this study because the strong magnets in the MR scanner might harm you. Another risk is the possibility of metal objects being pulled into the magnet and hitting you. To lower this risk, all people involved with the study must remove all metal from their clothing and all metal objects from their pockets. We also ask all people involved with the

study to walk through a detector designed to detect metal objects. It is important to know that no metal can be brought into the magnet room at any time. Also, once you are in the magnet, the door to the room will be closed so that no one from outside accidentally goes near the magnet.

We want you to read and answer very carefully the questions on the MR Safety Questionnaire related to your personal safety. Take a moment now to be sure that you have read the MR Safety Questionnaire and be sure to tell us any information you think might be important.

This MR study is for research purposes only and is not in any way a health care examination of the brain. The scans performed in this study are not designed to find abnormalities. The principal investigator, the lab, the MR technologist, and the Magnetic Resonance Research Center are not qualified to interpret the MR scans and are not responsible for providing a health care evaluation of the images. If a worrisome finding is seen on your scan, a radiologist or another physician will be asked to review the relevant images. Based on his or her recommendation (if any), the principal investigator or consulting physician will contact you, inform you of the finding, and recommend that you seek medical advice as a precautionary measure. The decision for additional examination or treatment would lie only with you and your physician. The investigators, the consulting physician, the Magnetic Resonance Research Center, and Yale University are not responsible for any examination or treatment that you receive based on these findings. The images collected in this study are not a health care MR exam and for that reason, they will not be made available for health care purposes.

Infusion of glucose and insulin:
Intravenous (IV) catheters will be placed under sterile conditions by experienced staff members. All studies will be performed under the direct supervision of a physician or nurse practitioner. All solutions for infusion will be pyrogen free and prepared in a sterile environment.

The infusion of 2H-glucose to achieve hyperglycemia (~220 mg/dl) for 2 hours is not associated with any specific symptoms or significant adverse effects. This modestly high glucose level can be seen in poorly controlled diabetic patients following a meal. Using 2H-glucose will allow us to monitor how glucose from the blood makes its way into the brain. 2H-glucose is safe, and there are no known side effects to using it.

Infusion of insulin to normalize plasma glucose levels is normally not associated with any specific symptoms. There is a small risk that plasma glucose may fall to lower levels resulting in symptoms of hypoglycemia. All such symptoms are rapidly reversible with an intravenous dextrose infusion. To avoid excess hypoglycemia, plasma glucose levels will be checked every 5 minutes using a bedside glucose monitor. Based on these measurements, the plasma glucose will be adjusted via the 20% dextrose infusion.

Infusion of 2H-Glucose.

The infusion of 2H-glucose involves no radioactivity, and the glucose is metabolized just as unlabeled glucose. During the glucose infusion, blood samples will be obtained every 5 minutes to monitor the plasma glucose levels and the infusion rate will be adjusted to maintain plasma glucose concentrations within our target range (220 mg/dL). After the glucose infusion is discontinued, you will be given a regular meal. You will be discharged to home when plasma glucose concentrations are stable and you feel well.

CGM:

The CGM poses no major risks to the users. The CGM catheter will be placed under sterile conditions by experienced staff members. You may experience bruising and bleeding of the skin at the insertion site of the CGM sensor. This minor condition will resolve by itself in a few days. You may feel a mild discomfort (pin prick sensation) during the sensor insertion. Redness and discomfort (infection and inflammation) can occur at the sensor insertion site. Some individuals may be sensitive to the adhesive that keeps the sensor attached to the skin. If you notice significant skin irritation around or under the sensor, please contact us and it can be removed. Rarely sensors may break and a small piece may remain under the skin which will need to be removed by the physician. This may cause mild discomfort, bruising, or temporary bleeding. You will be given one of the study physician or nurse practitioner's cell phone number to contact for any questions, concerns or problems. If you have an MRI, a CT scan, or diathermy treatment, you must remove your sensor prior to the procedure.

Phlebotomy:
The maximum amount of blood that will be drawn is approximately 549 cc or 18 oz over the 3 months of the study if you complete the entire study (including the hyperglycemic clamp portions described above). If you agree to participate, blood draws include: 5cc at the screening visit, 272 cc at week 0 visit, and 272cc at week 12. For reference, a typical donation at the Red Cross is 473 cc or 16 oz.

We would advise you not to donate blood for at least 8 weeks after the completion of the study. Phlebotomy can result in anemia, although the amount of blood taken for these studies should not result in clinically-significant anemia. You will be excluded from participating in the study if your hemoglobin is less than 10 gms/dL. All subjects having donated blood within 30 days of the study will be asked to postpone study participation (with a repeat blood count prior to future enrollment), and you will be advised to refrain from blood donation for 30 days after study completion.

Questionnaires:
The questionnaires are generally benign in nature. The major inconvenience is the time taken to complete them and a possible breach of confidentiality.

How will I know about new risks or important information about the study?
We will tell you if we learn any new information that could change your mind about taking part in this study.

How can the study possibly benefit me?
You might benefit from the continuous glucose monitor free supplies and increased frequency of medical attention to lower your blood glucose into target ranges in addition you will benefit from the nutrition counseling.

How can the study possibly benefit other people?
The benefits to science and other people may include a better understanding of *type* 2 Diabetes which will potentially lead to general advancement of scientific knowledge.

Are there any costs to participation?
If you take part in this study, you will not have to pay for any services, supplies, study procedures, or care that are provided for this research only (they are NOT part of your routine medical care). However, there may be additional costs to you. These can include costs of transportation and your time to come to the study visits.

Tests and procedures that are done for your regular care (whether you are in this study or not) are called “standard of care” and will be billed to you or your insurance company. You will be responsible for any co-payments required by your insurance.

Will I be paid for participation?

You will be paid for taking part in this study as follows.

$25 for the screening visit
$25 for wearing the CGM at week -1
$150 for Hyperglycemic clamp/MRS scans at week 0
$25 for wearing the CGM at week 11
$225 for Hyperglycemic clamp/MRS scans at week 12

We will use a Bank of America pre-paid debit card to provide the payment for taking part in the study. After your first payment milestone (the screening visit), you will receive a card in the mail, which you will need to activate over the phone. Once you activate this card, all other payments during the study will go directly onto your card. Please note that we will have to share your name, address, and telephone number with Bank of America for ePayments. You are responsible for paying state, federal, or other taxes for the payments you receive for being in this study. Taxes are not withheld from your payments.

Parking vouchers will be provided for all study related visits.

What are my choices if I decide not to take part in this study?

The alternative would be not to participate in the study.
Get treatment without being in a study.
Take part in another study.

How will you keep my data safe and private?

Any identifiable information that is obtained in connection with this study will remain confidential and will be disclosed only with your permission or as permitted by U.S. or State law. Examples of information that we are legally required to disclose include abuse of an elderly person, or certain reportable diseases.

It is important for you to know that if you do not already have a medical record at YNHH; one will be made for your visit. Some information related to the care given to you during this visit will become part of your Yale New Haven Hospital (YNHH) medical record. For example, any laboratory test results that are sent to the YNHH lab for testing will appear in your medical record and any printed copies of your record. In addition, you need to know that when any person is admitted to the YNHH, the individual's previous medical records of other visits or admissions to YNHH become available to physicians and hospital staff to ensure that the best possible care can be provided to the individual during the hospital stay. Similarly, the researchers and staff will have access to whatever information is already in your YNHH medical records such as past surgeries or medical conditions, emergency room visits, or possibly clinic visits. If such access to your past medical history by researchers and staff responsible for the study is unacceptable to you, then you should not participate in the research study.

When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity unless your specific consent for this activity is obtained.

We understand that information about you obtained in connection with your health is personal, and we are committed to protecting the privacy of that information. If you decide to be in this study, the researcher will get information that identifies you and your personal health information. This may include information that might directly identify you, such as your name, date of birth, address and phone number. This information will be de-identified at the earliest reasonable time after we receive it, meaning we will replace your identifying information with a code that does not directly identify you. The principal investigator will keep a link that identifies you to your coded information, and this link will be kept secure and available only to the PI or selected members of the research team. Any information that can identify you will remain confidential.

All identifiable information that is obtained in connection with this study is stored in password protected secure computer data files and will remain confidential and will be disclosed only with your permission or as required by U.S. or State law. All the information obtained in this study is kept in locked files and will be kept confidential. When the study is completed subject information is stored at least for 7 years in locked cabinets within a locked storage unit that only the investigators of the study have access to. When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity unless your specific consent for this activity is obtained. The research team will only give this coded information to others to carry out this research study. The link to your personal information will be kept for 7 years, after which time the link will be destroyed and the data will become anonymous.

All health care providers subject to HIPAA (Health Insurance Portability and Accountability Act) are required to protect the privacy of your information. The research staff at the Yale School of Medicine and Yale-New Haven Hospital are required to comply with HIPAA and to ensure the confidentiality of your information. Some of the individuals or agencies listed below may not be subject to HIPAA and therefore may not be required to provide the same type of confidentiality protection. They could use or disclose your information in ways not mentioned in this form. However, to better protect your health information, agreements are in place with these individuals and/or companies that require that they keep your information confidential.

Authorized representatives of the National Institutes of Health and the FDA may need to review records of individual subjects. People from the FDA or other Health and Human Services agencies may see your name, but they are bound by rules of confidentiality not to reveal your identity to others.

You have the right to review and copy your health information in your research record in accordance with institutional medical records policies. This authorization to use and disclose your health information collected during your participation in this study will never expire.

Your biospecimens will not be used and/or shared for commercial use. All identifiable information that is obtained in connection to this study may be removed from any biospecimens obtained during the study and after removal biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative,

legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by NIH/NIDDK which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

What Information Will You Collect About Me in this Study?

The information we are asking to use and share is called "Protected Health Information." It is protected by a federal law called the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA). In general, we cannot use or share your health information for research without your permission. If you want, we can give you more information about the Privacy Rule. Also, if you have any questions about the Privacy Rule and your rights, you can speak to Yale Privacy Officer at 203-432-5919.

The specific information about you and your health that we will collect, use, and share includes:

- Research study records
- Medical and laboratory records of only those services provided in connection with this Study.
- Records about phone calls made as part of this research
- Records about your study visits
- Information obtained during this research regarding
    - Physical exams
    - Laboratory, x-ray, and other test results
    - Diaries and questionnaires

How will you use and share my information?

We will use your information to conduct the study described in this consent form.
Information about your study participation will be entered into your Electronic Medical Record (EMR) in Oncore and EPIC. Once placed in the EMR, these results are accessible to all of your providers who participate in the EMR system. Information within your EMR may also be shared with others who are appropriate to have access to your EMR (e.g., health insurance company, disability provider.)

We may share your information with:

- Representatives from Yale University, the Yale Human Research Protection Program and the Yale Human Investigation Committee (the committee that reviews, approves, and monitors research on human subjects), who are responsible for ensuring research compliance. These

individuals are required to keep all information confidential.

- Food and Drug Administration (FDA).
- Those individuals at Yale who are responsible for the financial oversight of research including billings and payments
- The Principal Investigator: Dr. Elizabeth Sanchez Rangel
- The study sponsor: NIH/NIDDK
- Health care providers who provide services to you in connection with this study.
- Laboratories and other individuals and organizations that analyze your health information in connection with this study, according to the study plan.
- Co-Investigators and other investigators
- Study Coordinator and Members of the Research Team
- Data and Safety Monitoring Boards and others authorized to monitor the conduct of the Study

By signing this form, you authorize the use and/or disclosure of the information described above for this research study. The purpose for the uses and disclosures you are authorizing is to ensure that the information relating to this research is available to all parties who may need it for research purposes.

We will do our best to make sure your information stays private. But, if we share information with people who do not have to follow the Privacy Rule, your information will no longer be protected by the Privacy Rule. Let us know if you have questions about this. However, to better protect your health information, agreements are in place with these individuals and/or companies that require that they keep your information confidential.

Why must I sign this document?

By signing this form, you will allow researchers to use and disclose your information described above for this research study. This is to ensure that the information related to this research is available to all parties who may need it for research purposes. You always have the right to review and copy your health information in your medical record.

What if I change my mind?

The authorization to use and disclose your health information collected during your participation in this study will never expire. However, you may withdraw or take away your permission at any time. You may withdraw your permission by telling the study staff or by writing to

Elizabeth Sanchez Rangel, M.D.
Yale University School of Medicine
300 Cedar street, TAC S147
PO Box 208020
New Haven, CT 06520

If you withdraw your permission, you will not be able to stay in this study but the care you get from your doctor outside this study will not change. No new health information identifying you will be gathered after the date you withdraw. Information that has already been collected may still be used and given to others until the end of the research study to insure the integrity of the study and/or study oversight.

Who will pay for treatment if I am injured or become ill due to participation in the study?

If you are injured while on study, seek treatment and contact the study doctors as soon as you are able.

Yale School of Medicine and Yale-New Haven Hospital do not provide funds for the treatment of research-related injury. If you are injured as a result of your participation in this study, treatment will be provided. You or your insurance carrier will be expected to pay the costs of this treatment. No additional financial compensation for injury or lost wages is available.

You do not give up any of your legal rights by signing this form.

What if I want to refuse or end participation before the study is over?

Taking part in this study is your choice. You can choose to take part, or you can choose not to take part in this study. You also can change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.

We would still treat you with standard therapy or, at your request, refer you to a clinic or doctor who can offer this treatment. Not participating or withdrawing later will not harm your relationship with your own doctors or with this institution.

To withdraw from the study, you can call a member of the research team at any time and tell them that you no longer want to take part.

The researchers may withdraw you from participating in the research if necessary. For example, you may be asked to withdrawal from the study if you are found to have a metal object in your body, or have a metal object placed in your body while you are enrolled in the study, if you experience significant discomfort during the procedures, are not able to follow instructions during the procedures, or are not compliant with scheduled appointments. The researchers may also withdraw you from the study if you are not able to tolerate the study drug and it is making you feel sick.

Who should I contact if I have questions?

Please feel free to ask about anything you don't understand.

If you have questions later or if you have a research-related problem, you can call the Principal Investigator at Dr. Elizabeth Sanchez Rangel at 203-737-4777 or diabetes.research@yale.edu.

If you have questions about your rights as a research participant, or you have complaints about this research, you call the Yale Institutional Review Boards at (203) 785-4688 or email hrpp@yale.edu.

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

Contact for Future Studies

We ask for your permission to contact you for participation in future studies that our group may conduct. We may use your telephone number, your email address or your physical address to contact you.

I agree to be contacted regarding future studies I may qualify for: (initial your choice)

_____YES _____No

Questions

We have used some technical terms in this form. Please feel free to ask about anything you don't understand and to consider this research and the consent form carefully – as long as you feel is necessary – before you make a decision

Authorization and Permission

Your signature below indicates that you have read this consent document and that you agree to be in this study.

We will give you a copy of this form.

Participant Printed Name	Participant Signature	Date

Person Obtaining Consent Printed Name	Person Obtaining Consent Signature	Date