CONSENT TO BE PART OF A RESEARCH STUDY

PART 1 OF 2: GENERAL INFORMATION

INFORMATION ABOUT THIS DOCUMENT:

You are being invited to take part in a research study conducted at several different locations (multi-site research). The University of Michigan is providing IRB oversight for all sites in this study. This consent form includes two parts. Part 1 (General Information) includes information that applies to all study sites. Part 2 (Site Information) includes information specific to the study site where you are asked to enroll. Both parts of consent form must be provided to you.

Study title:	Comparing Two Dietary Approaches for Type 2 Diabetes: The LEGEND (Lifestyle Education about Nutrition for Diabetes) Study
Company or agency sponsoring the study:	This research is sponsored by an R01 from the National Institutes of Health (NIH).

1. KEY INFORMATION ABOUT THIS STUDY

You may be eligible to take part in a research study. This form contains important information that will help you decide whether to join the study. Take the time to carefully review this information. You should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others such as your family, friends, or other doctors about joining this study. If you decide to join the study, you will be asked to sign this form before you can start study-related activities. Before you do, be sure you understand what the research study is about.

A research study is different from the regular medical care you receive from your doctor. Research studies hope to make discoveries and learn new information about diseases and how to treat them. You should consider the reasons why you might want to join a research study or why it is not the best decision for you at this time.

Research studies do not always offer the possibility of treating your disease or condition. Research studies also have different kinds of risks and risk levels, depending on the type of the study. You may also need to think about other requirements for being in the study. For example, some studies require you to travel to scheduled visits at the study site or elsewhere. This may require you to arrange travel, change work schedules, find childcare, or make other plans. In your decision to participate in this study, consider all these matters carefully.

This research is studying whether changing an individual's behaviors may have an impact as a treatment or outcome for type 2 diabetes. This research will compare two promising dietary approaches for improving glucose control and other diabetes-related outcomes: a plate-method approach or a very low-carbohydrate approach. Your health-related information, including questionnaire responses, blood samples, and body scan results, will be collected for this research study.

This study involves a process called randomization. This means that the dietary approach you'll follow in the study is not chosen by you or the researcher. The study design divides study participants into two groups, based on chance (like the flip of a coin), to compare different treatments or procedures. If you decide to be in the study, you need to be comfortable not knowing which study group you will be in.

There can be risks associated with joining any research study. The type of risk may impact whether you decide to join the study. For this study, some of these risks may include side effects that are usually short-lived as you adjust to the diet such as leg cramps, headaches, or bad breath; inconvenience due to at-home tasks and travel for appointments; or loss of privacy. More detailed information will be provided later in this document.

This study may offer some benefit to you now or others in the future by improving your health outcomes and/or providing information that will affect how physicians treat type 2 diabetes in the future. More information will be provided later in this document.

We expect the amount of time you will participate in the study will be about 14 months – approximately 1 month to determine if you're eligible, 12 months as part of the study, and one month for your follow up appointments.

You can decide not to be in this study. Alternatives to joining this study include continuing care for your type 2 diabetes as usual.

Even if you decide to join the study now, you are free to leave at any time if you change your mind.

More information about this study continues below.

2. PURPOSE OF THIS STUDY

2.1 Study purpose:

Type 2 diabetes is one of the largest and most prevalent contemporary public health problems in the U.S. If the current trajectory of prevalence continues, 1 in 3 U.S. adults will have diabetes by 2050. Nutrition and lifestyle interventions are central to management of type 2 diabetes, but dietary recommendations remain mixed; both a plate-method method, which teaches you how to organize your plate by type of food, and a very low-carbohydrate diet, which involves avoiding sugars and starches and adding healthy fats, seem promising for people with type 2 diabetes. This study will compare the two approaches by assigning participants to one of the diets and supporting you as you make diet and lifestyle changes over the course of 12 months.

3. WHO MAY PARTICIPATE IN THE STUDY

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

3.1 Who can take part in this study?

You have already completed initial screening surveys and screening lab tests and you are so far eligible to participate in the LEGEND Study. These screening steps helped us determine that you have type 2 diabetes, are willing and able to participate in an online, group intervention, and that you don't have other conditions that would make you ineligible.

3.2 How many people are expected to take part in this study?

This is a multi-site research study, meaning we're looking for participants in both California and Michigan. We expect 180 participants to join this study overall.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

Enrollment

You have already completed several tasks to determine your eligibility for this trial. Next, you'll review and sign this consent form with a study staff member over a video call (you'll sign the form online during the call). Also during our video visit with you, we'll:

- Answer any questions you have about the trial.
- Schedule an upcoming in-person appointment with you for a body scan.
- Ask for more information, such as your physician's name and location.
- Ask you to sign a release form that allows us to communicate with your primary care doctor about medication adjustments and severe medical issues.

After you sign this consent form and complete the video visit, you'll complete the following steps:

- An in-person appointment for a body composition scan (called a dual-energy x-ray absorptiometry or DEXA). If you are taking or have recently been taking certain medications, you may not be able to have the Dexa scan. The study team will discuss this with you at the consent visit.
    - The technician at this appointment will take your weight and height.
    - You'll be directed to remove any metal from your person, including buttons on jeans and jewelry. You'll be able to wear a robe, if needed.
    - The DEXA will measure your bone density (thickness), and the amount of fat and lean (non-fat) tissue in your body. For this scan, you will be asked to lie flat on your back on a table as the scanning machine moves slowly over your body. The DEXA scan is like an X-ray, and generally takes about 30 minutes.
    - More information will be provided via email in advance of your appointment.
    - If you are a woman of child-bearing potential, you may be asked to take a pregnancy test prior to your DEXA appointment.
    - You may be required to wear a mask and answer covid-19 screening questions at this appointment and any of your in-person visits.
    - *See Part 2 (Site Information) for site specific DEXA information.*
- One dietary recall over the phone. A member from our team will reach out to you twice over the phone to ask you about what you ate the day before. You won't need to prepare for these calls, and we won't be able to tell you exactly when they'll happen, but we will ask you to provide us with information about your general availability for these calls. The call will take about 20-30 minutes.
- A longer, online survey about your habits, health, and well-being.
- Another fasting blood draw. A reminder that fasting means you shouldn't eat or drink anything except for water for 12 hours before your blood draw. You can take your medications as normal.
    - Research staff will email you the results using secure emails.
    - These blood tests will measure your glucose control, lipids, and bone health.
    - *See Part 2 (Site Information) for site specific blood draw information.*

You may have a few weeks to complete the above enrollment steps. It is possible that you will need to complete these steps more quickly. The study staff will go over the schedule and timeline to enroll with you.

While you're completing the above steps, the study staff will inform your primary care provider about participation in this study. Your doctor may request that the study team informs them directly about any recommendations for medication adjustments, but we will ask you to keep your doctor informed about your medication adjustments. Additionally, you'll be asked to inform the study staff of any side effects or symptoms you experience throughout the study, but you should let your doctor know about any serious or long-lasting side effects or medical events that occur. Your personal doctor will be able to contact the study physicians about any medication changes they make or other medical information about you that might be important to your safety. You will sign forms authorizing the study team and your personal doctor to communicate about your medical care.

Randomization

After you complete all enrollment steps, you'll be randomized to one of two groups. You'll either be assigned to follow a plate-method or very low-carbohydrate diet. Neither you nor the research team will have any say about what group you'll be assigned to, so to join this trial, you must be okay with participating in either group. Here's a bit more information:

Plate method. Following a plate-method approach means that you'll be eating different categories of foods based on the proportions on your plate, balancing proteins, vegetables, fruits, starches, and fats.

Very low carbohydrate. Also called a ketogenic or "keto" diet, means you'll be eating foods like non-starchy vegetables, leafy greens, cheese, meats, berries, nuts, and seeds and avoiding starchy foods like pasta, bread, rice, beans, many fruits, etc. Cutting out carbohydrates in your diet can bring you into "ketosis," which means your body will start burning fat for energy instead of carbohydrates.

If you have any concerns about participating in the study, you should speak with a member of the study team before agreeing to be randomized. Once you are randomized, you cannot be replaced in the study. You should only complete the randomization step if you are willing and able to: a) follow either study diet, b) attend nearly all of the study classes, and c) complete the study assessments through 12 months.

Medication Management

If you take glucose-lowering medications that may increase your risk of hypoglycemia, you will meet with study physicians after you're randomized but before you begin attending classes. You'll be instructed about monitoring and managing your glucose at home. Study physicians may recommend changes to your diabetes medication either at the start of the trial or throughout, depending on your glucose levels. If you are taking certain glucose-lowering medications at the start of the trial, like an SGLT2 inhibitor, you may be asked to stop that medication. If you've been asked to stop an SGLT2 inhibitor (like canagliflozin, dapagliflozin, or empagliflozin), you will not be able to join the trial unless you agree to stop taking that medication. Additionally, if you seem to be experiencing symptoms of low blood pressure, you may be asked to modify your blood pressure medications. You'll be asked to keep your primary care doctor informed of any changes made to your medications during the study.

Study Procedures

In the LEGEND study, you'll be randomly assigned to one of two dietary approaches, either the plate-method or a very low carbohydrate approach. No matter which you're assigned to follow for 12 months, you'll have a diet teacher who will support you along the way and give you tools and tips during live, video-based group classes. You'll have a core phase and a maintenance phase of this study; the core phase will last for about 4 months and will involve weekly or every other week classes, home assignments, and brief (5-minute) weekly check-in surveys. The maintenance phase will last for the remaining time, with classes and check-in surveys approximately once a month.

Core phase: For the first about four months of the LEGEND study, you'll transition to and follow your assigned diet. You'll participate in group classes over Zoom. We'll send you reminders about your class with the link to join the video call. Additionally, you'll receive surveys for you to tell us how you are doing with the diet and any problems you are having with it.

Classes: Classes will be led by a diet teacher, who will share a presentation each week, teach you about incorporating your new way of eating into your life, help you troubleshoot any issues and address any concerns. You will attend classes only for the diet to which you've been randomly assigned and other participants, following the same dietary approach, will be in the class with you. You are encouraged to participate actively in each class and to ask any questions you have during class time. You'll be encouraged to use your camera. Each class will be recorded so the study team can assess teacher performance; your name and other identifiers will be removed from any class recordings and only approved study team members will hear the recordings.

Home assignments: You may receive "homework" to complete between classes. These assignments will not be required or particularly time consuming but are designed to help you transition or maintain your new diet; for example, you may be asked to track what you eat for a few days to self-check your progress. You'll be sent an about weekly check-in survey for the first 4 months; we'll ask you about how the prior week has gone for you, if you've had any changes to your medications, if you've experienced any health symptoms or concerns, and whether you plan to attend the upcoming class session.

Glucose monitoring: If you are taking glucose-lowering medications other than metformin, you will be asked to check your blood glucose regularly with your own glucometer; the study doctors will go over the schedule with you. Keep track of these readings; you'll be asked about any highs or lows during your weekly check-in surveys. You should always self-manage any low blood glucose readings or symptoms. You will be asked to inform study team if you have hypoglycemia or low blood glucose readings. You may be contacted by study staff or a study physician if it appears medication changes are necessary, and you will be asked to keep your primary care physician in the loop about your blood glucose and medications. You can always reach out to study staff via email or phone (see section 10 in *Part* 2 and emails from the study) if you have any questions or concerns.

Possible mailed items: If you do not have a scale at home that you can use regularly, you will receive one in the mail paid for by the study. This is for tracking any weight changes throughout the study and submitting your weight to us at baseline, 4 months, and 12 months. If you are randomly assigned to the very low-carbohydrate group, you'll receive ketostix in the mail, which are urine dipsticks that will help you transition to this new dietary approach. If you do not have a printer at home, you'll be mailed a lab slip for your LabCorp blood draws.

4-month assessments: After 4 months of classes, you'll complete your 4-month assessments, most of which you also completed at the beginning of the trial. A study team member will contact you prior to your assessment window to remind you of study tasks. These include: your weight on your home scale; a longer (30-45 minute) online survey about your health, well-being, and experience in the program thus far; one 24-hour dietary recall over the phone; and a fasting blood draw. You'll receive a $40 via Amazon or Visa gift card when all 4-month measurements are completed.

Maintenance phase: The remaining time, you will continue following your assigned diet and you'll have classes approximately once a month. You'll be sent reminders a few days prior to each class with link to the Zoom session and a brief (5-minute) check-in survey. You will no longer complete weekly surveys, but you may still reach out to the study team if you have questions or concerns that you can't or don't want to bring up in the next class session.

12-Month Assessments: After 12 months total of classes, you'll complete your final study measures. A few weeks prior to the end of the program, the study team will remind you about the study measures and schedule your in-person appointment for body scan. You'll complete one 24-hour dietary recall over the phone; a longer online survey about your health, well-being, and experience in the program; a fasting blood draw; and an in-person appointment for a body composition scan (DEXA) and weight measurement. You'll receive $45 via Amazon or Visa gift card for completing all study measures and an additional $50 via Amazon or Visa gift card for completing the DEXA body scan.

Optional Interview: At month 4 or month 12, you may be given the option to participate in an interview about your experience in the program and with your assigned diet. It is possible you will not be contacted to participate in an interview at either time point. The interview is optional, and you can still participate in the study if you do not want to be interviewed. Interviews will take place over Zoom and will be recorded.

Study materials: You will receive some study materials directly from Amazon, including gift cards and, if necessary, a scale. This means we will provide Amazon with your address to mail you these items.

How will your blood samples be stored and used?

Blood tests will be performed by LabCorp, who will destroy any leftover blood samples after they've been analyzed. Approximately 1.5-2 tbsp. of blood will be drawn at each blood draw appointment.

Will I receive my test results?

You will receive copies of your blood test results throughout the study. You may be able to receive your body scan test results at the end of the study. You may share these results with your primary care doctor if you wish.

What are my responsibilities?

As a participant in this research study, you have certain responsibilities, such as ensuring that you arrive at all your scheduled appointments or video visits, follow the study diet guidelines, and report any side effects you may experience to the study team during the study.

4.2 How much of my time will be needed to take part in this study?

Your participation in this study will take about 14 months; one month before the study for your enrollment activities, twelve months participating in the program, and then one month after the study for your final measurements. You will have one virtual and one in-person visit at the start and one in-person visit at the end of the study, each visit lasting about an hour. At baseline, 4, and 12 months, you will complete an online survey that will take approximately 30-45 minutes. At baseline and month 12, you will complete two 24-hour diet recalls over the phone, lasting 30 min each. During the 12-month program, you'll have classes weekly and then monthly, each class lasting an hour. You'll have weekly surveys for the first 4 months of the study and monthly surveys for the remaining 9 months, which should each take you less than 5 minutes to complete.

4.3 When will my participation in the study be over?

The study period is about 14 months. Your participation in the study will end at this time. We would like to keep your contact information for up to five years in case you may be eligible or interested in future research studies. You can opt out of this in Section 12.

4.4 What will happen with my information and/or biospecimens used in this study?

Your collected information may be shared with the National Institutes of Health (NIH), who sponsors this study.

With appropriate permissions, your collected information may also be shared with other researchers, here, around the world, and with companies.

Your identifiable private information may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent.

See Part 2 (Site Information) for details about any special procedures at your site.

5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

1. *Blood draw:* Your blood draw includes a possibility of bleeding, bruising, and dizziness. It is common for the site of the test to bleed after the blood sample has been taken; however, this should stop quickly after a cotton wool pad or gauze patch has been placed on the wound. Mild bruising around the area where the needle went into the vein and/or slight dizziness during or after a blood test is common. If you are feeling faint before or during a blood test, tell the person taking your blood so that they can help you.
2. *Dual energy X-Ray absorptiometry (DEXA):* The DEXA scan involves radiation exposure, which is less than a person would receive from a standard X-ray or a dental X-ray. If you feel uncomfortable during the scan, talk to the technician, who will try to make sure you're comfortable throughout the process.
3. *Questionnaires:* Some of the questions may make you uncomfortable or upset, but you are free to discontinue your participation at any time.
4. *Diet:* As you change your diet you may experience some side effects, particularly in the very low-carbohydrate group, such as constipation, headache, bad breath, and muscle cramps. These symptoms usually go away after the first couple of weeks. If this happens, you can talk to the study staff. The study staff will provide resources for eating a plate-method or very low-carbohydrate diet and aid in management of any side effects, though you can and should consult your doctor if any side effects are concerning to you or become severe.

5. *Dietary changes:* You could find it difficult to change your diet. Also, your friends or family may not support the changes you are making to your diet or lifestyle. If this happens, you can speak to study staff about this.
6. *Hypoglycemia (very low blood sugar):* Carefully following the diet and lifestyle recommendations in this program may improve your glucose levels. If you are on certain diabetes medications, the study doctors may recommend that you reduce your medications as you adopt the study diet to reduce the risk of hypoglycemia. However, there is still some risk that your glucose will drop too low. If your blood glucose is too low, you may have trouble thinking, get sweaty, feel anxious, or have other symptoms. If serious low glucose develops, you should self-treat right away by consuming sugar, like fruit juice or glucose tablets, and rechecking your glucose every 15 minutes. You will be provided resources regarding self-treatment.
7. *Low blood pressure*: Following the diet and lifestyle recommendations in this trial may improve your blood pressure. If you are taking blood pressure medications, it's possible you might experience low blood pressure with symptoms like dizziness, lightheadedness, nausea, dehydration, or blurred vision. Stay hydrated and eat regularly to help manage signs of low blood pressure. You will be provided resources regarding self-treatment. Additionally, you may be asked to lower your blood pressure medications or to speak with your physician for modification.
8. *Home assignments:* You may find it inconvenient to complete the home assignments, including the regular, group-based video classes or the online questionnaires. Also, you could experience distressing emotions during some of the home assignments or sessions. If this happens, you can stop and speak to the study staff.
9. *Recording:* The group Zoom sessions will be recorded. If you are given the option and you choose to participate in an interview about your study experience at month 4 or month 12, your interview will also be held over Zoom and recorded. All recordings will be saved on encrypted, University computers and University-managed cloud storage. We will avoid using any personal information in the group sessions or interviews and, if names are used, they will not be included in any transcripts. Recording and transcription comes with the possibility of loss of privacy, though this is rare.

Additionally, there may be a risk of loss to confidentiality or privacy. See Section 9 of this document for more information on how the study team will protect your confidentiality and privacy.

As with any research study, there may be additional risks that are unknown or unexpected.

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?

The researchers have taken steps to minimize the risks of this study. Even so, you may still have problems or side effects, even when the researchers are careful to avoid them. Please tell the researchers listed in Section 10 about any injuries, side effects, or other problems that you have during this study. You should also tell your regular doctors. The study physicians may reach out to your primary care doctor directly if they become aware of any serious medical issues or make any medication adjustments throughout the trial (your doctor will have the chance to request direct communication from the study team). You will sign a form authorizing this communication. You will be encouraged to tell your doctor about medication adjustments that the study physicians recommend while you're in the study.

We'll ask you to complete a survey for the first about 4 months of the program, as you transition to your new way of eating. This survey will include a space for you to let us know about any health concerns or symptoms you're experiencing. You'll also be able to inform your diet teacher during class sessions or you can contact the study team for suggestions or support. If you're on glucose-lowering medications that increase the risk of hypoglycemia, you'll be asked to check your blood glucose regularly; the study doctors will go over the schedule with you. You'll report your blood glucose readings to us in your weekly check-in surveys.

5.3 If I take part in this study, can I also participate in other studies?

Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study.

5.4 How could I benefit if I take part in this study? How could others benefit?

You may not receive any personal benefits from being in this study. However, others may benefit from the knowledge gained from this study. However, some subjects may experience improved glucose control and weight loss as a result of this trial.

5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?

Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

6. ALTERNATIVES TO PARTICIPATING IN THE STUDY

6.1 If I decide not to take part in this study, what other options do I have?

There may be other ways of treating your condition. These include talking to your primary care physician about your type 2 diabetes or continuing you care as normal. Although this diet and lifestyle program is available as part of this clinical study, you should check with the researcher and/or your primary care physician to discuss your options including how to obtain any alternative treatments and whether they must be obtained through a physician or require medical supervision.

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?

You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please tell one of the study team persons listed in the Part 2 *Site Information* section. Data collected from you up to that point will remain in the study database and will be used in planned analyses, but if you request, your name and other personal identifiers can be deleted. We aim to get 12-month follow-up data on everyone who enrolls so that we can evaluate how the study diets work for all participants, including participants who are unwilling or unable to follow the diet for the full 12 months. If you decide to stop coming to the study classes, you may be invited to complete follow-up assessments, but you are not required to do so. If you have concerns about participation at any time, please discuss these with the study team so that they have a chance to address your concerns.

7.2 Could there be any harm to me if I decide to leave the study before it is finished?

No harm will come to you if you decide to leave the study before it is finished. We may ask you why you've decided to stop your participation to better understand how we could improve the program for future participants.

7.3 Could the researchers take me out of the study even if I want to continue to participate?

Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- You do not follow instructions from the researchers.
- The study is suspended or canceled.

8. FINANCIAL INFORMATION

8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?

The study will pay for research-related items or services that are provided only because you are in the study. You will not be billed for any study related activities. The study will pay for your group classes, study blood draws, DEXA body scan, any visits you have with study doctors, and anything we send you in the mail (like a body weight scale). For a complete list of all study activities, see Section 4.1 above or ask the researchers for a list. You should not receive a bill for anything you receive as a participant in this study; if you get a bill you think is wrong, call the researcher's telephone number listed in Part 2 *Site Information* section.

You or your health plan will pay for all the things you would have paid for even if you were not in the study, like:

- Health care given during the study as part of your regular care.
- Monitoring by your own doctor for side effects or other problems.
- Deductibles or co-pays for visits or services provided by your own healthcare team.

If you do not have a health plan, or if you think your health plan may not cover these costs during the study, please talk to the researchers listed in Part 2 *Site Information* or call your health plan's medical reviewer.

See Part 2 *Site Information* for additional information on this topic.

By signing this form, you do not give up your right to seek payment if you are harmed because of being in this study.

8.2 Will I be paid or given anything for taking part in this study?

You will receive a $35 electronic gift card to Amazon via email or a physical Visa gift card at the start of the study for completing your DEXA (body scan) appointment. You'll also receive $40 Amazon gift card or a physical Visa gift card for completing all 4-month measurements, a $45 Amazon gift card or a physical Visa gift card for completing all 12-month measurements, and an additional $50 Amazon gift card or a physical Visa gift card for completing your 12-month DEXA appointment. If you complete all these assessments, you could get a total of $170 in electronic Amazon gift cards or Visa gift cards during the 1-year study.

8.3 Who could profit or financially benefit from the study results?

Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

Part 2 *Site Information* may have additional information on this topic.

9. CONFIDENTIALITY OF SUBJECT RECORDS

The information below describes how the confidentiality of your research records will be protected in this study, and any sub-studies described in this document. See Part 2 *Site Information* for information pertaining to Protected Health Information (PHI) and the Health Insurance Portability and Accountability Act (HIPAA).

9.1 How will the researchers protect my information?

Your research information will be stored on encrypted servers and computers accessible only by study staff. You will receive a participant ID that will be used in place of your name on study related communications. All information is protected and confidential. If we send any sensitive information to you or to your primary care physician, we will use a secure form of communication.

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 the National Institutes of Health 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.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.

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.

9.2 What individually identifiable information about me could be seen by the researchers or by other people? Why? Who might see it?

Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required for you to take part in the study.

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- University, Food and Drug Administration (FDA) and/or other government officials, auditors, and/or the IRB may need the information to make sure that the study is done in a safe and proper manner.
- Study sponsors or funders, or safety monitors or committees, may need the information to:
    - Make sure the study is done safely and properly
    - Learn more about side effects
    - Analyze the results of the study
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

The results of this study could be published in an article, but it would not include any information that would let others know who you are.

The University of Michigan and the University of California, San Francisco are partnering to conduct this trial. Both institutions will see your study information, including the results of your blood tests and survey responses. Members of the study team at either institution may reach out to you for study-related procedures (like your consent visit).

END OF PART 1 *GENERAL INFORMATION*

SEE PART 2 *SITE INFORMATION* FOR ADDITIONAL INFORMATION ABOUT THE SITE WHERE YOU ARE ENROLLING

CONSENT TO BE PART OF A RESEARCH STUDY

Part 2 of 2: SITE INFORMATION

University of California, San Francisco

INFORMATION ABOUT THIS DOCUMENT:

This part of the consent form includes additional information about being a research participant at your enrolling site. Before making your decision to join the study, review both the General study information and this Site information.

Study title: Comparing Two Dietary Approaches for Type 2 Diabetes: The LEGEND (Lifestyle Education about Nutrition for Diabetes) Study

Site Name: University of California, San Francisco

SITE-SPECIFIC PROCEDURES

4. Information about Study Participation

4.1 What will happen to me in this study?

Enrollment

Rick Hecht, MD and his associates at the UCSF Osher Center for Integrative Medicine and Laura Saslow, PhD at the University of Michigan, are conducting a research study.

The majority of the enrollment procedures are described in *Part 1 (General Information).*

DEXA: You will attend an in-person appointment for a body composition scan (called a dual-energy x-ray absorptiometry or DEXA). This appointment will occur at the UCSF China Basin campus at 185 Berry Street, Lobby 6, Suite 350 (next to Giant Stadium between 3rd and 4th street) in San Francisco. Appointments will be available during business hours on weekdays. Study staff will make this appointment for you, usually during your consent video visit.

Radiation risks: This research study involves exposure to radiation. Not all this radiation exposure is necessary for your medical care and is for research purposes only. The additional amount of radiation that you will receive in any 12 month period as a result of participating in this study will be less than annual background radiation received by persons in the U.S. from the environment. There is no evidence that this amount of radiation changes health risk. If you are pregnant or breast feeding, you SHOULD NOT participate in this study. If you have any questions regarding the use of radiation or the risks involved, please consult the physician conducting the study.

Pregnancy Test: If you are of child-bearing potential, you may be asked to take a urine pregnancy test at your DEXA appointment. . If you are pregnant, you will be ineligible to participate in the study and you will not go to your DEXA appointment.

Blood Draw: You will also attend a fasting blood draw. This blood draw will occur at the LabCorp location of your choice. You can walk in or make an appointment in advance. You will receive a lab slip via email (or by mail if you do not have printer access). This lab slip will include the study, your participant ID, and your date of birth. As mentioned in *Part 1*, **you must fast for 12 hours prior to your blood draw.**

Study Procedures

Your 4-month and 12-month blood draws will also require you to fast for 12 hours. You can walk in or make an appointment at a LabCorp location of your choice, bringing a lab slip from the study, just like at the beginning of the study.

Your 12-month DEXA scan will occur in the same location as your scan at the beginning of the study.

How will your blood samples be stored and used?

Your blood will be analyzed by LabCorp immediately following your blood draw. Any blood left over after analysis will be destroyed by the lab.

8(A) FINANCIAL INFORMATION (CONTINUED)

8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?

The sponsor has agreed to pay for all items associated with this research study; you or your insurer will not be billed.

Treatment and Compensation for Injury: If you are injured as a result of being in this study, the University of California will provide necessary medical treatment. The costs of the treatment may be billed to you or your insurer just like any other medical costs, or covered by the University of California or the study sponsor [sponsor name], depending on a number of factors. The University and the study sponsor do not normally provide any other form of compensation for injury. For further information about this, you may call the office of the Institutional Review Board at 415- 476-1814.

It is important that you tell the study doctor, Rick Hecht MD, if you feel that you have been injured because of taking part in this study. You can tell your doctor by calling him at 415.353.9723.

See the *Part 1* (*General Information)* section 8.1 for additional information on this topic.

8.2 Will I be paid or given anything for taking part in this study?

See the *Part 1 (General Information)* section 8.2 for information on this topic.

8.3 Who could profit or financially benefit from the study results?

See the Part 1 *General Information* section 8.3 for information on this topic.

9(A) CONFIDENTIALITY OF SUBJECT RECORDS AND AUTHORIZATION TO RELEASE YOUR PROTECTED HEALTH INFORMATION (CONTINUED)

9.1 How will the researchers protect my information?

See the Part 1 *General Information* section 9.1 for information on this topic.

We will do our best to make sure that the personal information gathered for this study is kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Authorized representatives from the following organizations may review your research data for the purpose of monitoring or managing the conduct of this study:

- Representatives of the National Institutes of Health
- Representatives of the University of California

The researchers will ask you and the other people in the group to use only first names during the group sessions. They will also ask you not to tell anyone outside the group what any particular person said in the group. However, the researchers cannot guarantee that everyone will keep the discussions private.

During the study, the research team will communicate with you by text message at times. Messages are encrypted and your information is secured, but there may not be end-to-end, 100% security or encryption at every point. We will therefore not use SMS to send you sensitive information, and will ask you not to send us sensitive information via SMS either. We will use secure email to send you any sensitive information (e.g. your lab results).

9.2 What protected health information (PHI) about me could be seen by the researchers or by other people? Why? Who might see it?

See the Part 1 *General Information* section 9.2 for additional information on this topic.

You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you.

9.3 What happens to information about me after the study is over or if I cancel my permission to use my PHI?

As a rule, the researchers will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission or the study is over.

Examples of reasons for this include:

- To avoid losing study results that have already included your information
- To provide limited information for research, education, or other activities. (This information would not include your name, social security number, or anything else that could let others know who you are.)
- To help University and government officials make sure that the study was conducted properly

9.4 When does my permission to use my PHI expire?

Your permission expires at the end of the study, unless you cancel it sooner. You may cancel your permission at any time by writing to the researchers listed in Section 10 "Contact Information" (below). If you withdraw your permission, you may no longer be eligible to participate in this study.

We would like your permission to keep your contact information and reach out to you for up to 5 years after you've completed the study in the event there are future or follow up research studies you may be eligible or interested in. You can opt out of this in Section 12.

10 CONTACT INFORMATION

Who can I contact about this study?

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Site Principal Investigator:	Rick Hecht, MD
Site Principal Investigator Contact:	Mailing Address: UCSF Osher Center for Integrative Health, UCSF Box 1726, San Francisco, CA, 94143 Telephone: 415-353-9723
Site Study Coordinator *(if applicable)*:	Patty Moran, Ph.D.

Site Study Coordinator Contact *(if applicable)*:	Study email: legendstudy@uscf.edu Telephone: 415-353-9723

You may also express a question or concern about a study by contacting the Institutional Review Board responsible for the review of the study:

University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 520, Room 3214
Ann Arbor, MI 48109-2800
Telephone: 734-763-4768
Fax: 734-763-1234
e-mail: irbmed@umich.edu

When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRBMED number (at the top of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.

11. RECORD OF INFORMATION PROVIDED

11.1 What documents will be given to me?

Your signature in the next section means that you have received copies of all of the following documents:

- This "Consent to be Part of a Research Study" document.
- "Experimental Subject's Bill of Rights"
- "UCSF Hipaa Authorization for Research "

12. SIGNATURES

You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to participate or to withdraw at any point in this study without penalty or loss of benefits to which you are otherwise entitled.
If you wish to participate in this study, you should sign below.

Sig-A

Consent to Participate in the Research Study

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with [NAME OF STUDY TEAM MEMBER OBTAINING CONSENT]

_____.

My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Sig-B

Consent to recording solely for purposes of this research

This study involves recording. If you do not agree to be recorded, you CANNOT take part in the study.

_____ Yes, I agree to be audio and video recorded.

_____ No, I do not agree to be audio and video recorded.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Sig-C

Consent to participate in an optional interview

You may be given the option to participate in an interview at month 3 or month 12 of this study, though it's possible you will not be asked for an interview. If you decide that you want the option to participate in an interview, you can change your mind later. Interviews are optional and you CAN still take part in the study if you decide you don't want to be interviewed.

_____ Yes, I would like the option to participate in an interview about the study.

_____ No, I do not want the option to participate in an interview about this study.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Sig-D

Consent to Contact for Future Research

This project involves the option to allow the study team to contact you for additional information or to invite you to future research for up to 5 years after your participation in this trial. I understand that it is my choice whether or not to allow future use of my contact information. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

_____ Yes, I agree to let the study team contact me for future information or research.

_____ No, I do not agree to let the study team contact me for future information or research.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Sig-G

Principal Investigator or Designee

I have provided this participant and/or his/her legally authorized representative(s) with information about this study that I believe to be accurate and complete. The participant and/or his/her legally authorized representative(s) indicated that he or she understands the nature of the study, including risks and benefits of participating.

Printed Legal Name: _____

Title: _____

Signature: _____

Date of Signature (mm/dd/yy): _____