UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Study Title: Delish Study: Diabetes Education to Lower Insulin, Sugars, and Hunger

This is a research study about helping people with Type 2 diabetes make and maintain diet and lifestyle changes that might help them better control their diabetes. The UCSF study researchers, Drs. Rick Hecht and Elissa Epel or their colleagues, will explain the study to you.

Research studies include only people who choose to take part. Please take your time to make your decision about participating, and discuss your decision with your family or friends if you wish. If you have any questions, you may ask the researchers.

You are being asked to take part in this study because you have type 2 diabetes.

Why is this study being done?

The purpose of this study is to learn whether mindfulness-based approaches might help people cope with food cravings and better follow a carbohydrate-restricted diet in order to manage their type 2 diabetes.

Who pays for this study?

This study is funded by a grant from the National Center for Complementary and Integrative Health at the National Institute of Health.

How many people will take part in this study?

About 120 people will take part in this phase of the study. About 60 people participated in an earlier phase of the study.

What will happen if I take part in this research study?

If you agree, the following procedures will occur:

Overview of study participation:
By the time you come for your first in-person visit and sign this consent form, you will have already completed a number of screening steps to determine if you might be eligible for the study. These may include: completing an online survey, watching a short online video about study participation; speaking to a study staff member by phone about your medical history as well as availability for study visits and classes, and completing 3 days of brief (1-3 min) text message surveys about your food cravings and eating. You will also have had a fasting blood draw to confirm that your hemoglobin A1c (HbA1c) and other common lab tests are in range to be eligible for the study. Once your survey and blood test results were back, study staff contacted you to tell you that you were eligible to continue enrollment steps for the study. Some people go through these screening steps and are not eligible for the study.

At your first in-person visit, after signing a consent form, you will answer some questions about your health history to confirm eligibility, then complete some baseline assessments as described in Section 1 below.

If the screening steps and initial visit confirm that you are eligible for the study and you wish to enroll, you will complete some online questionnaires from home, as well as have another blood draw at a LabCorp location convenient to you. You will then be randomized to participate in one of the two group programs for 12 weeks to learn a carbohydrate-restricted diet and develop skills to help you stick to this diet. You may also learn some mindfulness tools and use a smartphone app to help you cope with food cravings. After the first 12 weeks, you will enter the maintenance period. At the beginning of the maintenance period, you will be randomized again to one of three groups: (1) keep up skills and the diet on your own, (2) attend a monthly group, or (3) get the monthly group plus individual support.

You will have in-person follow-up visits, with blood draws, at approximately 3, 6, and 12 months after the start of class. You will also be asked to have a fasting blood draw at month 9 (without an in-person visit).

Throughout the study you will be asked to complete some study activities at home and during your day, including home blood glucose and ketone monitoring, and responding to text-messages regarding your experiences of cravings and emotional eating.

More detailed information about what will happen at study visits and what group participation will involve is described below.

Location: Study visits and group sessions will take place at the UCSF Osher Center for Integrative Medicine (1545 Divisadero St.). Blood draws will be done at a LabCorp lab near the Osher Center, or if it is more convenient for you, at another LabCorp lab in the Bay Area.

1. Consent/Screening Visit: This visit will take about 2 hours to complete. You will review the consent form with study staff, and, if you wish to participate, you will sign these forms. After you sign the consent form, you will do the following at this visit:

a. Have a brief medical history taken, including current medications, to confirm eligibility.
b. You will have your height and weight measurements taken with a gown on. You may have your weight measurement taken again on the first night of class, as it may have changed since your initial in-person visit. This will be done in private by a study research assistant.
c. You will sign a form that authorizes the study doctors and/or researchers and your personal physician to speak to one another about your participation in the study, and discuss possible changes to your diabetes medications.
d. You will do some tasks on the computer like a video game.

The total time to complete the consent/screening visit will be about 2 hours.

2. Baseline Assessments: After completing the in-person visit, if you are eligible for the study and still interested in enrolling, you will complete:

a. Online Questionnaires: Study staff will email you a link to the online questionnaires approximately 2-3 weeks before the class start date. They will take about 40-60 minutes to complete. These questionnaires will be about your demographics, food intake, personality, mood, stress, health behaviors, and physical and emotional well-being. You will need to complete these questionnaires in a timely manner (usually 3-4 days) to continue to be eligible for the study. If you don't have a computer or otherwise prefer to complete these questionnaires at UCSF, study staff will work with you to arrange a time to come to the UCSF Osher Center at the Mt. Zion campus to complete these questionnaires. Similarly, for any other questionnaires for the study, you may make an appointment at the Osher Center to fill out the questionnaires using a computer with access to the internet.

b. Blood draw: You will have a fasting blood draw of about 2 tablespoons at a LabCorp lab convenient to you. Study staff can help you identify possible convenient locations. Tests that will be done include fasting glucose, insulin, and lipids (cholesterol). Because some of the tests need to be done when you have not eaten, you will not be able to eat or drink anything (except water) after approximately midnight the night before the blood draw (or 8 hours before the blood draw).

c. Craving and eating text messages: You may again receive a text message a few times per day for three days asking you to complete some brief (1-3 min) questions about your food cravings and eating. This step may be repeated up to 6 times during the course of the study.

3. Randomization: After you complete these steps, you will be eligible to be randomized to one of two different diet and wellness programs. People in both groups will use a carbohydrate-restricted dietary approach and learn tools aimed at helping people change their diet to improve diabetes control, but one of the groups will also include an additional hour or so of instruction in mindfulness-based approaches (including the use of a mindful eating app) to cope with food cravings. You will have an equal chance (like a flip of a coin) of being assigned to the Education only group, as to the Education+Mindfulness group. Neither study staff nor you will make the choice. You will complete a short online questionnaire to confirm your continued interest and availability for the study classes and follow-up assessments; you may also complete some brief surveys about your recent mood and stress. At the end of the survey you will be told which class you have been assigned to.

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 this randomization step if you are willing and able to: a) follow a carbohydrate restricted diet, b) participate in either group (the Education only group or the Education+Mindfulness group including the use of the mindful eating app), c) can attend nearly all of the study classes, and d) can and will complete the study assessments through 12 months.

4. Study diet: All study participants will be asked to follow a lower-carbohydrate, higher fat diet with little sugar or starch (e.g. no bread, pasta, rice, or potatoes). Foods that are encouraged include green leafy and other non-starchy vegetables, nuts, seeds, olive oil, fish, poultry, tofu, and avocados. Other foods consistent with the diet include berries (in small amounts), meats, eggs, and cheese. In the classes we will discuss how to implement the diet in a healthy way and tools to help people stick to the diet. Because the diet may help reduce your blood glucose (sugar) levels, you may be advised by the study doctors to reduce diabetes medications.

5. Study Classes: The groups will meet weekly on weekday evenings for about 3 months. Depending on which group you are assigned, you will have 11-12 classes that will last 1.5-2.5 hours. Study staff will go over the exact dates and times of the classes with you. It is understandable that you may have a schedule conflict for one or two of the classes, but you should only participate if you can attend nearly all of the classes. You will be encouraged to stay on the carbohydrate restricted diet for the full 12 months of the study.

Education group: If you are assigned to the Education only group, your evening classes will last 60-75 minutes and will be taught by a nutritionist or other health professional who is experienced in helping people with diabetes follow a low-carb diet. The classes will focus on how to follow a carbohydrate restricted diet (described above). You will also learn skills to help you stick to the diet. You will be encouraged to do a moderate amount of exercise (like walking), but the class will not include instruction in exercise. There will be about 10-12 study participants in this class with you.

Education+Mindfulness group: If you are assigned to the Education+Mindfulness group, classes will last approximately 2.5 hours. Half of the class time, you will learn how to follow a carbohydrate restricted diet, the same as the Education only group (described above). The other half of the class time will be led by a mindfulness teacher and will focus on learning and using mindfulness to cope with food cravings and emotional or stress eating. You will be asked to use a mindful eating app at home, during the week, to learn and practice mindfulness skills for food-cravings and eating. Using the app, you will spend approximately 10 minutes 3 times per week viewing video content at home, as well as daily meditation of 10-20 minutes using guided meditation tracks from the app. There will be about 10-12 participants in this group with you.

Use of the mindful eating app: The research team will have access to your activity in the app, including your answers to questions and information about your cravings. This information is confidential, and will be used only to evaluate how the app is used and whether or not it is helpful. You will have the option to participate in a community discussion forum with other people who are using the app. Employees of Claritas Mindscience, the company that makes the app, review the forum and will remove content that is hostile or offensive. However, posts are not checked for accuracy or appropriateness to your situation. For example, someone could post their own opinions on mindfulness techniques or diet that are different from what you are learning in the study. The fact that they're on the forum does not mean that the researchers think they're correct. Participating in the forum is not part of the study, but you are free to use this part of the app if you choose.

Maintenance phase: We want to learn what works best to keep up a low-carbohydrate diet. After the 3 months of weekly classes end, you will be randomized to keep up skills on your own, attend a monthly group, or get the monthly group plus individual support.

6. Fingerstick home monitoring: You will be asked to complete a number of steps and activities at home including:

- Home glucose monitoring: You will need to monitor your blood sugar at home using a glucometer. Study staff will go over the specific schedule with you, based on the diabetes medications you are taking. You will report the numbers to study staff weekly. These will be reviewed by the study team and, if there are concerns that your blood sugar is too low or too high, you may be asked to speak with the study doctor to review your medications, diet, etc.
- Home ketone monitoring: You will be given a home ketone monitoring device and ketone strips, which measure beta-hydroxybutyrate. This is a glucometer device that also measures ketones from finger-stick blood if ketone strips are inserted instead of glucose strips. The device stores data, which may be checked periodically during class sessions. You will be asked to measure ketones before dinner approximately three times a week for four weeks early in the program (after 4 weeks of learning the diet). You will also be asked to test daily for certain one-week periods four times over the course of the study. During the maintenance phase, you will be asked to continue to check ketones periodically. This will involve checking your ketone levels about three times in a week for a week each month. You will receive reminders by text-message to check ketone levels and report values back. During study visits, you may be asked to bring in the meter so study staff can download data on your monitor to the study database.

Use of ketone monitoring apps: You may be asked to upload your ketone results to the Keto-Mojo smartphone app, which in turn integrates with the HeadsUpHealth app. This will allow you and the study team to track ketone and blood glucose data online. Study staff will be available to help you with any technical problems with downloading or using these apps. Uploading or connecting data other than Keto-Mojo results to the HeadsUpHealth app is not part of the study. If you choose to

connect any other devices or information sources to your HeadsUpHealth app, the study team will be able to view it, but will not use data other than ketone or glucose results for study purposes. The study researchers do not necessarily endorse advice or information that Keto-Mojo or HeadsUpHealth may provide.

7. Follow-up Visits: You will have in-person follow-up visits about 3, 6, and 12 months after classes start. These visits will occur in the morning and will take approximately 1 hour to complete. Because some of the tests need to be done when you have not eaten, you will be asked to not eat or drink anything (except water) after approximately midnight the night before the visit (or 8 hours before visit). The following procedures, previously completed at the consent visit (and described more fully in that section), will be repeated at this visit:

a. Fasting blood draw of about 2-3 tablespoons of blood at a LabCorp lab one block from the Osher Center. If it is more convenient for you to complete your study visit in the afternoon, you will be provided a lab slip to have a fasting blood draw at a LabCorp lab that is convenient to you the morning before this visit.
b. Weight measurement.
c. Medications and current health questions.
d. Computerized cognitive tasks.

9 month blood draw only: You may be asked to repeat the fasting blood draw at 9 months. Study staff will send you a lab slip and you will go to a LabCorp location convenient to you.

If you move out of the Bay Area or are otherwise unable to come for a follow-up study visit at 3, 6, and 12 months, study staff may want to work with you to complete questionnaires online and have a blood draw at a LabCorp lab in your community.

8. Diet assessments: Four times during the 12 month study, you will be asked to complete two phone interviews about what and how much you have eaten during the prior 24-hour period. These phone calls will take about 30-40 minutes to complete. So that you do not change your food intake specifically for this assessment, you will not be told exactly when you will be receive the phone calls. You will tell study staff the phone number and best times you can be reached for these calls.

9. Online questionnaires: At baseline, 3, 6, and 12 months you will complete online questionnaires on a computer. These questionnaires will take about 40-60 minutes to complete. The questionnaires will be about health, mood, stress, and physical and emotional well-being. You may also be asked to provide feedback about the classes, instructors, and study assessments. If you feel uncomfortable answering some of the questions, you may decline to answer them. If you have problems completing the online survey, you can call the study phone line for help. If you prefer to come to UCSF during business hours to complete these online questionnaires, you can schedule this with study staff. Depending on your preference, you may receive a text message, email, or phone call to remind you to complete these surveys.

10. Feedback questionnaires and interviews: One of the goals of this study is to get participant feedback on the class and some of the other study procedures so the researchers know what is working and what could be improved. You may be asked to do a brief interview (about 10-15 minutes) with study staff about the class and other study procedures (e.g. how useful the class was for you, how useful the text messages are). Interviews will happen up to three times during the study. The exact times will be arranged by study staff at times that work for you and you can choose whether to do this by phone or in person.

11. Secure email: To protect participant privacy, study staff are required by University policy to use the UCSF Secure Email System to email participants if there is any protected health information in the email. If you choose to participate in this study, you will be asked to create an account and choose a password if you don't already have one. You will be provided instructions for how to use the secure email system. If you need help, you can ask study staff. If you have no access to email, study staff will work with you to help provide access to a study computer and/or set up other ways (like phone calls and mail) to communicate with you.

12. Consultations with study doctors: Because the program may help reduce your blood glucose levels, study doctors may suggest reducing your diabetes medications. Study doctors will be available before the first class to go over your diabetes control and medications. You may be asked to arrive up to 45 minutes early for the first class in order to see a study doctor. The study doctor may wish to talk with you by phone at other times during the study. The main goal of the check-ins with study doctors is to help prevent the medications from lowering your blood glucose too much. How frequently you need to have doctor check-ins will depend in part on your glucose levels during the study. Study doctors may also suggest that you talk with your regular doctor about some things. If you have symptoms or concerns that you want to discuss with the study doctor, you can schedule a time with study staff to do this. For urgent concerns related to the study, you may contact one of the study doctors through study staff.

13. Coordination with your personal doctor: Because the study doctors may recommend that you reduce your diabetes medications, it is important that your personal physician know that you are participating in this study. The researchers will inform your doctor that you are participating in this study. They will also let your doctor know if the study doctor recommends any reductions to your medications and the reason for the recommended changes. Copies of your laboratory tests such as your fasting glucose and HbA1c will be sent to your physician. Similarly, your personal doctor may inform the study doctor about any medication changes he/she makes or other medical information about you that might be important to your safety. You will sign forms authorizing the study doctor/researchers and your personal doctor to communicate about your medical care.

14. Audio recording: Class sessions will be audio recorded to evaluate the course leader. A recorder will be placed in front of the class, nearest to the instructor. The purpose of the recording is to capture the instructor's voice and assess his/her effectiveness in teaching the class materials. However, there is a possibility that your voice may be recorded. You have the option to either sit in the back of the room, or stop the recorder while you are speaking if you do not want to be audio recorded. All recordings will be destroyed within three years of study completion. Any information that links your identity to the voice on the tape will not be included in the transcribed data.

How will my blood samples be stored and used?
Your blood will be sent to LabCorp laboratories immediately for testing (e.g. for glucose, cholesterol, etc.).

Will my blood be saved for future use?
No.

Will genetic testing be done on my blood or other specimens?
No.

Will I receive my test results?
If you wish, you will receive results of standard health measures: HbA1c, fasting glucose, insulin, cholesterol etc.

How long will I be in the study?
Your participation in the study will last about 14 months.

Can I stop being in the study?
Yes. You can decide to stop at any time. You will just tell the study researcher or staff person if you wish to stop being in the study. 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. 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.

Also, the study researcher may stop you from taking part in this study at any time if he or she believes it is in your best interest, if you do not follow the study procedures, or if the study is stopped.

What side effects or risks can I expect from being in the study?

1. Venipuncture: The risks of drawing blood include temporary discomfort from the needle stick, localized bleeding and bruising, lightheadedness, and rarely, fainting or localized infection.

2. Weight measurements: There is no risk involved in measuring weight though it does require measurement while wearing only a gown and underclothes which may cause you to feel uncomfortable. Also, you may feel uncomfortable being weighed. Measurement will be done by a trained research assistant in a private room.

3. Questionnaires: Some of the questions may make you uncomfortable or upset, but you are free to decline to answer any questions you do not wish to answer or discontinue participation at any time.

4. Randomization: You will be assigned to a group by chance. The group you are assigned to may prove to be less effective or to have more side effects than the other group or than other available programs. This will not be known until after the study is completed and the data have been analyzed.

5. Low glucose. Carefully following the diet and lifestyle recommendations in this program may improve your glucose levels. If you are on certain diabetes medications, however, this may involve 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 of low glucose. If serious low glucose develops and is not treated (for example by eating something), you could even develop hypoglycemic coma. To limit the risk of these problems, you will need to check your blood glucose levels and work with study doctors if your glucose is too high or low. While study staff and doctors will work carefully to prevent problems, medication related problems are still possible. Study investigators estimate the risk of serious problems like developing hypoglycemic coma to be less than 1%.

6. Low-carbohydrate diet: When following a low-carbohydrate diet, you may experience some side effects when you first reduce the amount of carbohydrate in your diet. These include constipation, headache, bad breath, muscle cramps, diarrhea, general weakness, and rash. These symptoms usually go away after the first couple weeks on the diet. If these problems occur, you can talk to the instructor or study staff either by phone or at the next class. If your concerns or side effects are severe, you can speak to the study physician. Suggestions for how to handle side effects will be discussed in the first class, and throughout the course as needed. You will receive handouts with suggestions for avoiding these problems.

7. Dietary changes: You could find it difficult or time-consuming to change your diet. You may find that you need or want to spend more time shopping for or preparing food, including learning new recipes or ways of preparing food. Also, your friends or family may not support the changes you make to your diet. If this happens, you can speak to your class instructor or study staff about this. How to respond to unsupportive family or friends will be discussed in the first class, and throughout the course as needed.

8. Audio recording: Your voice might be recorded in the audio recordings. If you do not wish your voice to be recorded, you have the option to sit in the back of the room where there is less likelihood that your voice will be recorded, or you can ask to have the audio recording stopped when you are speaking.

9. Home assignments: You may find it inconvenient to complete the home assignments for the class. Also, you could experience distressing emotions during some of the home assignments. If this happens, you can stop the exercise and speak to the instructor or study staff either by phone or at the next class. Suggestions for how to handle difficult emotions that come up during home assignments will be discussed in the first class, and throughout the course as needed.

10. Study visits: Participating in the study may be an inconvenience. Every effort will be made to schedule interviews at convenient times for you.

11. Fingerstick glucose and ketone monitoring: You may find it inconvenient or uncomfortable to do fingerstick testing for glucose or ketone monitoring during the study. At times, testing will be required for safety or for important study data. At other times, testing will be optional and you can decide whether to continue testing to see how you are doing with the diet. The study team will be available to discuss any problems you are having with testing and will also go over with you when testing is required versus optional. You may also find it inconvenient to download or use the ketone-monitoring apps. Study staff will be available to help you with technical problems with downloading or using these apps.

12. Time required: During the weeks that you are coming to study classes, you could spend up to 8 hours per week on study-related activities. This includes up to 2.5 hours in class, time spent traveling to and from class, 15-30 minutes of home assignments per day, completing weekly surveys, and time spent shopping and preparing food.

What happens if I am injured because I took part in this study?
It is important that you tell the Principal Investigator, Dr. Frederick Hecht, if you feel that you have been injured because of taking part in this study. His email is rick.hecht@ucsf.edu and his phone number is 415-353-9743. You may also contact Dr. Patty Moran, the Project Director, at (415) 353-9745 or patricia.moran@ucsf.edu.

Treatment and Compensation for Injury: If you are injured as a result of being in this study, treatment will be available. The costs of such treatment may be covered by the University of California, depending on a number of factors. The University does not normally provide any other form of compensation for injury. For further information about this, you may call the office of the Committee on Human Research at 415-476-1814.

Are there benefits to taking part in the study?

You will receive possible benefits of taking part in this study. These may include improved diabetes control, reduced need for diabetes medications, weight loss, reduced risk for diabetes complications, and decreased feelings of stress. The information that you provide may also help health professionals better understand how these programs can help people with diabetes improve their health and lower their risk for diabetes complications.

What other choices do I have if I do not take part in this study?

You are free to choose not to participate in this study. If you decide not to take part in this study, there will be no penalty to you. You will not lose any of your regular benefits, and you can still get care the way you usually do. If you do not participate, it will not affect your ability to participate in other programs at UCSF. There are a variety of diabetes education and support programs in the community you can participate in if you choose not to be part of this study.

Will information about me be kept private?

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. Organizations that may look at and/or copy your research records for research, quality assurance, and data analysis include:

- The University of California
- National Center for Complementary and Integrative Health

Participation in research may involve a loss of privacy, but information about you will be handled as confidentially as possible. The researchers will do their best to make sure that the personal information gathered for this study is kept private. However, they cannot guarantee total privacy. A loss of privacy may occur as a result of your participation in the group intervention. To minimize this possibility, the research staff will request that participants do not talk to others outside the group about information disclosed by other group participants.

Research records will be kept as confidentially as possible. All specimens as well as data collected will be coded (no names will be used).

Laboratory results such as your fasting glucose and HbA1c will be sent to your physician, and he/she will also be informed if the study doctor recommends any reductions or changes to your diabetes or blood pressure medications. The results of your study questionnaires will be kept confidential and will not be shared with your physician.

Because this study uses the internet, there's always the possibility that someone could eavesdrop on your connection and see the information you're sending us. Both UCSF as well as the makers of the apps used in this study (Claritas for the mindful eating app; Keto-Check Inc. for the Keto-Mojo ketone meter and app; phase2body, Inc. for HeadsUpHealth app and online platform that integrates data from Keto-Mojo), use industry-standard encryption to protect your communications. When you use these apps, some of the information you enter will be stored on the servers at these companies. These companies follow industry

standards for protecting your data and are strictly forbidden from using or sharing personally identifying information for any purpose other than operating the app.

PPG signal data will be associated only with a study ID numbers, not your names, so no one outside of the research team will be able to match your PPG data with other information about you. If you participate in this procedure, the company that makes this research app, Azumio, will have a record of your PPG signal, but they will have no way to link that measurement back to you as an individual or connect it with any of your other study data.

What are the costs of taking part in this study?

You will not be charged for any of the study treatments or procedures.

The phone questionnaires are sent by text message, and require you to respond on our website. We estimate that the maximum possible usage will be 20 text messages and 1.5 megabytes of data per month for 12 months. On most cell phone plans there will be no cost or very low costs for this, but you will need to check the fees for your cell phone provider. The study does not offer reimbursement for these costs.

Will I be paid for taking part in this study?

In return for your time, effort, and travel expenses, you will be paid for taking part in this study.

You will receive $20 for the baseline (consent) visit, $25 for the 3 month, $35 for the 6 month visit, and $45 for the 12 month visit. You will receive these payments in cash after completing these visits.

You will receive $20 for completing the 24-hour diet recall interviews at each of four timepoints during the study (baseline, 3, 6 and 12 months; total of $80). You will receive $15 for the 9 month blood draw. You can choose to receive these payments in cash at your next study visit, or if you prefer, you can be paid with an Amazon e-gift card.

Total possible payments if you complete all study assessments: $220.

You will not be paid for attending group program sessions. If needed, you can get reimbursement for public-transportation costs for the class sessions, up to $10 per session.

If you move or are otherwise unable to come to UCSF for follow-up visits, but complete questionnaires online and get a blood draw at a LabCorp lab in your community, you will receive $20. If you are not willing or able to do online questionnaires and a blood draw at a LabCorp lab, you will be asked to respond to an email or phone call inquiry at each of the remaining follow-up time points about your current diet, diabetes control and medication, your weight and whether you have started another diet approach.

If for some reason, the researchers cannot use cash to pay you, the researchers may pay you via Amazon e-gift card.

What are my rights if I take part in this study?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you

make, there will be no penalty to you in any way. You will not lose any of your regular benefits, and you can still get your care from our institution the way you usually do.

You will be told about new information or changes in the study that may affect your health or willingness to continue in the study.

Who can answer my questions about the study?

You can talk to the researchers about any questions or concerns you have about this study. You can either contact the Principal Investigator, Dr. Frederick Hecht (rick.hecht@ucsf.edu,415-353-9743) or the Project Director, Dr. Patty Moran (patricia.moran@ucsf.edu; 415-353-9745).

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 website will include a summary of the results. You can search this website at any time.

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please call the Institutional Review Board at 415-476-1814.

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OPTIONAL RESEARCH

Please note: This section of the informed consent form is about optional research studies that are being done with people who are taking part in the main study. You may take part in these optional studies if you want to. You can still be a part of the main study even if you say "no" to taking part in any of these optional studies.

You can say "yes" or "no" to the following study. Please mark your choice for the study.

PPG Study

We want to study whether a simple measurement, photoplethysmography (PPG), changes as people lower their carbohydrate intake. PPG uses the light from a camera to detect blood volume changes in the small blood vessels of the finger. Previous scientific studies have found some evidence that PPG signals may be useful in detecting some of the effects of diabetes or cardiovascular risk.

This information may help researchers better understand whether PPG may provide an accessible non-invasive way of measuring diabetes risk and severity. In the future, this information may help patients and doctors detect diabetes earlier and/or with fewer costs and risks.

At each of the main study visits (at baseline, 3, 6 and 12 months), you may have photoplethysmography (PPG) measured by placing your finger over a camera lens on a study smartphone for approximately one minute. The procedure is painless and should take less than 5 minutes.

The PPG data collection is not part of the main trial that is being funded by NIH.

If you decide to take part in this optional measurement, the only thing you will be asked to do is place your finger over a camera lens on a study smartphone for approximately one minute at each of the study visits. You may change your mind about providing the PPG measurement at any time.

Just like in the main study, we will do our best to make sure that your personal information will be kept private.

Please put your initials in the "YES" or "NO" box to indicate your answer.

I choose to take part in the PPG Study.

YES	NO

CONSENT

You have been given a copy of this consent form to keep.

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 be in this study, or to withdraw from it at any point without penalty or loss of benefits to which you are otherwise entitled.

If you wish to participate in this study, you should sign below.

_____ _____
Date Participant's Signature for Consent

_____
Print name of Participant

_____ _____
Date Person Obtaining Consent

_____
Print name of Person Obtaining Consent

Future contact with this study:
☐ This consent form only covers study assessments up to 14 months. If researchers are able to follow up with participants in this study in future years, they will contact you if you check this box.

Future contact for other studies:
☐ There are other studies that you may be eligible for in the future. UCSF may contact you to invite you to participate in other research studies if you check this box.