# UNIVERSITY OF MICHIGAN
# CONSENT TO BE PART OF A RESEARCH STUDY

## 1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

**Title of Project:** A small steps, breakfast-focused dietary self-management intervention for adults with poorly controlled type 2 diabetes

**Company or agency sponsoring the study:** This research is sponsored by a grant (R01) from the National Institutes of Health (NIH)

**Principal Investigator:** Laura Saslow, Ph.D., Assistant Professor in the Department of Health Behavior and Biological Sciences in the School of Nursing, University of Michigan, Ann Arbor

### 1.1 Key Study Information

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 in Ann Arbor 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 of 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 assess a promising approach for losing weight and improving the health and glucose control of people with type 2 diabetes, a very low-carbohydrate breakfast. Your health-related information, including questionnaire responses and blood samples, will be collected for this research study.

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 such as cramping, headaches, hypoglycemia, 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. More information will be provided later in this document.

We expect the amount of time you will participate in the study will be about 6 months – approximately 1 month to determine if you're eligible, 4 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 normal.

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 in Section 2 of this document.

## 2. PURPOSE OF THIS STUDY

**2.1 Study purpose:**

More than 15% of adults in the U.S. with type 2 diabetes have trouble controlling their blood sugar levels. This can be harmful to their health. Eating better can help control blood sugar, reduce medication, and lower body weight for these adults. The food we eat, especially carbohydrates, affects how our blood sugar behaves after meals.

A diet that's low in carbohydrates can really help control blood sugar. The American Diabetes Association recommends it for treating type 2 diabetes. But changing your whole diet can be hard. So, a plan that focuses only on changing breakfast to a low-carb one might work well.

We think a digital program that guides adults with type 2 diabetes, step by step, to have a low-carb breakfast could be really helpful. This could make it easier for them to lower their blood sugar and take fewer diabetes medications.

## 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?**

Earlier steps helped us determine that you have type 2 diabetes with an HbA1c of greater than or equal to 8% mg/dL, are willing and able to participate in an intervention, and that you don't have other conditions which might make you ineligible to participate, like type 1 diabetes, heart failure, or most cancers.

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

We expect 120 participants to join this study.

## 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. Feel free to reach out to us at breakfaststudy@med.umich.edu if you have a question you'd like to ask before our meeting.

- Ask you for your social security number for tax reporting purposes (please see section 9.2 of this document for more information).
- Schedule an upcoming online appointment.
- Get more information, like your physician's name and location.

After you sign this consent form and complete the video visit, you may be asked to complete the following steps:

- An online video appointment with a technician for adding on a continuous glucose monitor (CGM).
    - We'll mail you the supplies, and the technician will lead you through adding a CGM onto your arm. After two weeks, you'll mail it back to us in a pre-paid box. The CGM is a small device that continuously measures your blood glucose.
    - The online appointment should last less than 1 hour.
- 1-2 20-30 minute dietary recalls over the phone. A member from our team will reach out to you once over the phone to ask you about what you ate the date before. You won't need to prepare for this call, and we won't be able to tell you exactly when they'll happen – we'll use the availability you give us during the consent visit to plan your phone call.
- A longer, online survey about your habits, health, and well-being, which will take about 45 minutes.
- We'll mail you a scale from BodyTrace, to complete a weight measurement before starting the program.

- You'll receive a blood pressure cuff in the mail from Amazon to measure your blood pressure at home several times over the next few weeks.

You will have a maximum of about 8 weeks to complete the above enrollment steps (including the 2 weeks you'll be wearing the CGM). If your class start date is sooner than 6 weeks, you'll have until the start of the class to complete your enrollment steps. You'll be informed of the start date for your class and about any time constraints.

While you're completing the above steps, the study staff will inform your primary care provider about participation in this study; we will need confirmation from your doctor that they believe your participation in this program is safe. You may be asked to inform your doctor of any side effects or recommendations from study doctors. Additionally, the study team will share your test results with your primary care physician at the end of the study (we've already shared your baseline results with them, as indicated in the screening consent form).

**Study Procedures**

In the study, you'll be assigned to a dietary approach, a very low-carbohydrate breakfast. You'll have a diet coach who will support you along the way, providing you with tools and tips, and answer any questions. The diet coaches are experts on your assigned way of eating. You will have weekly check-in surveys. When you complete the survey every week, reporting your blood glucose (if required by the study doctor), then a $4 amount will be awarded per completed survey. The total amount after 16 weeks will be added to your $36 final gift card after completing the program, for a total of up to $100. You may have regular check-in video or audio calls and/or emails with your coach throughout the program. There may be additional meetings with the coaches that may include other participants. We may also send you a body weight scale. We'll also ask you to track what you're eating, so your coach can give you helpful suggestions and you can see if you're on track. Plus, we'll send you a cookbook and possibly a few food gifts along the way, plus text messages with information to support you, too.

**Optional Research – Medical Records**
Additionally, the research team would like your permission to retain your contact information and/or access your medical records for up to 5 years after you leave the study, so that we can see how your participation in the study has affected your health long term. You can opt out of this research activity in section 12.

**Measurements at Month 4**
After about 4 months in the program, you may be asked to repeat the majority of the measures you did at the beginning of the study:

- You'll complete a longer survey (similar to the one you completed at the beginning with additional questions about how the program is going for you). This should take about 45 minutes.
- Depending on what study staff tells you is our procedure at the time, you'll go to whatever LabCorp location that is most convenient for you. A list of locations will be provided to you when you receive your lab order for your blood draw. You will get a *fasting* blood draw. This means you should avoid food and beverages (except for water) for 12 hours before you get your blood drawn. Approximately 2 tsp will be drawn. Your blood draw should take approximately 15 minutes.
- You'll be contacted over the phone for 1-2 24-hour dietary recall; each phone call will last 20-30 minutes.
- You may weigh yourself on your own scale at home and send us a picture of your weight on the scale or you may be asked to measure your weight in person.
- You may be asked to measure your blood pressure several times at home.
- You may be asked to schedule an online video appointment with a technician for adding on a continuous glucose monitor (CGM).
    - We'll mail you the supplies, and the technician will lead you through adding the CGM onto your arm. After two weeks, you'll mail it back to us in a pre-paid box. The CGM is a small device that continuously measures your blood glucose.
    - The online appointment should last less than 1 hour.

For each weekly survey completed, you will earn $4, and the total amount after 16 weeks will be added to your $36 final gift card after completing the program. Once all measures are completed at 4 months, you'll receive up to $100 in the form of an Amazon gift card.

**Optional Interviews**
You may be asked if you'd like to participate in an optional interview at 4 months. This possible interview will be about your experience in the program and should take less than 30 minutes. The interview will be recorded, though only the study team or professional transcribers will hear your interview; if you decline to be recorded, we will not proceed with the interview. This is entirely optional, and you will be able to opt out at any time. We will avoid using any identifiable information in the interview.

**Medication Management**
If you take glucose-lowering medications that may increase your risk of hypoglycemia, you will meet with study physicians 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, you may be asked to stop 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.

*Glucose monitoring*: If you are taking glucose-lowering medications other than metformin, you will be asked to check your blood glucose regularly; the study doctor will go over the schedule with you. Keep track of these readings; you'll be asked about them during your weekly check-in surveys. You should always self-manage any low blood glucose readings or symptoms. You will be asked to inform your healthcare team (such as your primary care physician or specialty physician) and 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 medications. You can always reach out to your healthcare team or study staff via email or phone if you have any questions or concerns.

**How will your study supplies be provided to you?**

Some of your study materials and emails may be sent directly to you through vendors such as:

- Amazon (for mailing gift cards and other possible supplies)
  - Amazon privacy policy: https://www.amazon.com/gp/help/customer/display.html?nodeId=GX7NJQ4ZB8MHFRNJ,
- BodyTrace (for possible body weight scale or blood pressure cuff)
  - BodyTrace has signed a non-disclosure agreement with the University of Michigan, visible here: https://www.dropbox.com/s/zsam9epdjxjgzgy/NDA%20UM-Body%20Trace%205500020633Fully%20Executed%20033021.pdf?dl=0
- Qualtrics (for surveys)
  - Qualtrics privacy policy: https://www.qualtrics.com/privacy-statement/
  - The University of Michigan has an agreement with Qualtrics to ensure that it is HIPAA-compliant and secure to use with sensitive material.
- REDCap (for surveys)
  - REDCap privacy policy: https://projectredcap.org/software/mobile-app/privacypolicy/
  - The University of Michigan has an agreement with REDCap to ensure that it is HIPAA-compliant and secure to use with sensitive material.
- Zoom (for interacting with coach)
  - Zoom privacy policy: https://explore.zoom.us/en/privacy/?_ga=2.170714018.320876838.1637332774-1969838777.1573232342
  - The University of Michigan has an agreement with Zoom to ensure that it is HIPAA-compliant and secure to use with sensitive material.
- Twilio (for text messages)
  - Twilio privacy policy: https://www.twilio.com/en-us/legal/privacy
- Bandwidth, Inc. (for text messages)
  - Bandwidth privacy policy: https://www.bandwidth.com/privacy/
- SignalWire, Inc. (for text messages)
  - SignalWire privacy policy: https://m.signalwire.com/policies?doc=privacy
- FedEx (for mailing study materials)
  - FedEx privacy policy: https://www.fedex.com/en-us/trust-center/privacy.html.
- Lulu (for mailing study materials)
  - https://www.lulu.com/privacy-policy
- Microsoft Bookings (for scheduling study visits)
  - Microsoft Bookings privacy policy: https://privacy.microsoft.com/en-us/privacystatement

In addition, as part of the research, we may transcribe the audio recordings of the classes and optional interviews. Vendors who help with those transcriptions include:

- Production Transcripts. Their privacy policy: https://www.productiontranscripts.com/privacy-policy/
- Descript. Their privacy policy: https://www.descript.com/privacy

During the study, the research team may 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 (texting) 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).

By providing your number and signing this, you are agreeing to receive SMS messages from the Saslow Lab regarding the study you are involved in. You may Opt-Out at any time by replying STOP. Message frequency may vary and message and data rates may apply.

In this study, Labcorp will draw and analyze your blood. LabCorp may see some of your identifying information, such as your name and date of birth. LabCorp will analyze your blood right away and discard the samples.

By signing this consent form, you are allowing the study team to provide the vendors with your contact information to mail you something to your address or email you. You are also allowing us to share audio recordings with the transcription companies, but that will not include any contact information or other information about you. Not all of these companies have signed a confidentiality agreement with us. However, they each have their own privacy statements. They will not know the results of any of your tests or other research information.

**How will your blood samples be stored and used?**
Blood drawn at Labcorp will be discarded after analysis.

**Will I receive my test results?**
We will send you a secure email with the results of your blood tests at the start of the study and 4 months later. We will share other health results once the study is over. Study staff will share the blood results (securely) with your primary care provider.

**What are my responsibilities?**
As a participant in this research study, you have certain responsibilities, such as ensuring that you arrive at all of your scheduled appointments or video visits, follow the study meal plans, 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 6 months; one month before the study for your enrollment activities, 4 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 end of the study. During the 4-month program, you'll have online classes weekly plus check-ins with your coach. We'll be checking in with you with weekly surveys before classes about several factors, including your dietary adherence.

You'll complete study measurements two times, once at the beginning and again at the end of the study (after 4 months). These measurements will include a blood draw, which you can do whenever is convenient for you,

and it should take approximately 15 minutes. You'll also have online appointments =, which should take less than 1 hour each time (one at the beginning and one at the end of the study) to help properly place your continuous glucose monitor. A member of the study team will call you once at the beginning of the study and again after 4 months to ask you about what you ate the day or two before – these calls will take about 30 minutes. Finally, you'll complete a survey at each of the two timepoints, which will take about 45 minutes.

**4.3 When will my participation in the study be over?**
The study period is about 6 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. We would like to check your medical records for 5 years after your participation in the study ends, to see how your participation in the study has affected your health long-term. You can opt out of this at the end of the consent form or at any time after.

**4.4 What will happen with my information and/or biospecimens used in this study?**
Your biospecimens and collected information may be shared with the National Institutes of Health (NIH), who sponsors this study.

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

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

## 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 fairly 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 fairly 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. *Continuous glucose monitor*. There is a risk of infection at the point of insertion as well as a possible irritation. These risks are very low. It is possible to feel a slight discomfort when wearing the monitor. This is not expected to occur, but please reach out to study staff if it does.
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 to discontinue your participation at any time.
4. *Diet.* As you change your diet you may experience some side effects, 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. Additionally, kidney stones are common in the general population – you are advised to follow diet recommendations, eat a normal amount of protein, and increase your water intake to avoid kidney stones during the study. Other possible side effects include a rash. Temporary hair loss is also possible, which can occur whenever rapid weight loss occurs. The study staff will provide resources for eating a very low-carbohydrate breakfast 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. *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.
6. *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.
7. *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.
8. *Recording.* The sessions with coaches and interviews will be audio recorded. These recording will be saved on encrypted, University computers. We will avoid using any personal information in the interview or sessions and if names are used, they will not be included in the transcript. 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'll also be able to inform your diet coach during class sessions or your weekly/month phone calls or you can email or call the study team. You should also tell your regular doctors.

**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 your 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 persons listed in Section 10 “Contact Information”.

**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 in order 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. If you are not sure what these are, see Section 4.1 above or ask the researchers for a list. If you get a bill you think is wrong, call the researcher’s telephone number listed in Section 10.1.

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
- Items or services needed to give you study drugs or devices
- Monitoring for side effects or other problems
- Deductibles or co-pays for these items or services.

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 Section 10 below or call your health plan's medical reviewer.
By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

**8.2 Will I be paid or given anything for taking part in this study?**
You'll receive up to $100 via Amazon gift card for completing all 4-month measurements. When you complete the survey every week, reporting your blood glucose (if required by the study doctor), then a $4 amount will be awarded per completed survey. The total amount after 16 weeks will be added to your $36 final gift card after completing the program, for a total of up to $100.The blood pressure cuff, finger-stick glucose meter (if you do not already have a working one), body weight scale, and the printed study materials are yours to keep.

**8.3 Who could profit or financially benefit from the study results?**
The PI Dr. Laura Saslow's partner, Mr. Hovig Bayandorian, is an inventor of software being used in this research and provides this study a services agreement.

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.

## 9. CONFIDENTIALITY OF SUBJECT RECORDS AND AUTHORIZATION TO RELEASE YOUR PROTECTED HEALTH INFORMATION

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.

**9.1 How will the researchers protect my information?**
Your research information will be kept in locked filing cabinets or stored on encrypted servers and computers accessible only by study staff. Results of your blood tests will be shared with you and your primary care doctor through secure methods of communication. Signing this consent form means you agree to allow us to communicate directly with your primary care provider. 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.

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 NIH, 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 protected health information (PHI) 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 in order for you to take part in the study.

Medical information and billing records are protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA). This type of information is called protected health information (PHI). PHI about you for purposes of this research study may be obtained from other hospitals, doctors, and other health care providers involved in your care.

PHI about you may be obtained from any hospital, doctor, and other health care provider involved in your care, including:

- Hospital/doctor's office records, including test results (X-rays, blood tests, urine tests, etc.)
- All records relating to your condition, the treatment you have received, and your response to the treatment
- Demographic information
- Personal identifiers

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:

- The researchers may need the information to make sure you can take part in the study.
- The researchers may need the information to check your test results or look for side effects.
- 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
- Insurance companies or other organizations may need the information in order to pay your medical bills or other costs of your participation in the study.
- The researchers may need to use the information to create a databank of information about your condition or its treatment.
- Information about your study participation may be included in your regular UMHS medical record.
- If you receive any payments for taking part in this study, the University of Michigan finance department will need your name and address for tax reporting purposes. In a calendar year if: 1) your payments total greater than $400 for this study or 2) if you receive payments of greater than $400 for being in more than one study, the University of Michigan finance department will also require your

Social Security Number for tax reporting purposes. If you do not wish to provide your Social Security Number, you may continue to participate in research studies, but you will not be able to receive payment for the remainder of the calendar year.

- 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 would not include any information that would let others know who you are.

**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

Health System's privacy policies. For more information about these policies, ask for a copy of the University of Michigan "Notice of Privacy Practices". This information is also available on the web at http://www.uofmhealth.org/patient+and+visitor+guide/hipaa. Note that once your information has been shared with others as described under Question 9.2, it may no longer be protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

**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. The study team also requests your permission to access your medical records for up to 5 years after you've completed the study. This will allow us to see any long-term effects of your participation in the study.

You can opt out of both future research and medical record access 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
- Talk about study-related costs to you or your health plan
- 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

Principal Investigator:

- Laura Saslow; Mailing Address: Office 2178, 400 N Ingalls St, Ann Arbor, MI, 48109; Telephone: 734-764-7836

Study Coordinator:

Kate Raymond
Phone: 734-763-4995
Email: breakfaststudy@med.umich.edu

**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. (*Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file and may be entered into your regular University of Michigan medical record.)*

## 12. SIGNATURES

**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 audio and video 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-E**

**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): _____