UNIVERSITY OF MICHIGAN
CONSENT TO BE SCREENED FOR A RESEARCH STUDY
(ONE-TIME BLOOD OR SPECIMEN SAMPLE — MINIMAL RISK)

NAME OF STUDY AND RESEARCHERS

Title of Project: Glycemic reduction approaches in polycystic ovary syndrome: a comparative effectiveness study: The SUPER (Supporting Understanding of PCOS Education and Research) Study

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

GENERAL INFORMATION

We're doing a study to compare two dietary approaches for people with prediabetes. This research will test whether a DASH or very low-carbohydrate diet better improves outcomes like blood glucose control and body weight for adults with polycystic ovary syndrome (PCOS) who follow one of these approaches for 12 months.

Before you can join the study, we'll need to make sure you qualify. To find out whether you qualify, we'll check some of your blood tests. You may need to have more than one blood draw completed to determine if you are eligible. Approximately 1 tbsp. will be drawn from your arm. These results will become part of your baseline results for the SUPER study if you are eligible and decide to join the trial. These blood tests will check your overall health, as well as you blood sugar (HbA1c) and hormones.

You will have this fasting blood draw at a LabCorp location. You can go to whichever location is most convenient for you. Fasting means that you cannot have anything to eat or drink except for water for 12 hours before you arrive. Your blood will be drawn and analyzed by Labcorp. They will destroy whatever blood is leftover when the analysis is complete.

We will review your medical records as part of the screening process to ensure you seem eligible to participate in this study (checking previous hormone tests, for example).

We will inform you of your blood test results. Your eligibility for the SUPER study will be determined, in part, by your test results, and we will let you know if you may be eligible to join the study after we receive your results. If you are ineligible, it's possible that you may be eligible at a later date.

There is a small chance of infection with any blood draw. We will use a sterile needle and will clean your skin with alcohol where the needle goes in. The needle may sting a little and may leave a bruise. Some people may feel dizzy or faint. If you do, you may lie down during the blood draw. We'll give you first aid if you need it.

We'll label your blood sample with a code and your date of birth. That way, only members of our study team will know whose blood it is. We'll also label your medical information with a code, so that others won't know your identity.

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.

Determining whether you qualify for the SUPER study and participating in the additional, optional research won't benefit you directly.

Being in this study is voluntary. You don't have to join if you don't want to. Choosing not to be in this study won't affect your medical care in any way.

To thank you for taking part in this study**.** We will let you know your test results via secure email and will let you know if you are eligible to join the SUPER trial. If you qualify to be in the study and you are interested in joining, we'll give you another consent form to read and sign. That form will explain the rest of the study.

There is no charge to you or your health insurance for being in this study.

None of the information that we publish or discuss will enable others to figure out who took part in this study.

Like the information in your medical record, the records we create in this study will remain confidential and protected.

Dr. Laura Saslow's partner, Mr. Hovig Bayandorian, is an inventor of software used in this study, which has purchased a software services agreement for its use.

AUTHORIZATION TO RELEASE PROTECTED HEALTH INFORMATION

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. Your permission expires at the end of the study, unless you cancel it sooner. You may cancel your permission at any time by contacting the researchers listed below (under Contact Information).

Information 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 and dental records
- Any records relating to condition, the treatment received, and response to the treatment
- Demographic information
- Personal identifiers

It's possible that the researchers or others will need access to information about you during or after this study. For example:

- 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.
- The University of Michigan or a government agency 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, or analyze the results of 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.
- Federal or State law may require the study team to give information to the Food and Drug Administration (FDA) or other government agencies. For example, to prevent harm to you or others, or for public health reasons.

- If you receive any payments for taking part in this study, the University of Michigan accounting department may need your name, address, Social Security number, payment amount, and related information for tax reporting purposes.

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.

As a rule, the researchers will continue to use information about you until the study is over and will keep it secure until it is destroyed. Limited information about you may continue to be used after the study is over, for other research, education, or other activities. But use of this information would not reveal your identity.

As long as your information is kept within the University of Michigan Health System, it is protected by the Health System's privacy policies. For more information see http://www.uofmhealth.org/patient+and+visitor+guide/hipaa. Note that once your information has been shared with others, it may no longer be protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

A description of the SUPER study will be available on www.ClinicalTrials.gov. This website 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.

CONTACT INFORMATION

To find out more about the study, to ask a question or express a concern about the study, or to talk about any problems you may have as a study subject, you may contact one of the following:

Principal Investigator: Laura Saslow, PhD Mailing Address: Office 2178, 400 N Ingalls Street, Ann Arbor, MI, 48109 Telephone: 734-764-7836
Study Coordinator: Jenny Grone and Kate Raymond Telephone: 734-763-1227 Email: msuperstudy@med.umich.edu

You may also express a concern about a study by contacting the Institutional Review Board:

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

If you are concerned about a possible violation of your privacy or concerned about a study, you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111.

SIGNATURES

Research Subject:

I understand the information printed on this form. My questions so far have been answered.

Signature of Subject: _____ Date: _____

Name (Print legal name): _____

Date of Birth: _____

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.

Legal Name: _____

Title: _____

Signature: _____

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

UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Title of Project: Glycemic reduction approaches in polycystic ovary syndrome: a comparative effectiveness study: The SUPER (Supporting Understanding of PCOS Education and Research) Study

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, like diet, may have an impact on polycystic ovary syndrome (PCOS). This research will compare two promising approaches for losing weight and improving the health and glucose control of people with PCOS: a Dietary Approaches to Stop Hypertension (DASH) or very low-carbohydrate way of eating. 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 separate 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 such as cramping, 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 PCOS 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 1 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 PCOS 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:

Polycystic ovary syndrome (PCOS) is the most common endocrine disorder for women of reproductive age. Women with PCOS are at a high risk of health complications. For example, women with PCOS have an increased risk of developing type 2 diabetes. Experts recommend that the treatment for obese women with PCOS should focus on diet and lifestyle changes. Yet, experts disagree about the specific nutritional advice these interventions should encourage. This study will compare two recommended approaches for people with PCOS: a DASH diet and a very low-carbohydrate ('keto') diet.

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 PCOS, are willing and able to participate in an online intervention, and that you don't have other conditions which might make you ineligible to participate, like type 1 diabetes or heart failure.

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

We expect 220 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 msuperstudy@med.umich.edu if you have a question you'd like to ask before our meeting.
-
- Schedule an upcoming in-person appointment with you for a body scan (if local to Ann Arbor).

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

- An in-person appointment, if you're within driving distance from Ann Arbor, for adding on a continuous glucose monitor and for a body composition scan (called a dual-energy x-ray absorptiometry or DEXA).
    - The technician at this appointment will measure your weight and height as well as acne and hirsutism.
    - Then, you'll be directed to remove **any** metal from your person, including buttons on jeans and jewelry. You'll be given a gown to change into.
    - The hirsutism assessment includes a visual exam of the body, including the chest, upper thigh, abdomen and back. A chaperone may not be provided, so if you are not comfortable with this assessment, please let the technician know and they can limit the assessment to areas of the body that do not require undressing.
    - The DEXA will measure 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 will be asked to take a urine pregnancy test at this appointment. If you are pregnant, you will not be able to receive your DEXA and will be ineligible for the trial.
    - The technician will also add a continuous glucose monitor (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 is applied to the upper part of the back of your arm, which passively measures your blood glucose levels, such as how they change in response to what you are eating. It has no alarms, and can be worn when exercising, showering, and doing all typical activities. Per the instructions for the Libre Sensors being used, you will be asked to not take more than 500 mg of Vitamin C per day or more than 650 mg of aspirin per day while wearing the sensor during the study period.
    - You will receive a $20 Amazon gift card as a thank you for returning your CGM.
    - The in-person appointment should last less than 2 hours.
- If you are not within driving distance of Ann Arbor, you will not have this in-person appointment. However, you will do the following:
    - Body weight and self-report of height
    - Possible self-placement of a continuous glucose monitor (CGM) (participants will wear their CGM (which will not provide them with any feedback) for 2 weeks before they mail it back to the study team.)
- One 20-30 minute 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 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.

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.

Randomization
After all of your enrollment steps are completed, you'll be randomized to one of two groups. You'll either be assigned to follow one of two ways of eating. 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:

- ***DASH.*** Participants assigned to this group will be encouraged to eat whole grains, vegetables, fruit, low-fat dairy, and lean protein.
- ***Very low-carbohydrate.*** Participants assigned to this group will be encouraged to eat non-starchy vegetables, meats, healthy fats, berries, and to avoid starchy and sugary foods.

Study Procedures
In the SUPER study, you'll be randomly assigned to one of two dietary approaches.

You will be e-mailed class links weekly during the 4-month core phase and monthly during the 8-month maintenance phase that connect you to: a short check-in survey, a video to teach the topics, and links to resources. Class videos can be watched and read at your convenience and take about 10–30 minutes to complete.

No matter which you're assigned to follow for 12 months, you'll have a diet coach who will support you along the way, provide you with tools and tips, and answer any questions. The diet coaches are experts on your assigned way of eating. You may have check-in video or audio calls (depending on participant preference) and emails with your coach throughout the program. There will be additional optional group Q&A meetings (video or audio) with the coaches that will include other participants.

We'll also send you a body weight scale that automatically sends us your weight over the course of the study. 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. We recommend using MyFitnessPal, a popular website and phone app for dietary tracking, but you can use other resources if you prefer. If you're assigned to the very low-carbohydrate diet, we'll send you a way to measure your ketones, using urinary Ketostix, which will help you see if you're following that way of eating. Plus, we'll send everyone cookbooks along the way, and text messages with information to support you, too. The study will also send each participant a supply of pregnancy tests in order for participants to confirm a negative pregnancy test once per month.

Optional Research – Medical Records
The research team would like your permission to 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'll 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'll complete at the beginning with additional questions about how the program is going for you). This should take about 45 minutes.

- You'll go to whatever Labcorp location is most convenient for you to 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 3 tsp will be drawn. The blood draw should take approximately 15 minutes. We may mail you a blood test kit for you to complete at home. Everything you need to perform and mail the tests will be included in the kit. You may mail your blood sample to the lab when you complete the finger prick. This blood test will only measure your hemoglobin A1c (HbA1c).

- You'll be contacted over the phone for one 24-hour dietary recall; the phone calls will each last 20-30 minutes.
- You'll weigh yourself on your own scale at home.

Once all measures are completed, you'll receive a $65 Amazon gift card. The program will continue with monthly classes and check-in surveys, along with the group Q&A sessions offered twice monthly. Group Q&A sessions will be led by the coaches on Zoom and are an opportunity for you to meet other participants, ask questions, receive mutual support, and share your experiences with other women in the program. If you attend these group discussions during months 5 through 12, you will receive a monetary incentive of $5 per session to be added to your 12-month gift card after completing the program measurements.

Measurements at Month 12

After about 12 months total in the study (8 months after your previous measurements), you'll complete the same steps you completed at the start of the study and at month 4. You'll receive a phone call from the study staff to set up your in-person appointment and you'll be reminded of study task instructions over email.

- You'll complete a longer survey (similar to the one you'll complete at the beginning with additional questions about how the program is going for you). This should take about 45 minutes.
- You'll go to whatever Labcorp lab location is most convenient for you to 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 3 tsp will be drawn. The blood draw should take approximately 15 minutes.
- We may mail you a blood test kit for you to complete at home. Everything you need to perform and mail the tests will be included in the kit. You may mail your blood sample to the lab when you complete the finger prick. This blood test will only measure your hemoglobin A1c (HbA1c).
- You'll be contacted over the phone for one 24-hour dietary recalls; the phone calls will each last 20-30 minutes.
- You'll attend your in-person appointment at Domino's Farms and we'll measure your:
    - Weight and height
    - Acne and hirsutism
    - Body composition measured (DEXA scan); the scan itself lasting about 30 minutes.
        - You'll take a pregnancy test at the appointment if you're of child-bearing potential and will not receive the scan if you are pregnant.
    - Blood sugar with a CGM attached to your upper arm. After two weeks with the CGM, you'll remove the device and mail it back to us in pre-paid and labeled packaging.
        - You will be asked to not take more than 500 mg of Vitamin C per day or more than 650 mg of aspirin per day while wearing the sensor during the study period.
    - Your appointment should take less than 2 hours.
- You'll weigh yourself on your own scale at home.

- If you're not within driving distance to Ann Arbor, you will not have this in-person appointment. However, you will do the following:
    - Body weight and self-report of height
    - Possible self-placement of a continuous glucose monitor (CGM) (participants will wear their CGM (which will not provide them with any feedback) for 2 weeks before they mail it back to the study team.)

Once all measures are completed, you'll receive a $90 Amazon gift card. If you attended any group Q&A sessions during months 5 through 12, then your additional payment of $5 per session attended will be added to the gift card amount.

Optional Interviews
You may be asked if you'd like to participate in an optional interview at 4 or 12 months. This 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. You can agree to be recorded and potentially participate in these interviews in section 12 of this consent form. We may not be able to interview everyone who expresses interest.

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 study-related materials),
    - Amazon privacy policy: https://www.amazon.com/gp/help/customer/display.html?nodeId=GX7NJQ4ZB8MHFRNJ,
- 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
- BodyTrace (for scales)
    - BodyTrace privacy policy: https://www.bodytrace.com/medical/privacy.html
    - The University of Michigan has an agreement with BodyTrace to ensure that it is HIPAA-compliant and secure to use with sensitive material.
- Zoom (for interviews)
    - 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.
- DTI Laboratories (HbA1c home test kit)
    - DTI Laboratories privacy policy: https://www.dropbox.com/s/vi36pbpoop20hhw/DTIL-TBA%20HIPAA%20Document%20.pdf?dl=0

- The University of Michigan has an agreement with DTI Laboratories 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
- Microsoft Bookings (for scheduling study visits)
  - Microsoft Bookingsprivacy 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 will communicate with you by text messages 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 like lab results or other private health 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.

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.

By signing this consent form, you are allowing the study team to provide the vendors with your contact information in order to mail or email you study related materials. You are also allowing us to share audio recordings with the transcription companies (if you participate in an interview), 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 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 and 12 months later, and we will share your body composition results once the study is over.

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 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 less than two hours. During the 12-month program, you'll have online, video classes weekly and then monthly, each lasting less than 30 minutes. You'll have a brief check-in survey as part of each class; the surveys should take you about 5 minutes each.

You'll complete study measurements three times, once at the beginning, once at 4 months, and again at the end of the study (after 12 months). These measurements will include a blood draw, which you can do whenever is convenient for you and should take approximately 15 minutes, and an appointment at Domino's Farms (at baseline and 12 months), which should take less than 2 hours each time. A member of the study team will call you once at each the beginning of the study and after 4 and 12 months to ask you about what you ate the day before – these calls will take about 30 minutes. Finally, you'll complete a survey at each of the three timepoints, which will take about 45 minutes.

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. 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. You may be performing an at-home finger prick using a lancet and very small collection tube. You may be asked to prick your finger, collect a small amount of blood in a tiny tube, called a capillary tube, and then mail this back to the lab. The risks of pricking yourself for the at-home test kit include temporary discomfort from the stick, localized bleeding, or localized infection. For more information about the test see: http://www.dtilaboratories.com/accubase-video.html This test is

performed by DTI Laboratories, who is not affiliated with the University of Michigan or Michigan Medicine.

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. *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.
4. *Hirsutism*. This visual scan may make you uncomfortable, but you are free to decline to complete parts of the assessment that require undressing, if you wish. Talk to the technician, who will try to make sure you're comfortable throughout the process.
5. *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. You will have the option to upload images and video of your face for measures of acne and inflammation. These images will be saved on encrypted, University computers and will only be seen by members of the study team. Sharing images and video comes with the possibility of loss of privacy, though this is rare. You may decline to complete this optional section of the questionnaire if you wish.
6. *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. 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. Another possible side effect includes a rash. For participants in either diet group, rapid weight loss can cause temporary hair loss. Weight loss can also cause a gallstones, or hardened deposits that form in the gallbladder, which would cause symptoms such as pain in the upper abdomen that persists for 30 minutes or more, nausea, and vomiting. If you experience symptoms of gallstones or suspect that you may have them, you should contact your primary care provider for treatment and notify the study team. The study staff will provide resources 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.
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. *Hypoglycemia (very low blood sugar)*. Carefully following the diet and lifestyle recommendations in this program may improve your glucose levels. If you are on metformin, there is a very low 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.
9. *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.

10. *At-home tasks.* You may find it inconvenient to complete weekly and monthly classes online. Also, you could experience distressing emotions during some of the sessions. If this happens, you can stop and speak to the study staff.
11. *Recording.* If you participate in an interview or group session, your interview or session will be recorded. These recording will be saved on encrypted, University computers. We will avoid using any personal information in the interview 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 can report any issues you experience in your weekly or monthly class check-in surveys or email your coach. 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 PCOS 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 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 will receive a $20 Amazon gift card for sending in your CGM at the start of the study, a $65 via Amazon gift card for completing all 4-month measurements, and $90 via Amazon gift card for completing all 12-month measurements. If you attend the group Q&A discussions during months 5 through 12, you will receive a monetary incentive of $5 per session to be added to your 12-month gift card after completing the program measurements. The additional payment for attending Q&A sessions could total up to $80.

8.3 Who could profit or financially benefit from the study results?
Dr. Laura Saslow's partner, Mr. Hovig Bayandorian, is an inventor of software used in this study, which has purchased a software services agreement for its use.

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 and dental records
- Any records relating to condition, the treatment received, and 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 SUPER 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 Coordinators:

- Jenny Grone and Kate Raymond
  Telephone: 734-763-1227
  Email: msuperstudy@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 the study coordinator.

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 optional audio and video recording as part of an interview at month 4 or month 12 and during other interactions with the coach. If you do not agree to be recorded, you CAN take part in the study, but not in the interviews and interactions with your coach will be limited to email.

_____ 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 for Medical Record Access for Future Research

This project involves the option to allow the study team to access your medical records 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 medical records. 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 access my records for future research.

_____ No, I do not agree to let the study team access my records for future research.

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-E

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): _____

UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

NAME OF STUDY AND RESEARCHERS

Title of Project: Supporting Understanding of PCOS Education and Research: Provider Survey

Principal Investigator: Dr. Laura Saslow

GENERAL INFORMATION

We're doing a study to learn more about provider perspectives of dietary advice for polycystic ovary syndrome (PCOS). To get information, we'd like 184 people to answer a survey. We expect it to take about 15 minutes to complete the survey.

Answering this survey is voluntary. You don't have to answer it if you'd rather not. You can skip any questions that you don't want to answer, whatever the reason, and you don't have to tell us why. Choosing not to answer our survey won't affect the medical care you might receive at the University of Michigan Health System.

It's possible that some of the questions may make you feel uncomfortable. If a question makes you uncomfortable, you can just skip it and go to the next question.

To keep your information confidential, we will save your information on encrypted, password-protected University computers. We'll label your survey with a code, rather than your name or any other details that someone could use to identify you. Although we'll keep a list of all the people who answered our survey, no one outside our study team will be able to figure out who answered the survey or which people gave which answers. We plan to publish what we learn from this study, but we won't include any personal information that could reveal who answered the survey.

Answering our survey won't benefit you directly. We hope what we learn will help other people in the future.

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.

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.

Dr. Laura Saslow's partner, Mr. Hovig Bayandorian, is an inventor of software used in this study, which has purchased a software services agreement for its use.

To thank you for taking part in our study, we'll donate $10 to a charitable organization of your choosing after you take the survey.

A description of this clinical trial may be available on www.ClinicalTrials.gov. This website 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.

CONTACT INFORMATION

To find out more about the study, to ask a question or express a concern about the study, or to talk about any problems you may have as a study subject, you may contact one of the following:

Principal Investigator: Dr. Laura Saslow Mailing Address: Office 2178, 400 N Ingalls St, Ann Arbor, MI, 48109 Telephone: 734-764-7836 Email: saslowl@umich.edu	Study Coordinator: Sarah Greenwell Mailing Address: None Telephone: 734-763-1227 Email: saangree@med.umich.edu

You may also express a concern about a study by contacting the Institutional Review Board:

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

If you are concerned about a possible violation of your privacy or concerned about a study, you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111.

SIGNATURES

Research Subject:

I understand the information printed on this form. My questions so far have been answered.

Signature of Subject: _____ Date: _____

Name (Print legal name): _____

Patient ID:_____ Date of Birth: _____

Legal Representative (if applicable):
Signature of Person Legally
Authorized to Give Consent_____ Date: _____

Name (Print legal name): _____ Phone: _____

Address: _____
Check Relationship to Subject:

Parent Spouse Child Sibling Legal Guardian Other: _____

[If this consent is for a child who is a ward of the state (for example a foster child), please tell the study team immediately. The researchers may need to contact the IRBMED.]

Reason subject is unable to sign for self:
_____

_____