The University of Michigan PCOS Intervention Using Nutritional Ketosis

NCT03987854

6/18/2019

********************DO NOT DELETE OR ALTER THIS PAGE********************

**CAUTION: IF YOU HAVE PRINTED THIS CONSENT FOR USE WITH PARTICIPANTS, IT IS NOT THE IRBMED APPROVED VERSION. Access the approved/watermarked consent from the Documents Tab in the main study workspace. The approved/watermarked document *will not* contain this cover page and *will* have the approval watermark present in the header.**

**********

## INSTRUCTIONS FOR EDITING THIS DOCUMENT

1. Turn on Track Changes.
2. Make necessary changes in consent, and update the footer intended for study team version control.
3. Upload the revised consent into Section 10-1, maintaining the IRBMED standard naming convention as follows:
   - **Consent - Tracked**
   - **Consent -** *Concise Subtitle* **– Tracked** (provide a subtitle when there are multiple consents associated with the study)
   - **Assent - Tracked**
   - **Parental Permission/Assent - Tracked**
   - **Parental Permission – Tracked**

**NOTES:**
Words identified above in bold must not be changed; words identified in italics may be modified by the study team. Informed consent subtitles should be a one or two word descriptor, such as**:** **Consent – *Genetic* – Tracked** or **Consent – *Blood Draw* - Tracked**.

Each subsequent track changes version should be stacked on the previously uploaded track changes version.

**DO NOT** delete any documents or stacks of documents from eResearch; these are retained for historical and regulatory reference purposes.

**DO NOT** upload a clean version of the consent**.**

## ---------- IRB OFFICE USE ONLY ----------

**Study ID: HUM00113697 / Amendment ID: Ame00089991**

**Approval Date: 1/20/2019**

**Document Finalized: 6/18/2019 3:58 PM**

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

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

**Study title:** The PINK Study (PCOS Intervention using Nutritional Ketosis)

**Company or agency sponsoring the study:** This research is sponsored by the University of Michigan Diabetes Research Center.

**Names, degrees, and affiliations of the principal investigator and study coordinator (if applicable):**
**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 information that will help you decide whether to join the study. All information in this form is important. Take time to carefully review this information. After you finish, 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 friends, family, or other doctors about your possible participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you do, be sure you understand what the study is about.

## 2. PURPOSE OF THIS STUDY

**2.1 Study purpose:** This study is to explore the impact of a very low-carbohydrate, ketogenic diet for women with PCOS (polycystic ovary syndrome).

## 3. WHO MAY PARTICIPATE IN THE STUDY

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

### 3.1 Who can take part in this study?

You may be eligible for this study if you are a woman with PCOS interested in losing weight.

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

We expect up to 30 people to take part in this study.

## 4. INFORMATION ABOUT STUDY PARTICIPATION

### 4.1 What will happen to me in this study?

We will contact the pool of potentially eligible participants by sending them a letter describing the study, which we will also follow up with a phone call. We will also use flyers posted throughout our institution as well as advertise locally, in our referral areas, on our web site and on a variety of other

institutional web sites including https://umhealthresearch.org/ and national websites such as PCOS support groups. We will also promote the study to other physicians and healthcare providers.

You will be eligible if you meet our criteria: overweight or obese (BMI 25-50), 21-40 years old, have regular access to the internet, be able to engage in light physical activity, and willing and able to follow the assigned intervention. Your participation in the trial will need to be approved by your primary care physician or another healthcare provider who functions as your primary care physician, such as an endocrinologist.

After passing preliminary eligibility based on an online screening survey (using an online consent form), we will ask you to (1) have your primary physician approve your participation in the trial, (2) answer online surveys about self-reported physical and psychological well-being, (3) perform a 3-day food diary, (4) go to a lab for a blood draw, and (5) weigh yourself on the bodyweight scale that we will mail you.

Then, you will be assigned to our online low-carbohydrate diet. This diet has been shown to reduce blood pressure, insulin, and inflammation. In general, you will be advised to eat foods such as leafy greens, non-starchy vegetables, meat, eggs, cheese, berries, nuts, and seeds. You will be advised to avoid foods such as bread, pasta, potatoes, flour, and beans. You will also receive:

- An online program to support you and help you lose weight and get your blood sugar under control. This includes online videos and handouts. Each session will take about 15-60 minutes to complete. In the classes, you will learn how to implement the diet in a healthy way, tools to help you stick to the diet, and how to manage stress in your daily life. The total amount of out-of-class time will be about 2-5 hours a week.
- Text messages, which will provide reminders and encouragement.
- Materials mailed to you over the 4 months to help you change your diet, including cookbooks for your new meal plan.
- A coach that will help answer your questions and support you along the way.
- Information about positive affect skills (such as gratitude and positive reappraisal, in order to help you enjoy the program more and be able to stick with the program) and mindfulness and mindful eating skills (such as ways to better pay attention to what you are feeling and your level of hunger, in order to help you enjoy the program more and be able to stick with the program).

At the end of the 4-month program, we will ask you to repeat the same steps as at the start (self-report, 3-day food diary, blood draw, and body weight, as well as answering questions about your satisfaction with and feedback about the study and program. We may ask to interview at the end of the study about your experiences. You will receive $60 for finishing the 4-month measurements.

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

Each participant will receive diet and lifestyle recommendations over 4 months. You will have baseline and 4-month in-person blood test visit that will last less than 30 minutes. Other tasks associated with the study will take variable amounts of time.

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

Some of your study materials and e-mails will be sent directly to you through vendors such as Amazon and Zinc.io (for mailing gift certificates and cookbooks, as well as for encrypted storage), BodyTrace (body weight scale), GSuite/Gmail and Postmarkapp (for e-mails), Qualtrics (for surveys), and Twilio (for text messages). By signing this consent form you are allowing the study team to provide the vendors

with your contact information as needed to mail you something to your address, email you, or text 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 as these will be shared with you in a private manner, such as over the phone or through the Michigan Medicine patient portal.

**How will your blood samples be stored and used?**
Your blood will be frozen and stored until it is sent to a lab for testing. Blood tests may include diabetes tests (fasting glucose and hemoglobin A1c), dyslipidemia tests (serum lipid panel), and other tests including those related to hormones.

**Will you receive your test results?**
If you wish, you will receive these blood results from the study staff at the end of the 4-month program.

**What are your responsibilities?**
As a subject participating in this research study, you have certain responsibilities that may apply to this study, such as ensuring that you arrive at all of your scheduled appointments, follow the study meal plans, and report any adverse reactions you may have during the study.

**4.2 How much of my time will be needed to take part in this study?**
Your participation in the study will take about 4 months plus the time it takes for you to do the baseline and outcome measurements. Each assessment (at start and 4 months later) may take several hours to complete. Participation in the diet and lifestyle program will take varying amounts of time, but the materials may take 1-2 hours to read and apply each week

**4.3 When will my participation in the study be over?**
The study period is about 4 months in duration. At the end of the 4-month program, participants will be asked to complete a post-program tasks. Your participation in the study will end at this time.

**4.4 What will happen with my information and/or biospecimens used in this study?**
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 measurements:* It is very rare for a blood test to result in serious complications; however, there is a very small possibility of complications arising such as bleeding, bruising, and dizziness. For example, 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 is fairly common after a blood test; the person taking your blood will use common procedures to prevent more severe bruising to take place. Some people may experience dizziness during or after a blood

test; this is very common in people who have a fear of needles and injections. If you are feeling faint before or during a blood test, tell the person taking your blood so that they can help you.

2. <u>Questionnaires:</u> *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.*

3. <u>Diet:</u> *You may experience some side effects when you first reduce the amount of sugars and starches in your diet, such as constipation, headache, bad breath, and muscle cramps. These symptoms usually go away after the first couple weeks on the diet, especially if you follow our recommendations for lessening these effects. If this happens, you can talk to the study staff. If your concerns or side effects are severe, you should contact your physician.*

4. <u>Dietary changes:</u> *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.*

5. <u>Home assignments:</u> *You may find it inconvenient to complete the home assignments for the class. Also, you could experience distressing emotions during some of the home assignments. If this happens, you can stop and speak to the study staff.*

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

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

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

**5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?**
The researchers have taken steps to minimize the risks of this study. Even so, you may still have problems or side effects, even when the researchers are careful to avoid them. Please tell the researchers listed in Section 10 about any injuries, side effects, or other problems that you have during this study. You should also tell your regular doctors.

We will ask you to measure your blood pressure, blood sugar and/or ketone levels, and body weight in order to assess how your body changes in response to the diet and lifestyle recommendations. These changes may mean that your medications will need to be adjusted. Our research team will be in touch with your medical team and you about these changes.

**5.3 If I take part in this study, can I also participate in other studies?**
<u>*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*</u>. 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 participants may receive benefits. These may include reduced blood pressure, glycemic control, weight loss, reduced risk for PCOS complications, and decreased feelings of stress, but this cannot be guaranteed. The information that you provide may also provide benefit to other individuals like you, by helping health professionals and researchers better understand how to help people with these conditions improve their health and lower their risk for complications.

**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?**
You are free to choose not to participate in this study. If you decide not to take part in this study, there will be no penalty to you. You will not lose any of your regular benefits, and you can still get care the way you usually do.

## 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.

**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 all research-related items or services that are provided only because you are in the study. 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 $60 at the end of the study for finishing the outcome measurements. You will be paid with an Amazon.com gift certificate that will be e-mailed to you. In addition, you will be able to keep any materials that you may receive as part of the study.

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

This research is done without a financial conflict of interest.

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 information will be stored on encrypted servers and computers. We will mail class information weekly using e-mail and may send you text messages. You may e-mail or call us about questions pertaining to the study or your health. Participation in research may involve a loss of privacy, but information about you will be handled as confidentially as possible. Questionnaire responses are confidential and will not be shared with people outside the study. Your personal information may be given out if required by law.

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 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 accounting department may need your name, address, Social Security number, payment amount, and related information for tax reporting purposes.
- 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.
- As mentioned above, some of your study materials and e-mails will be sent directly to you through vendors such as Amazon and Zinc.io (for mailing gift certificates and cookbooks, as well as for encrypted storage), BodyTrace (body weight scale), GSuite/Gmail and Postmarkapp (for e-

mails), Qualtrics (for surveys), and Twilio (for text messages). By signing this consent form you are allowing the study team to provide the vendors with your contact information as needed to mail something to your physical address, email you, or text you.

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

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 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.

## 10. CONTACT INFORMATION

**10.1 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

**You may also express a question or concern about a study by contacting the Institutional Review Board listed below:**

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 (For International Studies, include the appropriate calling codes.)
Fax: 734-763-1234
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.
*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?**

You will be given the ability to download this "Consent to be Part of a Research Study" document, as a pdf file.

## 12. SIGNATURES

**Sig-A**

**Consent/Assent 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-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): _____