UNIVERSITY OF MICHIGAN

UNIVERSITY OF CALIFORNIA, SAN FRANCISCO

CONSENT TO BE SCREENED FOR ELIGIBILITY IN A RESEARCH STUDY

NAME OF STUDY AND RESEARCHERS

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

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

Principal Investigators:

University of Michigan: 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

University of California, San Francisco: Frederick (Rick) Hecht, MD, Director of Research at University of California, San Francisco, Osher Center for Integrative Health; Professor of Medicine University of California, San Francisco School of Medicine

GENERAL INFORMATION

We're doing a study to compare two dietary approaches for people with type 2 diabetes. This research will test whether a very low-carbohydrate or a plate-method diet better improves outcomes like blood glucose control and body composition for patients with type 2 diabetes 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 ask you some questions about your health history and you'll get a fasting blood draw to check your hemoglobin A1c (HbA1c), which is a measure of how well your glucose has been controlled over the previous few months, your liver and kidney health, your thyroid, and whether you have any other conditions that may make you ineligible to join the study. It's possible you may need a second blood draw based on your test results to see whether you are eligible to join the study.

You will have this blood draw at a LabCorp location closest to you and you'll be sent a lab slip to bring to your blood draw. Fasting means that you cannot have anything to eat or drink except for water for 8 hours before you arrive. It will take about one week to get the results.

No information will be taken from or added to your medical records.

We'll use a needle to take less than 2 tbsp of blood from your arm. This usually takes less than a minute.

There is a small chance of infection with any blood draw. A sterile needle will be used, and your skin will be cleaned 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. The staff at the clinic will give you first aid if you need it. We'll label your blood sample with a code and your date of birth. After the lab finishes analyzing your blood, they'll destroy what's left of your blood sample.

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.

Taking the survey about your health history and getting screening blood draws to find out whether you qualify for our study is voluntary. You don't have to take part if you don't want to. Choosing not to take part won't affect your medical care in any way. Even if you do qualify for the study and decide to join, you can change your mind later and leave the study.

Determining whether you qualify for the study won't benefit you directly.

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

Your signature in the next section means that you have received a copy of this consent document.

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:

If you are in Michigan	If you are in California
Principal Investigator: Laura Saslow, PhD Mailing Address: Office 2178, 400 N Ingalls Street, Ann Arbor, MI, 48109 Telephone: 734-764-7836	Principal Investigator: Rick Hecht, MD Mailing Address: UCSF Osher Center for Integrative Health, UCSF Box 1726, San Francisco, CA, 94143 Telephone: 415-353-9743
Study email: legendstudy@umich.edu Telephone: 734-763-1997	Study email: legendstudy@ucsf.edu Study Coordinators: Vierka Goldman or Vivian Liu Phone: 415-353-9723

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): _____