The Ohio State University Combined Consent to Participate in Research and HIPAA Research Authorization

Study Title:	A Low-INsulinemic Dietary Intervention to Reduce BReast Cancer RisK in High-Risk Women (LIN-BRiCK)
Principal Investigator:	Fred Tabung, PhD, MSPH
Sponsor:	American Cancer Society

- **This is a consent form for research participation.** It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.
- **Your participation is voluntary.** You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University, The James, or the Stefanie Spielman Comprehensive Breast Center. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.
- **You may or may not benefit as a result of participating in this study.** Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious depending on the nature of the research.
- **You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate.** If you decide to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider participating in this study for the reasons explained below.

Key Information About This Study

The following is a short summary to help you decide whether or not to be a part of this study. More detailed information is listed later in this form.

This 12-week dietary intervention study will assess the ability of participants to follow a new dietary pattern based on foods that lower the insulin response and inflammatory markers in blood. We will enroll women at high risk for breast cancer to complete a 12-week intervention consisting of: 1) seven 2-hour group nutrition education sessions focusing on food groups important to this new dietary pattern, tips for incorporating these foods into the diet, smart shopping tips, food tastings, short cooking demonstrations, and question/answer period; 2) three individual diet counseling and motivational interviewing sessions, which will be based on questions that arise at the group sessions, the individual's recent food intake, and the individual's body weight. To assess food intake, participants will be asked to complete 3-day food records several times throughout the study, as well as questionnaires at the start and end of the study. Two times, at the start and end of the study, participants will be asked to collect a 24-hour

urine sample and a stool sample at their home and will be asked to come to the lab to provide a blood sample. Height, weight, and waist circumference will also be measured, and activity will be monitored with a wearable physical activity tracker (activPAL accelerometer). If participants can follow this new dietary pattern, researchers can use it in future intervention studies targeting cancer prevention and control.

1. Why is this study being done?

This study is being done to see if people can follow a new dietary pattern that consists of foods that lower the insulin response and lower levels of inflammatory markers in the blood. This dietary pattern has been developed out of multiple, large epidemiologic cohorts, but has never before been evaluated in an intervention study. In the large epidemiologic cohorts, this new dietary pattern was associated with reduced risk of some cancers and reduced risk of long-term weight gain. Parts of this new dietary pattern are quite different from typical dietary recommendations, and much education will be needed. Overall, compared to the typical American diet, this new dietary pattern is moderately low in total fat and saturated fat, low in protein from animal foods but high in protein from plant sources, high in fruits and vegetables, high in whole grains, and high in dietary fiber.

2. How many people will take part in this study?

Approximately 30 postmenopausal women or women over the age of 45 years at high-risk for breast cancer will be recruited for participation in this study.

3. What will happen if I take part in this study?

Women who meet the eligibility criteria and choose to volunteer for this study will be consented. Participants will be asked to attend:

- The study orientation at the Stefanie Spielman Comprehensive Breast Center, where they will receive instructions on how to complete the study questionnaires, how to complete the 3-day food records, how and when to collect their urine and stool, and how to wear their physical activity tracker. They will also receive study bags, physical activity trackers, tools to measure dietary intake if needed (like measuring cups), and the necessary containers for urine and stool collection. This visit is expected to last 2 hours.

- Six group education sessions at the Stefanie Spielman Center, where participants will learn how to follow the new dietary pattern. These will be held at week 0, week 1, week 2, week 3, week 5, and week 6, and are expected to last about 2 hours. These group sessions will include education on food groups important to the new dietary pattern, ideas for incorporating these foods into the diet, smart shopping tips, food tastings, short cooking demonstrations, and a question/answer period. These sessions will be recorded and will be able to be accessed electronically by participants if they are unable to make it to the session or if they need a refresher.

- Three individual nutrition counseling and motivational interviewing sessions with a registered and licensed dietitian, either at the Stefanie Spielman Center or remotely (through a HIPAA-compliant telehealth program). These will be held between weeks 3 and 5, between weeks 7 and 9, and between weeks 9 and 11. These sessions are expected to last 30 minutes, and will be based on questions that arise at the group sessions, the individual's recent food intake, and the individual's body weight and energy needs. These sessions will be recorded so that the interviewing technique can be evaluated by an external researcher.

- Two assessment visits at the Stefanie Spielman Center, at week 0 and week 12. Participants will be asked to collect a single stool sample and collect their urine for 24 hours before each of these visits. They will be asked to bring both samples with them to the assessment visit (carrying bags will be provided). Participants will be asked to either bring their 3-day food records to the assessment visits, or submit them electronically before the assessment visit. Participants will have their blood drawn (approximately 8.5 tsp/42 ml) by lab personnel, and will have their height (week 0 only), body weight, and waist circumference measured by one of the study coordinators. They will also be asked to complete several online study questionnaires before this visit. These questionnaires could also be completed on the study iPad at the visit if the participant prefers this. These visits are expected to last 15 minutes if the questionnaires were completed before the visit, or 2 hours if the questionnaires were not completed before the visit.

Participants will be asked to complete the following questionnaires. All questionnaires can be completed at home via a secure online portal, or on the study iPad at the appropriate study visit.

- Diet History Questionnaire-III, which measures a person's habitual diet over the previous 3 months by asking questions about how frequently they consume different foods. This questionnaire takes about 1 hour to complete, and will be completed at week 0 and week 12.
- International Physical Activity Questionnaire, long version, which measures self-reported physical activity. This questionnaire takes about 10 minutes to complete, and will be completed at week 0 and week 12.
- International Physical Activity Questionnaire, short version, which measures self-reported physical activity. This questionnaire takes about 5 minutes to complete, and will be completed at week 4 and week 8.
- Patient-Reported Outcomes Measurement Information System (PROMIS) scales 29, which measures a person's physical function, social roles, fatigue, depression, anxiety, pain, and sleep disturbance. This questionnaire takes about 5 minutes to complete, and will be completed at week 0 and week 12.
- Global Health Short Form, which measures general physical and mental health. This questionnaire takes about 5 minutes to complete, and will be completed at week 0 and week 12.
- Food preference questionnaire, which will help researchers choose appropriate foods for each participant on Instacart. This questionnaire takes about 10 minutes to complete, and will be completed at week 0, week 4, and week 8.

- Program evaluation, which will assess participants' satisfaction with this intervention and nutrition education and counseling program. This questionnaire takes about 5-10 minutes to complete, and will be completed at week 12.

Participants will be asked to collect samples for the following biological outcomes before or during the week 0 and week 12 assessment visits:

- Body measurements (body weight, waist circumference)
- Blood pressure and heart rate
- Fasting blood draw (lipids – total cholesterol, LDL cholesterol, HDL cholesterol, triglycerides; glycemic control and insulin response biomarkers – fasting glucose, insulin, HbA1c, C-peptide, HOMA-IR, HOMA-B, IGFBP-1, IGFBP-2; markers of chronic inflammation – C-reactive protein, IL-6, TNFα-R2, adiponectin, leptin; metabolomics and lipidomics analyses.
- 24-hour urine collection for metabolomics and lipidomics analyses.
- Single stool sample for microbiome, metabolomics, and lipidomics analyses.

Participants will be asked to complete the following before week 0, week 4, week 8, and week 12:

- Three-day food record, which measures all food and drink consumed for three separate non-consecutive days (two weekdays and one weekend day). Participants will be asked to record every food, drink, and dietary supplement that they consume, including the exact type and amount. Each 3-day food record takes 45-60 minutes to complete. Participants will be asked to either bring their 3-day food records to the week 0 and week 12 assessment visits and the counseling visits in week 4 and week 8, or submit them electronically.

Participants will be asked to track their activity levels by wearing a physical activity tracker (activPAL accelerometer), provided at no cost to the participant. The physical activity tracker is a device you wear on your thigh that counts the number of steps you take and also measures other movements. The study team will teach you how to wear your activity tracker properly. At the week -1 orientation visit, a member of the research team will show you how to attach the activity tracker to your thigh using Tegaderm, a brand of medical tape. You can attach the activity tracker to your thigh when you get home, and it should be left on for the next 7 days. You will be asked to wear it again for 7 consecutive days during the last week of the study. Instructions will be provided on how to re-attach the physical activity tracker.

When needed, participants will receive phone calls from study staff using the Google Voice app.

Participants will receive a grocery delivery via Instacart every 1-2 weeks, with foods especially important to the new dietary plan. These foods will be chosen by the OSU research team, and will not cost you anything. Your address and mobile number will be stored in a secure Instacart account that only the OSU research team can access. The Instacart shopper will have access to your address and mobile number for delivery and contact purposes. You will not receive any Instacart promotional texts. You will be able to choose the delivery address, choose a day and time window for your grocery delivery, and provide delivery instructions for the shopper. The

delivery will need to be accepted by a person and cannot be left outside your door. You will receive an SMS text message from Instacart when your delivery has been scheduled. If absolutely necessary, you will have the opportunity to change your delivery time if you happen to have a conflict on that particular day. **However, we ask that you try your best to be available during your delivery window and to minimize changes to the delivery day and/or time.** Participants will also receive a text from Instacart when the groceries are delivered.

4. How long will I be in the study?

The nutrition intervention study will last for 12 weeks. You will be asked to follow the diet as best as you can for the entire duration of the study. The total time commitment is estimated to be about 25 hours over the entire 12-week study. The specific time commitment for individual study activities is as follows:

Orientation and group classes: 2 hours x 7 classes	= 14 hours
Individual counseling: 30 minutes x 3 sessions	= 1.5 hours
Assessment visits: 15 minutes x 2 visits	= 0.5 hour
Urine and stool collection: 30 minutes x 2 collections	= 1 hour
Questionnaires:	= 3.5 hours
3-day food records: 1 hour x 4 records	= 4 hours
Total time over 12-week study:	**= 23.5 hours**

5. Can I stop being in the study?

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University, The James, or the Stefanie Spielman Comprehensive Breast Center.

6. What risks, side effects or discomforts can I expect from being in the study?

The questionnaires may result in uncomfortable feelings and anxiety from specific questions or fatigue resulting from completing the questionnaires. Participants have the option to skip questions they prefer not to answer.

The risks associated with the assessments are expected to be minimal. The risks of drawing blood include pain, a bruise at the point where the blood is taken, redness and swelling of the vein and infection, and a rare risk of fainting. The medical tape used to attach the physical activity tracker to a participant's leg can cause skin irritation. The physical activity tracker can be moved to the other leg if irritation occurs.

In the unlikely case of any adverse events, Drs. Tabung (study principal investigator) and Sardesai (study physician) will be notified immediately.

7. What benefits can I expect from being in the study?

You will be contributing to society's knowledge of the benefits of nutrition programs for women at high risk for breast cancer. You will have the opportunity to receive six free nutrition education classes and three individual nutrition counseling sessions, free food deliveries, and free fitness tracking.

8. What other choices do I have if I do not take part in the study?

You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled.

9. What are the costs of taking part in this study?

There are no costs related to participation in this study.

10. Will I be paid for taking part in this study?

At no cost to you, you will receive a grocery delivery via Instacart every 1-2 weeks with foods chosen by the research team that are deemed essential to this diet intervention (valued at $35-40 for each delivery).

11. What happens if I am injured because I took part in this study?

If you suffer an injury from participating in this study, you should notify the study doctor immediately (Sagar Sardesai, MD, MPH), who will determine if you should obtain medical treatment at The Ohio State University Wexner Medical Center.

The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health care expenses for this study.

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

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of research participants.

13. Will my de-identified information and bio-specimens be used or shared for future research?

Yes, it/they may be used or shared with other researchers without your additional informed consent.

14. Will my study-related information be kept confidential?

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law.

Also, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- U.S. Food and Drug Administration;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- The sponsor supporting the study, their agents or study monitors; and
- Your insurance company (if charges are billed to insurance).

If we find information that significantly impacts your health, we will share it with you. We will notify you via a phone call if your blood pressure, total cholesterol, LDL cholesterol, HDL cholesterol, triglycerides, fasting glucose, insulin, CRP, or HbA1c are out of the normal ranges.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search the website at any time.

We will work to make sure that no one sees your survey responses without approval. But, because we are using the Internet, there is a chance that someone could access your online responses without permission. In some cases, this information could be used to identify you. Your data will be protected with a code to reduce the risk that other people can view the responses.

15. HIPAA AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

I. What information may be used and given to others?

- Past and present medical records;
- Research records;
- Records about phone calls made as part of this research;
- Records about your study visits;

- Information that includes personal identifiers, such as your name, or a number associated with you as an individual;
- Information gathered for this research about:
  Laboratory and other test results
  Diaries and questionnaires

II. Who may use and give out information about you?

Researchers and study staff.

III. Who might get this information?

- The sponsor of this research. "Sponsor" means any persons or companies that are:
  - working for or with the sponsor; or
  - owned by the sponsor.
- Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information;
- The Ohio State University Medical Center Comprehensive Cancer Center's Data Safety Monitoring Board;
- If this study is related to your medical care, your study-related information may be placed in your permanent hospital, clinic, or physician's office record;
- American Cancer Society (sponsor)
- OSUCCC Shared Resources

IV. Your information <u>may</u> be given to:

- The U.S. Food and Drug Administration (FDA), Department of Health and Human Services (DHHS) agencies, and other federal and state entities;
- Governmental agencies in other countries;
- Governmental agencies to whom certain diseases (reportable diseases) must be reported; and
- The Ohio State University units involved in managing and approving the research study including the Office of Research and the Office of Responsible Research Practices.

V. Why will this information be used and/or given to others?

- To do the research;
- To study the results; and
- To make sure that the research was done right.

VI. When will my permission end?

There is no date at which your permission ends. Your information will be used indefinitely. This is because the information used and created during the study may be analyzed for many years, and it is not possible to know when this will be complete.

VII. May I withdraw or revoke (cancel) my permission?

Yes. Your authorization will be good for the time period indicated above unless you change your mind and revoke it in writing. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the researchers. If you withdraw your permission, you will not be able to stay in this study. When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

VIII. What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study and receive research-related treatment. However, if you are being treated as a patient here, you will still be able to receive care.

IX. Is my health information protected after it has been given to others?

There is a risk that your information will be given to others without your permission. Any information that is shared may no longer be protected by federal privacy rules.

X. May I review or copy my information?

Signing this authorization also means that you may not be able to see or copy your study-related information until the study is completed.

16. Who can answer my questions about the study?

For study questions, concerns, or complaints, to withdraw consent and HIPAA authorization, or if you feel you have been harmed as a result of study participation, you may contact the **Principal Investigator, Dr. Fred Tabung, at fred.tabung@osumc.edu or 614-293-7398**.

For questions related to your privacy rights under HIPAA or related to this research authorization, please contact:

Medical Center Privacy Office
650 Ackerman Rd
Columbus, OH 43202
Phone: 614-293-4477
Email: privacyoffice@osumc.edu

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the Office of Responsible Research Practices at 1-800-678-6251.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact **Dr. Sagar Sardesai at sagar.sardesai@osumc.edu or 614-366-8541**,

Signing the consent form

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this combined consent and HIPAA research authorization form**.**

Printed name of participant	**Signature of participant**
	AM/PM
	Date and time
Printed name of person authorized to consent for participant (when applicable)	**Signature of person authorized to consent for participant (when applicable)**
Relationship to the participant	**AM/PM** **Date and time**

Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

Printed name of person obtaining consent	**Signature of person obtaining consent**
	AM/PM
	Date and time

Witness(es) - *May be left blank if not required by the IRB*

Printed name of witness	**Signature of witness**

_____ AM/PM
Date and time

_____ _____
Printed name of witness Signature of witness

_____ AM/PM
Date and time