COMPOUND AUTHORIZATION AND CONSENT FOR PARTICIPATION IN A RESEARCH PROJECT YALE UNIVERSITY SCHOOL OF MEDICINE – YALE-NEW HAVEN HOSPITAL 200 FR. 4

Study Title: Lifestyle, Exercise, and Nutrition Study Early after Diagnosis (LEANer)
Principal Investigator: Tara Sanft, MD
Funding Source: National Cancer Institute, Breast Cancer Research Foundation

Invitation to Participate and Description of Project

You are invited to participate in a research study because you have been diagnosed with breast cancer and will be receiving chemotherapy. This study will include 172 women and is designed to find out if keeping a healthy lifestyle, in terms of diet and physical activity, helps women comply with their treatment for breast cancer, for example have chemotherapy treatments as planned.

In order to decide whether or not you wish to be a part of this research study, you should know enough about its risks and benefits to make an informed decision. This consent form gives you detailed information about the study, which a member of the research team will also discuss with you. This discussion will go over all aspects of this research: its purpose, the procedures that will be performed, any risks of the procedures, possible benefits and possible alternative treatments. Once you understand the study, you will be asked if you wish to participate; if so, you will be asked to sign this form.

Description of Procedures

If you agree to participate in this study, you may meet with our study staff at Yale-New Haven Hospital four times over the two-year study. If you are unable to complete the in-person visits you will complete all the questionnaires online, by mail or by phone. If you are eligible after you have completed the first visit whether in-person or by phone, you will be placed by chance (like the toss of a coin) into one of two study groups: the nutrition and physical activity counseling group or usual care.

At the first visit, you will learn more about the study and complete some questionnaires (in-person, online or by mail) related to your health history and lifestyle. These will include questions on your diet and exercise habits, medical history, family history of cancer, alcohol use, smoking, quality of life, demographic factors, such as age and education, use of and compliance with medications and supplements and treatment. In addition, if you complete the first visit in-person:

- Height and weight will be measured
- Waist and hip circumference will be measured.
- Grip strength will be measured. This involves squeezing a small rubber ball as hard as possible.
- A research nurse or other trained staff member will take a fasting blood sample of about 3 tablespoons (or 40 ml) from a vein in your arm. Fasting means you may not eat or drink for 12 hours before your appointment. Your appointment is scheduled in the morning so that it is easier for you to fast. Drinking water is allowed and encouraged.

The blood tests are for research purposes only and are done in a research laboratory. No identifying information other than your study ID will be included on the blood tubes.

- A trained staff member will measure the carotenoid level in your skin by placing your thumb in a scanner that uses white light. It takes about a minute to give a reading. You will not feel anything while the reading is being taken.
- You will also have an X-ray examination, called a DEXA scan, that measures your total body fat and bone density. The test involves lying still on a padded table with your clothes on for about 15-20 minutes. The scanner will not touch you and you will not feel any discomfort. With your permission, a copy of the DEXA scan results for this and subsequent visit will be sent to your doctor.

Home activities around the time of each visit that you may be asked to do. A member of the research team will let you know if we would like to do these tasks, however they are optional.

- We will ask you to collect a stool sample using standard procedures. We will give you a kit to complete the home collection after the baseline, post chemotherapy and 1-year. Upon completion, you will return the packet by mail in a specialized self-addressed pre-paid package.

At the second visit which will be scheduled when you finish chemotherapy:

- You will complete several questionnaires about any side-effects you may have had while in chemotherapy, your diet and physical activity, medication, work you have done since starting chemotherapy and thoughts about the study.

If you come for an in-person visit, you will:

- You will have a DEXA scan, similar to that done at your first visit, to measure body fat and bone density.
- A research nurse or other trained staff member will take a fasting blood sample of about 3 tablespoons (or 40 ml) from a vein in your arm. The blood tests are for research purposes only and are done in a research laboratory. No identifying information other than your study ID will be included on the blood tubes.

- Height, weight, waist and hip circumference and grip strength will be measured.
- Like at your first visit, a trained staff member will measure the carotenoid level in your skin by placing your thumb in a scanner that uses white light.

At the third (1-year after starting the study) and fourth (2-years after starting the study) visits:

- We will ask that you complete similar questionnaires to those you completed at baseline plus questionnaires about your thoughts about medications that you may be taking for breast cancer and work you have done since your last visit.

In addition, if you complete these visits in-person:

The procedures (blood draw and DEXA) will be repeated as described above.

- Height, weight, waist and hip circumference and grip strength will be measured
- A trained staff member will measure the carotenoid level in your skin by placing your thumb in a scanner that uses white light.
- If you are taking an aromatase inhibitor, we will also ask for a urine sample. Your urine will be analyzed for aromatase inhibitors.

Assessments	**Screening**	**Baseline**	**Post-chemotherapy**	**1-year**	**2-year**
Questionnaires	**X**	**X**	**X**	**X**	**X**
Height, weight, waist and hip circumference measured#		**X**	**X**	**X**	**X**
Grip strength#		**X**	**X**	**X**	**X**
Blood collection#		**X**	**X**	**X**	**X**
Skin carotenoid measurement#		**X**	**X**	**X**	**X**
DXA scan#		**X**	**X**	**X**	**X**
Urine collection*#				**X**	**X**
Stool collection@		**X**	**X**	**X**	

*If you are take an aromatase inhibitor
#If you complete your visit in-person at Yale New Haven Hospital
@The research assistant will let you know if we wish you to complete this assessment

Usual Care Group

As described above you will be asked to come again to Yale-New Haven Hospital to repeat the initial exams and measurements after chemotherapy, 1 and 2-years, and to complete questionnaires as you did at the beginning of the study. At the post-chemotherapy visit, you will be given information about attending the Yale Survivorship Clinic to receive diet, physical activity counselling and a survivorship care plan. Information will be provided to you about the clinic.

At the end of the 2-year study you will be given the LEAN Lifestyle, Exercise and Nutrition Book and Journal that have been designed for breast cancer survivors who have completed treatment. You will also be able to have an individualized diet and physical activity counselling session with one of our Registered Study Dietitians.

Healthy Lifestyle Group

If you are placed in the Healthy Lifestyle group, one of our Registered Dietitians will meet with you 3 times in the first month, then 2 times each month for months 2 through 5, and then 5 times over the next 6 months (16 sessions in total). You can choose to communicate with the Dietitian either by phone, in-person or by video conferencing for each session. The in-person counseling session(s) will

occur at Smilow Hospital or at a Smilow Care Center at the time you receive chemotherapy or meet with your medical oncologist. Each session will last about 30 minutes. You will also be asked to walk or exercise on your own. You will be counselled to include home based strength training at a safe and gradual pace. The types of exercise will be individually tailored to your needs, but the daily exercise intensity will be equivalent to at least 30 minutes of brisk walking five days per week. There will be a series of videos posted online showing how to do each of the strength training exercises and you will be given a set of weights to use as directed. We will provide you with a Fitbit to wear to record your activity in your log book. To help you meet your physical activity goals, if you so wish, we will provide you with a 1-year membership to a YMCA. Please let a member of the research team know if you wish to have YMCA gym membership. Many YMCA's offer the Livestrong or a similar program for cancer survivors and we encourage participation in this program.

At the post-chemotherapy visit, you will be given information about attending the Yale Survivorship Clinic to receive diet, physical activity counselling and a survivorship care plan. Information will be provided to you about the clinic.

Risks and Inconveniences

Blood Draw

There is a small risk of bleeding, bruising, infection, inflammation, phlebitis, blood clot or discomfort at the site of the blood collection. Attention will be taken to apply pressure following the procedure to reduce bleeding. You may feel dizzy or faint when blood is being withdrawn. We will ask you to lie down for a few minutes until any dizziness passes.

DEXA Scan

A DEXA scan x-ray involves exposure to radiation. Although it can vary from person to person, the whole-body radiation exposure from each scan will be about 80 mrem. Over the 2-year study the total radiation exposure will be 320 mrem, and is approximately equivalent to a uniform whole body exposure of 390 days (approximately a year) of exposure to natural background radiation. The risk of harm from this amount of radiation is low and no harmful health effects are expected. Women who are pregnant or intend to get pregnant during the 2-year study time period are excluded from the study. Women who can get pregnant will have a urinary pregnancy test prior to each DEXA scan, if the pregnancy test is positive the woman will not be able to enroll in the study or, if already enrolled, will no longer be able to participate in the study. However, the data collected prior to pregnancy will be included in the study.

Skin Carotenoid scan

There is no risk from the use of the scanner.

Grip Strength

There are no risks associated with measuring grip strength.

Stool and Urine Collections

There are no risks associated with the stool or urine collection.

FitBit Usage

We will assist in the set up of a FitBit if you are in the Healthy Lifestyles group.

Benefits

You may benefit from participation in this study by learning how to eat and exercise in a safe and effective way. Other women may benefit in the future if we find that following national dietary and exercise guidelines improves compliance with treatment for breast cancer.

Economic Considerations

There is no cost associated with your participation in this study. If you are in the 'healthy eating and exercise group' you will NOT have to pay for counseling or any part for the intervention. You will receive a Fitbit ($50) and a set of weights ($50) to use at home for strength training. You will also receive a 1-year membership at a YMCA if you so wish. Please let a member of the research team know if you wish to have YMCA gym membership. If you are in the 'usual care group' you will receive a visit with a study dietitian and LEAN materials at the end of the study. Whichever group you are in, you will receive a healthy eating cookbook at your final (2-year) visit.

Treatment Alternatives/Alternatives

An alternative treatment is simply to not participate. You will receive the information routinely provided by the medical staff to all patients on diet and physical activity and you can choose to attend the Survivorship Clinic, which provides information on diet and physical activity after the end of your treatment. As mentioned, this study is fully voluntary.

Confidentiality and Privacy

Any identifiable information that is obtained in connection with this study will remain confidential and will be disclosed only with your permission or as required by U.S. or State law. Examples of information that we are legally required to disclose include abuse of a child or elderly person, or certain reportable diseases. We will take several precautions to protect confidential information. All data will be stored on password-protected secure server or computer that are accessible only to the Principal Investigator and the study staff. When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity unless your specific consent for this activity is obtained. Representatives from the Yale Human Investigation Committee may inspect study records during internal auditing procedures. However, these individuals are required to keep all information confidential.

We understand that information about you obtained in connection with your health is personal, and we are committed to protecting the privacy of that information. If you decide to be in this study, the

researcher will get information that identifies you and your personal health information, including data from your electronic medical record (EPIC). This may include information that might directly identify you, such as your name and address. This information will be de-identified at the earliest reasonable time after we receive it, meaning we will replace your identifying information with a code that does not directly identify you. The principal investigator will keep a link that identifies you to your coded information, and this link will be kept secure and available only to the PI or selected members of the research team. Any information that can identify you will remain confidential, stored in locked cabinets, on a secure server or on password-protected computers. The data will be kept in this anonymous form indefinitely.

Online questionnaires will be used which use Qualtrics, this is online survey software which meets all necessary Yale Information Technology Service security requirements. All information you provide in the survey is only accessible to our study staff and is never accessible to Qualtrics. Any identifiable information (e.g. email addresses) you provide in our online survey will be stored in a separate dataset from your answers to the survey questions. In addition, the food questionnaire can be completed online. The online questionnaire is administered by the Fred Hutchinson Cancer Research Center. You will not be asked to provide any identifiable information when completing the questionnaire.

The information about your health that will be collected in this study includes:

- *Research study records*
- *Records from your Electronic Medical Records (EPIC) about your cancer, dates of medical appointments, the treatment for your cancer and any side effects of your treatment, other medical care connected to your cancer, other health problems you may have, medications you are prescribed.*
- *Laboratory records including those services provided in connection with this Study.*
- *Records about phone calls made as part of this research, including about your diet*
- *Records about your study visits and study counseling sessions*
- *Questionnaires*

Information about you and your health which might identify you may be used by or given to:

- *Representatives from Yale University and the Human Investigation Committee (the committee that reviews, approves, and monitors research on human subjects), who are responsible for insuring research compliance. These individuals are required to keep all information confidential.*
- *Those individuals at Yale who are responsible for the financial oversight of research including billings and payments*
- *The Principal Investigator: Tara Sanft, MD*
- *Study Coordinator and Members of the Research Team .*
- *The U.S. Department of Health and Human Services (DHHS) agencies*

By signing this form, you authorize the use and/or disclosure of the information described above for this research study. The purpose for the uses and disclosures you are authorizing is to ensure that the information relating to this research is available to all parties who may need it for research purposes.

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 National Cancer Institute 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 for any purpose you have consented to in this informed consent document including to investigators at Yale; the U.S. Department of Health and Human Services (DHHS) agencies; health care providers who provide services to you in connection with this study; laboratories and other individuals and organizations that analyze your health information in connection with this study, according to the study plan; representatives from Yale University, the Human Investigation Committee, and the Yale Cancer Center Office of Protocol Review and Monitoring (OPRM), who are responsible for ensuring research compliance; the Principal Investigator (Tara Sanft, Ph.D.); Co-Investigators and other investigators; Study Coordinator and Members of the Research Team.

As a participant in a clinical research study involving the Yale-New Haven Hospital (YNHH) Research Unit (HRU), it is important for you to know that your previous medical records of other visits or admissions will become available to the researchers and to the staff of the HRU when information from the HRU visits are added into the medical record.All health care providers subject to HIPAA (Health Insurance Portability and Accountability Act) are required to protect the privacy of your information. The research staff at the Yale School of Medicine and Yale New Haven Hospital are required to comply with HIPAA and to ensure the confidentiality of your information. Some of the individuals or agencies listed above may not be subject to HIPAA and therefore may not be required to provide the same type of confidentiality protection. They could use or disclose your information in ways not mentioned in this form. However, to better protect your health information, agreements are in place with these individuals and/or companies that require that they keep your information confidential.

You have the right to review and copy your health information in your medical record in accordance with institutional medical records policies.

This authorization to use and disclose your health information collected during your participation in this study will never expire.

In Case of Injury

It is unlikely that you will incur injury as a result of participation in this research. Should you have an injury as a result of your participation in this study, treatment will be provided. You or your insurance carrier will be expected to pay the costs of this treatment. You do not waive any of your legal rights by signing this form.

Voluntary Participation and Withdrawal

You are free to choose not to participate and/or donate your blood or/and stool sample. Refusing to participate will involve no penalty or loss of benefits to which you are otherwise entitled (such as your health care outside the study, the payment for your health care, and your health care benefits). If you do become a participant, you are free to stop and withdraw from this study at any time during its course. If you sign this authorization, you may change your mind at any time, but the researchers may continue to use information collected before you changed your mind to complete the research. The researchers will anonymize all data collected, including blood specimen data by removing and destroying all identifiers and links to identifiers so that it cannot be associated with you, but the researchers will not destroy the blood specimen.

To withdraw, you can call a member of the research team at any time and tell them that you no longer want to take part or by writing to Dr. Tara Sanft, Department of Medical Oncology, 300 George Street, Suite 120, New Haven, CT 06651. This will cancel any appointments in the future.

Withdrawing from the study will involve no penalty or loss of benefits to which you are otherwise entitled. If you choose not to participate or if you withdraw it will not harm your relationship with your own doctors or with Yale-New Haven hospital.

If you become pregnant during the study you will no longer be able to participate in the study. Please contact one of the study staff or write to Dr. Tara Sanft, Department of Medical Oncology, 300 George Street, Suite 120, New Haven, CT 06651 if you become pregnant. There are no other circumstances that result in termination from the study.

Optional Specimens for Future Storage

You are invited to allow some of your samples (called specimens) and related information to be stored (banked) for future research to investigate blood or stool biomarkers associated with breast cancer. This may help researchers in the future learn more about how to prevent, find and treat breast cancer.

Your specimens will be stored for an unlimited time. When your specimens and information are stored, we are careful to try to protect your identity from discovery by others. Your samples and information will receive a unique code. Other researchers, who may be located at other institutions, will only receive coded samples and information, and will not be able to link the code to you. Strict security safeguards are in place to reduce the chance of misuse or unplanned release of information.

Using your specimens for research will probably not help you. We do hope the research results will help people in the future.

There is a risk that your information could be misused, such as loss of confidentiality. The chance of this happening is very small. We have protections in place to lower this risk such as only using ID number and date of collection on the samples.

Your specimens and information will only be used for research and will not be sold. There is a possibility that this research may lead to development of products that will be commercialized. If this happens, there is no plan to share any financial gain with you.

Research results will not be returned to you or your doctor. If research results are published, your name and other personal information will not be given.

The choice to take part is up to you. You may choose not to let us store and use your samples, and your care will not be affected by this decision. If you change your mind your samples will not be destroyed but the code connecting your identifiers to the samples will be deleted so your samples will then be anonymous. You can contact the study staff by phone or mail Dr. Tara Sanft, Department of Medical Oncology, 300 George Street, Suite 120, New Haven, CT 06651 to let them know that you have changed your mind about storing your identified samples and request your samples be made anonymous.

I give my permission for my blood and stool sample to be stored and used for other studies related to breast disease after the end of the current study

YES [ ] NO [ ]

I give my permission to be contacted following the end of this study regarding future studies.

YES [ ] NO [ ]

Questions

We have used some technical terms in this form. Please feel free to ask about anything you don't understand and to consider this research and the consent form carefully – as long as you feel is necessary – before you make a decision.

Authorization and Permission

I have read (or someone has read to me) this form and have decided to participate in the project described above. Its general purposes, the particulars of involvement and possible hazards and inconveniences have been explained to my satisfaction. My signature also indicates that I have received a copy of this consent form.

By signing this form, I give permission to the researchers to use [and give out] information about me for the purposes described in this form. By refusing to give permission, I understand that I will not be able to be in this research.

Name of Subject:_____

Signature:_____

Date:_____

_____ _____
Signature of Principal Investigator Date

or

_____ _____
Signature of Person Obtaining Consent Date

If you have further questions about this project or if you have a research-related problem, you may contact the Principal Investigator Tara Sanft at (203) 737-5686. If you have any questions concerning your rights as a research subject, you may contact the Human Investigation Committee at (203) 785-4688. If after you have signed this form you have any questions about your privacy rights, please contact the Yale Privacy Officer at 203/436-3650.