Protocol IO-OS-BC
Breast Cancer Integrative Oncology: Prospective Matched Controlled Outcomes Study
Bastyr IRB No. 09E-1237-01, NIH Grant No. 1R01AT005873, CT.gov No. NCT01366248

INFORMED CONSENT FORM

Research Sponsor:
Bastyr University Research Institute (BURI)                     Fred Hutchinson Cancer Research Center (FHCRC)
Leanna J. Standish, PhD, ND, LAc, FABNO                     M. Robyn Andersen, PhD, MPH
Co-Principal Investigator                                Co-principal Investigator

Funding Sponsors:
National Institutes of Health (NIH)/National Center for Complementary & Alternative Medicine (NCCAM)
Lotte & John Hecht Memorial Foundation

Clinical Site Contacts:

BASTYR INTEGRATIVE ONCOLOGY AT BASTYR CENTER FOR NATURAL HEALTH
Leanna J. Standish, ND, PhD, LAc, FABNO – Principal Investigator
Erin Sweet, ND, MPH, FABNO – Co-investigator
Barbara Osborne, RN – Research Nurse Manager
Morgan Weaver – Clinical Research Coordinator

Researchers’ Statement

We are inviting you to be in a research study to find out how well patients do who receive integrative oncology care. Integrative Oncology (IO) clinics use complementary and alternative therapies prescribed by licensed health care providers (for example, naturopathic physicians and doctors of traditional Chinese medicine (TCM) to support conventional cancer treatments.

The purpose of this consent form is to give you the information you will need to help you decide whether to be in the study or not. Please read the form carefully. You may ask questions about the purpose of the research, what we would ask you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions, you can decide if you want to be in the study or not. This process is called “informed consent.” We will give you a copy of this form for your records.

PURPOSE AND BENEFITS

We want to know if receiving integrated naturopathic and TCM oncology care, in addition to surgery, chemotherapy and radiation, will help people with cancer to live longer, healthier lives. We want to determine how well our patients being treated at IO clinics do over time. We also want to compare how patients who receive IO care do compared to cancer patients who do not receive IO care. With the help of Fred Hutchinson Cancer Research Center (FHCRC) in Seattle we will attempt to find people in the Western Washington Cancer Surveillance System (CSS) registry who are like you in terms of age and cancer staging but have not received naturopathic or TCM oncology care. We are also interested in learning more about your thoughts and feelings about your health. If you agree to participate, we will ask you to fill out questionnaires about your experience with cancer and your health in general.

You will not directly benefit from participating in the study and filling out the questionnaires. However, the information gathered during the course of this study may help us begin to assess how well patients do
who use IO services and the longer-term effects of integrated naturopathic and TCM oncology care on health and quality of life in cancer patients.

**PROCEDURES**

We will ask you to give us permission to retrieve information about your cancer diagnosis and treatment from your medical records. We will also ask you about your decisions about your cancer treatment, about your health, and about your health-related quality of life. Your IO clinic study physician or research staff will ask you to complete a medical records release and a baseline questionnaire to obtain this information. You will then be assigned a unique study ID number and enrolled in study group 1.

We will also search for your name in the Washington State Cancer Registry. Since 1990, a law has required the Washington State Department of Health to collect information about cancer. The registry is kept confidential and only researchers who have been approved may access the information. We plan to link your name to the registry to see if you are listed. The FHCRC and the CSS cancer registry staff will determine if there are other cancer patients in the CSS database who are similar to you in age, race, cancer stage at diagnosis, zip code and marital status.

If we are not able to find a match for you in the CSS database, you will remain in study group 1 and the FHCRC will mail you questionnaires at 6 months and 1 year after enrollment. If we are able to find a match for you, you will be enrolled in study group 1A, and FHCRC will mail you additional follow-up questionnaires at 2, 3, 4, and 5 years after enrollment, or longer if additional funding is available. For both groups 1 and 1A, we will continue to collect data from your medical records for 5 years after enrollment or longer if additional funding is available.

It will take approximately 30 minutes to complete each questionnaire for a total study time commitment of approximately 1.5 hours for study group 1 participants, and approximately 3.5 hours for study group 1A participants over a 5 year period.

To protect your privacy, your information will be assigned a confidential study number. The link between the number and your name will be kept in a secure location, separate from the study information. This link will be kept up to six years after the study completion for data analysis and will then be destroyed. Your name or other identifying information will be used only for the purposes of identifying you in the CSS registry and to identify matching comparison people. Your privacy will be protected at all times, and your identifying information will not be used to contact you for other purposes or provided to anyone else. If we publish the results of this study, we will not use your name or provide information that would allow you to be identified. Only study staff trained in human subject ethics and who have signed a research subject confidentiality agreement form will be permitted to access confidential medical records. Trained personnel may include licensed health care providers, clinic administrators, researchers, preceptors, and research assistants.

**RISKS, STRESS, AND DISCOMFORT**

Filling out questionnaires about your health and health care can sometimes be stressful. Though there is some small chance that your personal information might not remain confidential, all efforts will be made by research staff to preserve your confidentiality at all times.

**OTHER INFORMATION**

**Voluntary Nature of the Study**

Participation in this study is voluntary. You may choose not to participate in this study for any reason and it will not affect your ability to receive care, nor will it affect the quality of care you receive. You may refuse to answer or leave unanswered any questions in the study questionnaires. Your decision whether or not to participate in this study will not affect your current or future relations with your IO clinic, your IO clinic physician, with the research team or with Bastyr University. If you decide to participate, you are free to withdraw at any time without affecting those relationships. The alternative to taking part in this study is to not take part in this study.
Study Costs/Compensation
There is no cost and no payment to you for participating in this study. You will be responsible for any costs related to your clinical care which is not covered by your health care insurance.

Research Related Injury
Risk of injury related to this study is minimal. In the extraordinary event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment and follow-up care as needed. Care for such injuries will be billed in the ordinary manner to you or your insurance company. If you think that you have suffered a research related injury, let your study physician know right away.

Confidentiality
The records of this study will be kept private. In any publications or presentations, we will not include any information that will make it possible to identify you as a subject. Your consent to participate in this study includes consent for the principal investigator and research staff to review all your medical records as may be necessary for the purpose of the study. The principal investigator and research staff will consider your records confidential to the extent permitted by law. We will label the information about you with a number, not your name. If study data is transmitted via the internet, only participant number will be used. We will keep your name, address, telephone number, and other information that might identify you separate from your laboratory reports and study data. The record that links the number with your name will be kept only by the researchers in a separate, secure location. Your records and results will not identify you in any publication. BURI, FHCRC, the funding sponsor, National Center for Complementary and Alternative Medicine (NCCAM), Hecht Memorial Foundation, and authorized representatives of their respective Institutional Review Boards (IRBs) may review the data in this study and may also review your records for up to six years after the conclusion of the study.

If you decide to participate in this study, some private health information about you will be stored in a computer database at Bastyr University and Fred Hutchinson Cancer Research Center for up to six years after the conclusion of the study. This information will include your name and medical record number, your date of birth, your diagnosis, your race/ethnicity and information about your participation in this study. Your personal health information will not be used in any study reports or publications.

The data collected and stored in the database may be used by researchers in the future to help evaluate the safety, effectiveness, and costs of IO breast cancer treatments, and may be kept indefinitely for this purpose. This database will not contain any identifying or protected health information (PHI).

Parties who may receive or use your individual health information include:
- Government agencies including the Office for Human Research Protections (OHRP) and the funding sponsors, NCCAM and Hecht Memorial Foundation. These agencies may review the research to see that it is being done safely and correctly.
- IRBs including the BURI IRB, the FHCRC IRB, and your own IO clinic’s IRB may review the research study to protect your rights as a study participant;
- BURI study research staff (Kenmore, WA);
- FHCRC study research staff (Seattle, WA).

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.
Protected Health Information (PHI)
Your PHI created or received for the purposes of this study is protected under the federal regulation known as Health Insurance Portability & Accountability Act (HIPAA). Refer to your IO clinic HIPAA authorization for further details concerning use of your protected health information.

Contacts and Questions
If you have questions about this study, please contact Bastyr University Principal Investigator, Dr. Leanna Standish, at 425-602-3166. If you have any questions about your rights as a research subject, you may contact Lizbeth Adams, Ph.D., Director of the Bastyr University Office of Research Integrity, at (425) 602-3416; 14500 Juanita Dr. N.E. Kenmore WA 98028.

______________________________ Date
Signature of IO clinic study physician or designated study staff
member for consent process

______________________________
Printed name of person obtaining consent from volunteer

__________ Date
Initials of IO clinic study physician after review of signatures

Participant's statement:
"The study above has been explained to me. I voluntarily consent to participate in this activity. I have had an opportunity to ask questions. I understand that future questions I may have about the research or about my rights as a participant will be answered by one of the individuals listed above."

______________________________
Printed Name of Participant

______________________________ Date
Signature of Participant

Request for permission to contact you for future research:
"I give the research staff permission to contact me about future research studies at Bastyr University. I have had an opportunity to ask questions. I understand that future questions I may have about the research will be answered by one of the investigators listed above."

______________________________
Printed Name of Participant, Parent, or Guardian

______________________________
Signature of Participant, Parent or Guardian

Date

Copies to: Participant and Patient Chart