



**BASTYR UNIVERSITY RESEARCH INSTITUTE  
CONSENT FORM**

**BASTYR INTEGRATIVE ONCOLOGY RESEARCH CENTER (BIORC)  
BREAST CANCER OUTCOMES STUDY:**

**Evaluating health outcomes in breast cancer patients receiving care at the BIORC.**

<b>Leanna J. Standish, ND, PhD</b>	<b>Principal investigator Research Professor</b>	<b>Bastyr University Research Institute</b>	<b>425-602-3166</b>
<b>M. Robyn Andersen, PhD</b>	<b>Co-principal investigator</b>	<b>Fred Hutchinson Cancer Research Center</b>	<b>206-667-6684</b>
<b>Erin S. Sweet, ND</b>	<b>Co-investigator Program Manager</b>	<b>Bastyr University Research Institute</b>	<b>425-602-3434</b>
<b>Barbara Osborne, RN</b>	<b>Research Nurse</b>	<b>Bastyr University Research Institute</b>	<b>425-602-3311</b>

**RESEARCHERS' STATEMENT**

We are inviting you to be in a research study to find out how well our patients do who receive care at the Bastyr Integrated Oncology Research Clinic (BIORC). 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 Chinese 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 the Bastyr Integrated Oncology Research Clinic (BIORC) do over time. And we want to compare how our BIORC patients do compared to cancer patients who do not receive the kind of integrated oncology care we provide. With the help of Fred Hutchinson Cancer Research Center in Seattle we will attempt to find people in the Western Washington Cancer Surveillance System registry who are like you in terms of age and cancer staging but have not received naturopathic or Chinese 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 the study or the study activities such as the questionnaires or information entered in the database. However, information gathered during the course of this study may help us begin to assess the longer-term effects of integrated naturopathic and Chinese oncology care on health and quality of life in cancer patients. You may benefit from the medical care you receive at BIORC.

## PROCEDURES

The activities involved in being a research participant involve filling out questionnaires regarding quality of life. Our research staff will ask you to complete a research questionnaire at your first visit at BIORC. Additional questionnaires will be mailed to you in six months and then yearly for one to five years to obtain this information. You will be provided a return stamped envelope to mail back these questionnaires. It should take 15-30 minutes to complete each questionnaire for a total study time commitment of 1.75 to 3.5 hours.

Another activity involves our research staff retrieving information relating to your cancer diagnosis and treatment from your medical records and entering it into a secure database. We will ask you to sign a Medical Records Release form to allow us to request medical records relating to your diagnosis and treatment from your other doctors. Medical records will be used for research and patient care purposes.

Your name will be given to Fred Hutchinson Cancer Research Center to find matched control subjects from the Cancer Surveillance System Western Washington database. We will search for your name in this Washington State Cancer Registry. Since 1990, a law has required the Department of Health to collect information about cancer in Washington State. 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 in the registry. Using this database, Dr. Andersen at the Fred Hutchinson Cancer Research Center and the CSS cancer registry staff, will determine if there are cancer patients in the CSS database who are similar to you in age, race, cancer stage at diagnosis, zip code and marital status.

The patient care provided at BIORC includes Complementary and Alternative Medicine (CAM) and Integrative Oncology (IO). CAM and IO is based on scientific methods and 'best practices' have arisen in the field. IO treatment commonly used are designed to influence some aspect of the cancer or immune system. The main CAM approaches used in BIORC include acupuncture, nutraceutical therapy (supplements), dietary, botanical therapy (herbal therapy), as well as physical and psychological rehabilitation after primary cancer treatment. For a review of the of these IO practice guidelines see Abrams and Weill (eds.) *Textbook of Integrative Oncology*, Oxford University Press 2009.

### Principles of IO treatment include:

- 1) Avoidance of most herbal products during chemotherapy because of drug-herb interactions
- 2) Avoidance of most antioxidants during radiotherapy and chemotherapy
- 3) L-glutamine orally to prevent peripheral neuropathy during chemotherapy protocols that are likely to induce this side effect
- 4) Alpha lipoic acid after platinum-containing regimens to prevent and treat nephropathy
- 5) Acupuncture therapy for nausea, vomiting, fatigue, menopausal hot flashes and leukopenia concurrent with chemotherapy and radiation
- 6) Acupuncture therapy for peripheral neuropathy and cancer-related pain
- 7) Melatonin for the treatment of insomnia and for its immunomodulatory properties
- 8) Assessment of vitamin D serum levels and oral replacement therapy if levels are below normal range
- 9) Assessment of immune function using natural killer cell functional activity as a biomarker before and after primary cancer treatment
- 10) Use of polysaccharide peptides from specific mushroom species for enhancing innate and cell mediated immunity pertinent to cancer biology
- 11) Bromelain and pancreatic enzymes for the prevention and treatment of lymphedema
- 12) Co-enzyme Q10 after completion of cardiotoxic chemotherapy drugs to prevent and treat cardiomyopathy and poor ejection fraction
- 13) Acetyl-l-carnitine to prevent and treat chemotherapy-related cognitive decline
- 14) Core secondary prevention program to prevent cancer recurrence that includes natural products that inhibit NF Kappa B (curcumin, ginger, holy basil ginseng and green tea extract), block P53 mutations (quercetin), enhanced tumor surveillance immunity (*Trametes versicolor* extract.)
- 15) Use of mindfulness-based stress reduction (MBSR) and psychological counseling for improving psychoneuroimmunological status during and after primary treatment and when indicated assignment to yoga, tai chi or qi gong classes
- 16) Dietary prescription for vegetable-based low calorie diet
- 17) Daily aerobic exercise prescription

## **RISKS, STRESS, AND DISCOMFORT**

Filling out questionnaires about your health and health care can sometimes be stressful. Some questions may be sensitive in nature, the questionnaire may seem lengthy and time consuming. 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**

BIORC is a clinic dedicated to supporting research. Receiving care at BIORC and taking part in this study are voluntary, but they are linked. If you choose not to participate in BIORC research we will end your care here at BIORC and provide you with other names of Integrative Oncology Clinics.

Participation in this study is voluntary.

- If you decline participation, your appointment at BIORC will be cancelled and we will provide you with a list of other Integrative Oncology Clinics. Your decision whether or not to participate in this study will not affect your current or future relations with Bastyr University or Bastyr Center for Natural Health.
- If you decide to participate, you are free to withdraw at any time. You will then end your care at BIORC and we will provide you with a list of other Integrative Oncology Clinics. Withdrawing from the study will not affect relationships with Bastyr University or Bastyr Center for Natural Health
- Alternatives to taking part in this study include seeking care with other Integrative Oncology Clinics, continuing to receive standard medical oncology care, or doing nothing at all.
- As you are completing the study questionnaires, you may refuse to answer or leave unanswered any or all questions in the study questionnaires. You will still be considered a participant in the 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**

In the 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 the study physicians 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 investigator and his/her assistants to review all your medical records as may be necessary for the purpose of the study. The investigator and his/her assistants will consider your records confidential to the extent permitted by law. We will label the information about you with a number, not your name. We will keep your name, address, telephone number and other information that might identify you separate from your study data. The record that links the number with your name will be kept only by the researchers. Your records and results will not identify you in any publication. Bastyr University and the National Center for Complementary and Alternative Medicine (NCCAM) and authorized representatives of the Fred Hutchinson Cancer Research Center's Institutional Review Board may review the data in this study and may also review your records for audit purposes for up to 5 years after the conclusion of the study. Every effort will be made to respect your privacy. To these extents, confidentiality is not absolute.

Parties who may receive or use my individual health information include:

- Bastyr University and the Fred Hutchinson Cancer Research Center Institutional Review Boards, a group of people who review the research study to protect your rights;
- Bastyr University research staff, Kenmore, WA
- The Fred Hutchinson Cancer Research Center research staff, Seattle, WA

- Government agencies including the Office for Human Research Protections, (OHRP) and the National Center for Complementary and Alternative Medicine (NCCAM). These agencies may review the research to see that it is being done safely and correctly.

**Protected Health Information (PHI)**

Your PHI created or received for the purposes of this study is protected under the federal regulation known as HIPAA. Refer to the attached HIPAA authorization for details concerning the use of this information.

**Contacts and Questions**

If you have questions about this study, please call Barbara Osborne, RN, Research Nurse, at 425-602-3311. 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, 14500 Juanita Dr. N.E. Kenmore WA 98028. Dr. Adam's phone number is (425) 602-3416.

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Signature of Principal Investigator or designated study staff member for consent process

\_\_\_\_\_ Date

\_\_\_\_\_

Printed name of person obtaining consent from volunteer

\_\_\_\_\_ Initials of Principal Investigator after review of signatures

\_\_\_\_\_ Date

**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 investigators listed above."

\_\_\_\_\_ Printed Name of Participant

\_\_\_\_\_ Signature of Participant

\_\_\_\_\_ Date

**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, patient chart**