



**BASTYR UNIVERSITY RESEARCH INSTITUTE  
CONSENT FORM**

**BASTYR INTEGRATED ONCOLOGY RESEARCH CENTER (BIORC) OUTCOMES STUDY: Evaluating health outcomes in 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>Clinical Coordinator</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.

**PURPOSES 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, but 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.

**PROCEDURES**

We will ask you to give us permission to retrieve information about your treatment from your BIORC medical chart and answer a questionnaire about your decisions about your cancer treatment and your health and health related quality of life. BIORC is a clinic dedicated to supporting research. Your participation in this research study entails both the medical care you receive and filling out research research-related questionnaires. BIORC patients can choose not to participate and will be referred to other facilities for care. The activities involved in being a research participant involve only filling out questionnaires regarding quality of life and permitting Fred Hutchinson Cancer Research Center to find matched control

subjects from the Cancer Surveillance System Western Washington database. You will not receive benefit from filling out these questionnaires, but the information gathered may help us to assess how well patients do who utilize integrative oncology services. However, you may benefit from the medical care you receive. BIORC patient care is individualized, is not free, and is typically paid for by patient's medical insurance or at time of service. Our study coordinator will ask you to complete a research questionnaire at your first visit, in six months and then yearly for five years to obtain this information. It should take 15-30 minutes to complete each questionnaire for a total study time commitment of 1.75 to 3.5 hours.

We will also search for your name in the 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.

Receiving care at BIORC and taking part in this study are voluntary, but they are linked. You may stop receiving care at BIORC at any time. However, we would like your permission to contact you on a yearly basis to find out how you are doing. If you no longer wish to participate in this research project you will be asked to discontinue care at BIORC. You may continue to consult with BIORC physicians in their other non-research practice sites.

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 secured location, separate from the study information. This link will be kept for up to five years upon completion of the study 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 subjects ethics and who have signed the Bastyr research subject confidentiality agreement form will be permitted to access confidential medical charts. Trained personnel may include licensed health care providers, clinic administrators, preceptors, and work-study students.

### **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. Physician level CAM and IO is evidence based and 'best practices' have arisen in the field. Each of the IO treatment commonly used are designed to influence some aspect of tumor inhibition including anti-inflammatory, immunomodulatory, anti-angiogenic, or anti-metastatic activity (see Standish et al 2002, 2007, 2009 for doses, rationale, and literature review) [19, 20]. The core CAM approaches used in BIORC include acupuncture, nutraceutical therapy, dietary, botanical therapy, as well as physical and psychological rehabilitation after primary cancer treatment. For a review of the evidence base for each 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

## **OTHER INFORMATION**

### **Voluntary Nature of the Study**

Participation in this study is voluntary. 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 the University. If you decide to participate, you are free to withdraw at any time without affecting those relationships. Alternatives to taking part in this study include seeking care with BIORC physicians in their other non-research practice sites, seeking care privately with non-BIORC physicians or doing nothing at all.

### **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, Kenmore, WA
- The Fred Hutchinson Cancer Research Center, 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, Clinical Coordinator, 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.

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

\_\_\_\_\_  
Date

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

\_\_\_\_\_  
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**