

BASTYR

UNIVERSITY
BASTYR UNIVERSITY
CONSENT FORM

BIORC OUTCOMES STUDY: Evaluating health outcomes in cancer patients receiving care at the Bastyr Integrated Oncology Research Center

Leanna J. Standish, ND, PhD	Principal investigator Research Professor	Bastyr University Research Institute	425-602-3166
M. Robyn Andersen, PhD	Co-principal investigator	Fred Hutchinson Cancer Research Center	206-667-6684
Erin S. Sweet, ND	Co-investigator and Study Coordinator	Bastyr University Research Institute	425-602-3434

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 Center (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 Center (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. Our study coordinator will ask you to complete a research questionnaire to obtain this information. It should take 15-30 minutes to complete. All follow up questionnaires should also take approximately 15-30 minutes to complete.

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 be treated by BIORC physicians in their practice sites at your own expense. If you choose not to receive care at BIORC or refuse to participate in the study, you may do so without penalty or loss of benefits to which you are otherwise entitled.

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 clinical administrators, physicians, clinical and postdoctoral fellows, medical residents, 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.

OTHER INFORMATION

You may refuse to answer or leave unanswered any questions in the study questionnaires. You may refuse to participate or may withdraw from the clinic and the study at any time. There is no cost and no payment to you for participating in this study. If you have questions about this study, please call Erin Sweet, N.D. at 425-602-3434. 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.

_____ 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

Parent or guardian statement:

"The study has been explained to me and my child. I give permission for my child to participate in this activity. We have had an opportunity to ask questions. We understand that future questions we may have about the research or about my child's rights as a participant will be answered by one of the investigators listed above."

Printed name of participant's parent
or guardian

Signature of parent or guardian

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, and Investigator