INFORMED CONSENT FORM

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INTRODUCTION

Bastyr University Research Institute is dedicated to supporting cancer research and studying overall outcomes in patients receiving integrative oncology care. This study is an observational study where we collect data on patients receiving integrative oncology care at Bastyr Center for Natural Health and Anderson Medical Specialty Associates who consent to participate in the study.

What is Integrative Oncology (IO) care? Integrative Oncology care is defined as comprehensive support for each stage of a cancer patient’s experience (from diagnosis to treatment decisions and restoration of immune function and health after completion of standard treatments). Patients can receive care from licensed naturopathic physicians, nutritionists and acupuncturists, all of whom have advanced oncology training.

Treatment options include mind/body medicine, acupuncture, botanical medicine, nutritional support, and advanced intravenous therapies. In IO care doctors communicate with each participant’s medical and radiation oncologists to ensure truly integrated care. The goal is to improve not just the quality of life of people living with cancer, but also to reduce the risk of cancer recurrence. Integrative oncology care is conducted according to community standards of care. IO care is individualized and typically paid for by the patients themselves or by patients’ medical insurance.

RESEARCHERS’ STATEMENT

We are inviting you to be in a research study to find out how well patients do who receive IO care. 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
This observational study seeks to describe the outcomes for individuals who choose to receive IO care. We will report on clinical outcomes of our patients in terms of whether cancer comes back after treatment (recurrence rates) and survival. We are also interested in identifying therapies recommended to our patients. 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 integrative naturopathic, traditional, Chinese and palliative medicine on cancer patients.

PROCEDURES
We are asking you to give us permission to collect data from your medical records about your health status and treatments you receive. This is done by asking you to sign a Medical Records Release Form. We will request updated medical records annually throughout the 5 year study period. To insure good patient care and research we will ask you to schedule 3-6 month follow-up visits with your naturopathic doctor but you may schedule additional appointments if you wish.

RISKS, STRESS, AND DISCOMFORT
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.

VOLUNTARY NATURE OF THE STUDY
Participating in this study is voluntary. If you choose to participate in the study you may schedule IO care appointments at Bastyr Center for Natural Health’s Practitioner Care program which offers one-on-one visits with a specific licensed naturopathic provider or you may schedule appointments at Anderson Medical Specialty Associates. If you do not wish to participate in the study but still wish to receive IO care you may make an appointment at Bastyr Center for Natural Health’s Team Care program where you will be seen by a licensed naturopathic provider and two advanced student clinicians. You may withdraw from the study at any time and continue IO care in the Team Care program or seek other IO specialists in non-research practice sites. Your decision whether or not to participate in this study will not affect the quality of your care provided at BCNH nor your relations with Bastyr University. Patients who receive care at Anderson Medical Specialty will be invited to participate in the outcomes study. Participation is voluntary.

We may also invite you to participate in a separate study that is specific to your cancer diagnosis. Your participation in a separate cancer-specific study is completely voluntary and will not affect your care. If you do choose to participate in a separate cancer-specific study, you will remain enrolled in this study. We will access your medical records for research data collection for both studies.

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.
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 and Accountability Act (HIPAA). Refer to the attached HIPAA authorization for details concerning the use of this information.

CONFIDENTIALITY: 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. The link between your identifiable information and your data will be destroyed 5 years after you complete the study. De-identified data may be stored indefinitely. If we obtain additional funding to continue this study we may contact you to get your permission to continue to follow you for a longer period of time. Your privacy will be protected at all times and your identifying information will not be used to contact you for other purposes or be 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, study personnel, clinic administrators, clinical and work-study students.

Bastyr University's Institutional Review Board, a group of people who review research studies to protect your rights, may also 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. A government agency the Office for Human Research Protections (OHRP) may review research to see that it is being done safely and correctly.

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. Adams' 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 ___________

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 or Guardian __________________ Signature of Participant or Guardian ___________ Date ___________

Copies to: Participant, research file
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IRB APPROVED
Approved on: 5/9/14
Approved by: [Signature]