CONSENT TO PARTICIPATE IN RESEARCH

Advanced integrative oncology treatment for adult and pediatric patients with cancer: A prospective outcomes study

Therry Rose Eparwa, DNP, MSN, RN, FNP-BC	**Principal investigator Assistant Professor**	**Seattle University**	**(206) 296-2344**
Leanna J. Standish, ND, PhD, Lac, FABNO	**Co-Principal investigator Research Professor**	**AIMS Institute**	**(206) 420-1321**
Sunil K. Aggarwal, MD, PhD, FAAPMR	**Co-Principal investigator**	**AIMS Institute**	**(206) 420-1321**

Researchers' Statement

We are inviting you to be in a research study to find out how well our patients do when they receive care at the AIMS Institute. 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 this document 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 naturopathic and integrative 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, who receive treatment at AIMS Institute, do over time. You will not directly benefit from the study. However, you may benefit from the medical care you receive and information gathered during the course of this study may help us begin to assess the longer-term effects of integrative oncology outpatient care on health in cancer patients.

SOURCES OF SUPPORT

This study does not have any external funding or any other type of support.

PROCEDURES

Participation in this study is voluntary. If you decide to withdraw from the study, your care at the AIMS Institute as a patient will not be affected. Participation in the research study is completely optional and voluntary. Participation in this study does not influence the type of care you will receive at the AIMS Institute. This is an observational study of clinical outcomes in our patients. We will ask you to give us permission to retrieve information about your treatment from your AIMS Institute medical chart. AIMS Institute patient care is individualized and is not free. Your medical insurance may cover the costs of physician consultations. However, medical insurance does not cover most integrative oncology medicines and therapies. The clinic will ask you to pay for medicines and therapies at the time of service using cash, check or credit card.

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 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 AIMS Institute research subject confidentiality agreement form will be permitted to access confidential medical charts. Trained personnel may include licensed health care providers, clinic administrators, preceptees, and work-study students.

RISKS, STRESS, AND DISCOMFORT

This is an observational study and therefore it is a minimal risk study. There are no additional office visits, questionnaires or procedures required to participate in this study. Absolute confidentiality cannot be guaranteed. However, all efforts will be made by research staff to protect your privacy including your identity and protected health information (PHI) at all times. 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.

WHAT IS INTEGRATIVE ONCOLOGY?

Physician level naturopathic and integrative oncology is evidence based and 'best practices' have arisen in the field. However, many of the therapies commonly used in our medical community are considered investigational and few are approved by the Food and Drug Administration. For this reason, health insurance companies do not pay for these therapies.

Each of the treatments commonly used is designed to influence some aspect of tumor inhibition including anti-inflammatory, immunomodulatory, anti-angiogenic, or anti-metastatic activity. Our therapies are based on state-of-the science molecular biology, genomics, immunology, pharmacology and mind-body medicine. The core approaches used at the AIMS Institute include nutraceutical therapy, dietary, botanical therapy, as well as physical and psychological rehabilitation and specialty palliative care after primary cancer treatment. For a review of the evidence base for each of these IO practice guidelines see Abrams and Weil (eds.) *Textbook of Integrative Oncology*, Oxford University Press 2014.

Principles of IO treatment include:

1) Avoidance of some 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 nephropathology
5) Acupuncture therapy for nausea, vomiting, fatigue, menopausal hot flashes and leukopenia concurrent with chemotherapy and radiation
6) Acupuncture therapy for peripheral neuropathy, cancer-related pain and fatigue
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 optimal 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) Intravenous nutrition in patients who cannot maintain adequate nutrition by eating
16) Use of tumor and circulating tumor cell DNA testing to identify targeted therapies for patients with metastatic cancer
17) Intravenous botanical medicines used as therapies targeted at specific aspects of cancer genetics and expression of genes
18) Use of mindfulness-based stress reduction (MBSR) and psychological counseling for improving psychoneuroimmunological status during and after primary treatment and when indicated assignment to meditation, yoga, tai chi, or qi gong classes
19) Drug-assisted psychotherapy
20) Dietary prescription for vegetable-based low calorie diet
21) Broth and water fasting
22) Fasting prior to chemotherapy treatments
23) Daily aerobic exercise prescription
24) Oxygen therapy
25) Hyperthermia
26) Medical cannabis education

OTHER INFORMATION

Voluntary Nature of the Study

Participation in this study is voluntary and you may withdraw at any time for any reason. Participation in this research study does not influence the type of treatment you will receive at the AIMS Institute. Either your insurance company, you as the patient, or your family will pay for treatment. The co-investigators on this research study are the founders of the AIMS institute. These investigators have a financial interest in treatment, as the Institute's co-founders and co- directors.

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 that are not covered by your health care insurance. Insurance companies will not pay for 'investigational' therapies, including intravenous nutrition and botanical medicines and many of the oral and topical medications used in our clinic.

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.

Summary of Results
A summary of the results of this research will be supplied to you, at no cost, upon request. Please contact (206) 446-3521 or eparwat@seattleu.edu.

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. Seattle University 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:

- The research study staff
- The Seattle University Institutional Review Board, a group of people who review the research study to protect your rights.

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.
A description of this clinical trial will be available at 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.

MEDICAL RECORDS RELEASE/HIPAA AUTHORIZATION
We are asking for your permission to access your medical records relating to your cancer diagnosis, and any treatments for cancer or related problems. Please read the following information about your rights as a research participant regarding your protected health information and how that information will be used during the period outlined below.

What are my rights as far as my medical records and this study are concerned?
You have rights regarding the privacy of medical information that is collected before, during, and after your participation in this study. This medical information, called "protected health information" (PHI), includes demographic information and the results of some or all of the following tests: physical exams, analysis of blood or tissue specimens, X-rays and other diagnostic and medical procedures, as well as your medical history. You have the right to limit the use and sharing of your PHI.

What does my signature on this Release Form mean?
By signing this release form, you are allowing the research team to have access to your PHI, as well as relevant medical record information obtained from any physicians that provide medical care or treatment relating to your cancer diagnosis and treatment. You do not have to give permission for disclosure of your PHI. However, if you decide not to give permission, you will not be able to participate in this research study.

How will this study protect my privacy?
Information gained from your medical chart will only be identifiable by a special study identification number, and your name will not appear in any reports or publications about this research. The research team that will have access to your PHI collected for this study includes the investigators listed on the consent form you completed for this study. Your PHI will be used only for the research purposes described in the consent form and will not be sold or distributed. If necessary, the PHI we have collected will be shared with the Institutional Review Board (IRB) and with any person or agency that is required by law. Your name and personal contact information will remain in a confidential database and will not appear on any specimens or family and medical history data shared with the research organization.

How long will this information be stored?
By signing this form, you are authorizing us to store the PHI specified in this form in a confidential database for five years after conclusion of this study. You may revoke this authorization at any time by providing written notification to AIMS Institute researchers at the address on the following page. If you revoke this authorization, no additional PHI will be collected; however, the PHI already stored in the database and repository may still be used. Once your PHI has been shared with study researchers and staff, the Privacy Rule in a federal law called the Health Insurance Portability and Accountability Act ("HIPAA") may no longer apply. The Privacy Rule protects the rights of individuals by governing the release of PHI from health care institutions to researchers, but does not govern the use of your PHI once it has been released. However, other confidentiality protections under federal and state law are in place to protect your rights during your participation in research studies.

I hereby authorize the disclosure of all medical records relating to my cancer diagnosis and any treatments for cancer to:

AIMS Institute Study Investigators

TR Eparwa, DNP, MSN, RN, FNP-BC	Principal Investigator
LJ Standish, ND, PhD, Lac, FABNO	Co-principal Investigator
SK Aggarwal MD, PhD, FAAPMR	Co-principal Investigator

I understand that this medical records release authorizes research personnel to periodically review my medical records for up to five years in order to obtain information relating to any treatments for cancer and my risk for cancer, including results of genetic testing that relate specifically to my cancer diagnosis. Relevant medical record information, such as prior history of cancer and treatment, may be obtained from any physicians that provide medical care or treatment relating to my cancer. I understand that information obtained from my medical chart will only be identifiable by a special study number and that my name will not appear on any reports of the results of these studies. I understand that this authorization may be revoked in writing at any time. I understand that I am entitled to receive a copy of this authorization to keep for my records.

CONTACTS AND QUESTIONS:

- If you have questions about this research study, please contact Dr. TR Eparwa at (206) 446-3521 at Seattle University, 901 12th Ave, Seattle, 98122 or Dr. LJ Standish at (206) 420-1321 at AIMS Institute, 2825 Eastlake Ave E, #115, Seattle, 98122
- If you have questions about your rights as a research participant, you may contact Dr. Michelle DuBois, Chair of the Seattle University Institutional Review Board at (206) 296-2585.

Participant's Consent to Participate in Research

I understand that I am being asked to participate in a research study about the impact of advanced integrative oncology care on survival in advanced cancer patients. This study has been explained to me by a study investigator or designee.

I have read this Informed Consent Form (or have had this document read to me). All my questions have been answered to my satisfaction. If I decide at a later stage in the study that I would like to withdraw my consent, I may do so at any time.

I understand that all of the information collected for this study will be kept confidential and will be stored in an electronic database. I understand that this information will only be used for scientific objectives.

I understand that future questions I may have about the research will be answered by one of the investigators listed above.

I voluntarily agree to participate in this study.

_____

Name of Participant (Please Print)

_____ _____

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 AIMS Institute. 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."

_____ _____

Signature of Participant Date

Investigator Statement (or Person Explaining the Consent)

I have carefully explained to the research participant the nature of the above research study. To the best of my knowledge, the research participant signing this consent form understands the nature, demands, risks and benefits involved in participating in this study. I acknowledge my responsibility for the care and well-being of the above research participant, to respect the rights and wishes of the research participant, and to conduct the study according to applicable Good Clinical Practice guidelines and regulations.

_____

Name of Investigator/Designee (Please Print)

_____ _____

Signature of Investigator/Designee Date

Copy to Participant

Original signed copy uploaded to study database

Documentation of Informed Consent Process (Research staff use only)		
_____ Printed name of clinic investigator or designee for consent process	_____ Signature of clinic investigator or designee for consent process	_____ Date