

PARENT/GUARDIAN PERMISSION FORM

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

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Researchers' Statement

We are inviting your child 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 and your child 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 and your child to do, the possible risks and benefits, your child's 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 and your child 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.** Your child will not directly benefit from the study. However, your child may benefit from the medical care received 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 child's treatment from their AIMS Institute medical chart. AIMS Institute patient care is individualized and is not free. **Your child's 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.

Receiving care at AIMS Institute and taking part in this study are voluntary, but they are linked. Your child may stop receiving care at AIMS at any time. Your child may withdraw your consent to participate at any time. If your child no longer wishes to participate in this research project your child will be asked to discontinue care at AIMS. We will refer your child to Bastyr University Center for Natural Health or other qualified providers.

To protect privacy, your child's information will be assigned a **confidential study number**. The link between the number and your child's 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 child's privacy will be protected at all times and identifying information will not be used to contact you or your child for other purposes or provided to anyone else. If we publish the results of this study, we will not use your child's name or provide information that would allow for identification. 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 privacy including your child's identity and protected health information (PHI) at all times. Though there is some small chance that your child's personal information might not remain confidential, all efforts will be made by research staff to preserve your child's 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 or your child may withdraw at any time for any reason. Participation in this research study does not influence the type of treatment your child will receive at the AIMS Institute. Either your insurance company, your child as the patient, or you 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 or your child for participating in this study. **You will be responsible for any costs related to your child's clinical care that are not covered by 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 your child has 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 your child as a subject. Your consent for your child to participate in this study includes consent for the investigator and his/her assistants to review all your child's medical records as may be necessary for the purpose of the study. The investigator and his/her assistants will consider your child's records confidential to the extent permitted by law. We will label the information about your child with a number, not your child's name. We will keep the name, address, telephone number and other information that might identify your child separate from your child's study data. The record that links the number with your child's name will be kept only by the researchers. Your child's records and results will not identify your child in any publication. Seattle University Institutional Review Board may review the data in this study and may also review your child's records for audit purposes for up to 5 years after the conclusion of the study. Every effort will be made to respect privacy. To these extents, confidentiality is not absolute.

Parties who may receive or use my child's 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 child's rights.

Protected Health Information (PHI)

Your child's 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 your child. 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 child's medical records relating to your cancer diagnosis, and any treatments for cancer or related problems. Please read the following information about your child's rights as a research participant regarding your child's protected health information and how that information will be used during the period outlined below.

What are my child's rights as far as their medical records and this study are concerned?

You and your child have rights regarding the privacy of medical information that is collected before, during, and after your child's 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 child's medical history. You have the right to limit the use and sharing of your child's 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 child's PHI, as well as relevant medical record information obtained from any physicians that provide medical care or treatment relating to your child's cancer diagnosis and treatment. You do not have to give permission for disclosure of your child's PHI. However, if you decide not to give permission, your child will not be able to participate in this research study.

How will this study protect my child's privacy?

Information gained from your child's medical chart will only be identifiable by a special study identification number, and your child's name will not appear in any reports or publications about this research. The research team that will have access to your child's PHI collected for this study includes the investigators listed on the permission form you completed for this study. Your child's 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 child's 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 child's 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 child's 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 child's cancer diagnosis and any treatments for cancer to:

AIMS Institute Study Investigators

TR Eparwa, DNP, MSN, RN, FNP-BC

LJ Standish, ND, PhD, Lac, FABNO

SK Aggarwal MD, PhD, FAAPMR

Principal Investigator

Co-principal Investigator

Co-principal Investigator

I understand that this medical records release authorizes research personnel to periodically review my child's medical records for up to five years in order to obtain information relating to any treatments for cancer and my child's risk for cancer, including results of genetic testing that relate specifically to my child's 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 child's cancer. I understand that information obtained from my child's medical chart will only be identifiable by a special study number and that my child's 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 child's rights as a research participant, you may contact Dr. Michelle DuBois, Chair of the **Seattle University Institutional Review Board** at (206) 296-2585.

Voluntary Permission for My Child to Participate in Research

I understand that my child 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 Parent/Guardian Permission Form (or have had this document read to me). All my questions have been answered to my satisfaction. If I or my child decide at a later stage in the study that we would like to withdraw consent, we 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 for my child to participate in this study.

Name of Participant (Please Print)

Signature of Participant Date

Name of Participant's Parent or Guardian

Signature of Participant's Parent or Guardian Date

For participants age 8 or younger:

My child is age _____ and my child's birthdate is _____.

As my child's parent or guardian, I believe my child is currently below the age at which my child can provide assent to participate in the study. If my child is still participating in the study by the age of 8, the AIMS staff and I will revisit the issue of assent with my child.

Signature of Participant's 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 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 Parent or Guardian

Original signed copy uploaded to study database

Documentation of Parent/Guardian Permission Process (Research staff use only)

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 Printed name of clinic investigator
 or designee for permission process

 Signature of clinic investigator or
 designee for permission process

 Date