# PARENT/GUARDIAN PERMISSION FORM

**Advanced integrative medical science institute 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 advanced integrative specialty care, in addition to conventional care, will help people with illness to live 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 they receive. Information gathered during the course of this study may help us begin to assess the longer-term effects of integrative specialty outpatient care on health in chronically and seriously ill patients or patients with mental health conditions.

**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 many integrative 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 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. 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, such as in the case of theft, all efforts will be made by research staff to preserve your confidentiality at all times.

**WHAT IS ADVANCED INTEGRATIVE SPECIALTY CARE?**

The NIH's National Center for Complementary and Integrative Health defines integrative healthcare as care which "often brings conventional and complementary approaches together in a coordinated way. It emphasizes a holistic, patient-focused approach to health care and wellness--often including mental, emotional, functional, spiritual, social, and community aspects--treating the whole person rather than, for example, one organ system. It aims for well-coordinated care between different providers and institutions."

At AIMS Institute, we are providing integrative medical care in conjunction with specialty medical care to expand the reach of integrative care to more chronically and seriously ill patient populations. This is Integrative Specialty Care. The core specialties being employed with an integrative approach are naturopathy, naturopathic oncology, palliative care, psychiatry, psychotherapy, and rehabilitation medicine. The integrative approach is achieved through coordinated and team-based care delivered by allopathic medical and psychiatric specialists, psychotherapists, specialized naturopathic physicians, a family practitioner, and targeted health educators, with the much of care provided covered by insurance. The AIMS Institute incorporates advanced experimental treatment approaches such as medical cannabis education, drug-assisted psychotherapy, sympathetic blocks, and some intravenous therapies for symptom relief and disease-modification--promising 'advanced' approaches which presently are at the periphery of mainstream healthcare. However, while many of the therapies are commonly used in the specialty integrative medical community, they 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. Outside therapists, practitioners, and community resources are utilized via referral.

**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.

**Summary of Results**
A summary of the results of this research will be supplied to you, at no cost, upon request. Please contact (206) 296-2344 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 outcomes study 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.

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**MEDICAL RECORDS RELEASE/HIPAA AUTHORIZATION**
*We are asking for your permission to access your child's medical records relating to your condition(s), and any past treatments for this 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 condition(s) 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 may still be used. The database is stored in a password-protected, HIPAA compliant, Google Suite Business services cloud. This data is accessible by AIMS Institute office personnel only. 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**

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| 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 child's medical records for up to five years in order to obtain information relating to any treatments. Relevant medical record information, such as prior medical history and treatment, may be obtained from any physicians that provide medical care or treatment relating to my child's condition(s). 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) 296-2344 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 specialty care on health outcomes in patents. 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.

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Name of Participant (Please Print)

_____ _____

Signature of Participant Date

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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.

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Name of Investigator/Designee (Please Print)

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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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| _____<br>Printed name of clinic investigator or designee for permission process | _____<br>Signature of clinic investigator or designee for permission process | _____<br>____<br>Date |