

TITLE	Financial Conflicts of Interest	
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POLICY

SUMMARY

Seattle Children’s Research Institute (SCRI) is dedicated to maintaining public trust in the integrity of our research-related activities. The U.S. Department of Health and Human Services (HHS) has issued a final rule in the Federal Register that amends the Public Health Service (PHS) regulations on Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought (42 C.F.R. Part 50, Subpart F) and Responsible Prospective Contractors (45 C.F.R. Part 94). This policy addresses the crucially important responsibilities of SCRI, Investigators, faculty, and staff in both safeguarding research objectivity and complying with the requirements of all applicable state and federal regulations.

POLICY

- A. No Research or technology transfer activities occurring at, on behalf of, or through Seattle Children’s shall be adversely affected by the financial interests of persons involved in those activities. Any investigator possessing a financial interest related to their Institutional Responsibilities must disclose the interest to the Office of Research Compliance (ORC) at least annually and/or prior to participating in a research or technology transfer activity. The Office of Research Compliance is responsible for reviewing disclosures and instituting an adequate plan for the elimination, reduction or management of any identified financial conflicts of interest. The goal of this policy is to protect; research participants, the integrity and credibility of activities related to research and to maintain public trust and confidence in Seattle Children’s and its employees.
- B. All Research and technology transfer activity undertaken at Seattle Children’s shall be conducted in compliance with the following regulations and policies, as applicable:
 - 1. PHS regulations on Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought (42 CFR Part 50, Subpart F August 25, 2011);
 - 2. PHS regulations on Responsible Prospective Contractors (45 CFR Part 94 August 25, 2011);
 - 3. The United States National Science Foundation’s Investigator Financial Disclosure Policy (60 FR 35820 – 35823 July 11, 1995);
 - 4. RCW Chapter 42.52, the Washington State Ethics in Public Service Act, as prescribed by the UW Grants Information Memorandum 10 (GIM 10), as applicable.
- C. Persons failing to comply with this policy shall be subject to sanctions as provided herein.
- D. Investigator Responsibilities - All Investigators are required to:
 - 1. Disclose financial interests
 - a. Annually;
 - b. Within 30 days of discovering or acquiring a financial interest.

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- i. In the case of Sponsored or Reimbursed Travel, the disclosure must be made within 30 days of the trip end;
 - ii. Regarding the disclosure of sponsored or reimbursed travel, if an Investigator can reasonably anticipate the occurrence of travel, the Investigator may elect to disclose such travel up to twelve (12) months in advance of the anticipated travel. If an advance disclosure of travel becomes materially inaccurate, the Investigator must provide an updated disclosure within 30 days of the change.
 - c. Upon direction from ORC or the Intellectual Property Core (IPC).
 2. Certify that their financial disclosure is current at the time of submission of a grant proposal/application to the Office of Sponsored Research (OSR).
 3. Ensure their financial disclosure is current prior to the approval and throughout the lifecycle of an IRB study.
 4. Disclose individual or family members' financial interests that reasonably appear to be related to their Institutional Responsibilities or have any of the following financial interests in an entity that is sponsoring the research, or an entity that is manufacturing the product or service being tested:
 - a. Any remuneration from the entity in the previous twelve months that exceeds \$5,000, when aggregated for the individual and their immediate family. (Remuneration includes salary and any payment for services not otherwise identified as salary, such as consulting fees, honoraria, or paid authorship).
 - b. Any equity interest in the entity (equity interest includes any stock, stock option, or other ownership interest).
 - c. Any intellectual property rights and interests (e.g., patents, copyrights, IP rights assigned to SCRI, and agreements to share in royalties related to such rights).
 - d. Any governance or executive relationship with the entity (e.g., founder, board of director, CEO).
 5. Comply with any Management Plan established by ORC and/or the Research Conflict of Interest Committee (RCOIC).
 6. Required Financial Conflict of Interest (FCOI) Training:
 - a. Seattle Children's offers self-directed, online, FCOI training through the online Learning Center program. Per Federal regulations and SCRI policies, Investigators are required to complete FCOI training:
 - i. At least every 4 years;
 - ii. As part of the on boarding process after joining SCRI;
 - iii. As mandated by ORC, upon determination of non-compliance with this policy or an existing Management Plan;
 - iv. When SCRI revises this policy in any manner that affects the requirements of investigators;
 - v. As otherwise dictated by SCRI.
- E. Principal Investigator Responsibilities - in addition to the responsibilities outlined for all Investigators above, Principal Investigators (PI's) are required to:
 1. Ensure all Investigators involved in a research project, including newly hired Investigators, have a current financial interest disclosure on file prior to their participation in the project;
 - a. Ensure all Investigators involved in a research project promptly disclose any new or updated financial interests (see section D.1. above);

- b. Ensure all Investigators involved in a research project have completed the FCOI training required under this policy (see section D.6. above);
- c. Identify the Key Personnel on a research project upon request;
- d. Indicate, upon submission of a proposal/application to OSR, if they or any project Investigators have a Significant Financial Interest (SFI) that may be related to the proposed project.

F. Review of Disclosures

1. ORC shall review Investigators financial interest disclosures and determine if the financial interest is “significant” and if so, determine if the interest is related to the Investigator’s research.
 - a. If additional information is needed during the review process, ORC shall send a request for clarification to the Investigator explaining the details of such request.
 - b. Depending on the nature of the disclosed SFI, ORC may implement measures regarding the Investigator’s participation in the research project between the date of disclosure and the completion of the SFI review.
 - c. ORC will provide a summary of the interim plan to the investigator and Institutional Review Board (IRB) of record.

G. Management of FCOI

1. ORC, along with the RCOIC, determines the criteria used for, and adequacy of all management plans (low, moderate, and high). FCOI management plans will address the following key areas: 1) The nature of the conflict; 2) the relatedness of the conflict to the research; 3) the perceived risk to the integrity of the research as a result of the conflict; 4) if applicable, the specific risks to human subjects; 5) if the conflict can be sufficiently managed by a management plan; and 6) the perceived risk to the reputation of the institution.
2. The RCOIC’s charge is to review and manage financial conflicts of interest (FCOI) of individual Investigators involved in research at Seattle Children’s in accordance with this Policy. The RCOIC will develop new and review renewals of FCOI management plans. The RCOIC reports to Seattle Children’s Chief Executive Officer.
3. The Institutional Conflict of Interest Committee (ICOIC) and the RCOIC will share with the other information obtained and determinations made that are relevant to inform and coordinate the work of each committee. In addition, the RCOIC may seek consultation or escalate a conflict of interest issue or management plan to the ICOIC for review and input.
4. If ORC and/or the RCOIC determines that a reported SFI constitutes an FCOI relating to a research project, it shall develop and implement a Management Plan specifying terms and conditions that have been, or will be, taken that in the reasonable judgement of ORC and/or the RCOIC will reduce or manage the FCOI and may contain one or more of the following terms and conditions:
 - a. Disclosure of financial interest(s) relating to conflicted research study(ies) in publications, presentations, and any public communication of research results;
 - b. Disclosure of financial interest(s) relating to conflicted research study(ies) to all research personnel affiliated with and potential human subjects participating in the research;
 - c. Prohibited from obtaining informed consent of human subject participants;
 - d. Prohibited from production of data involving subjective scoring or similar methods;
 - e. Prohibited from conducting data analysis;

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- f. Prohibited from performing adverse event causation analysis;
 - g. Provide research personnel with access to a senior faculty member;
 - h. If decision maker, recuse oneself from making future decisions on behalf of SCH relating to financial interest(s);
 - i. Update financial disclosure within 30 days of known changes;
 - j. Upon request, provide a Management Plan Compliance Report to ORC;
 - k. Upon request, make available all research data and results for independent data monitoring;
 - l. Upon request, provide information for independent review of study design;
 - m. Prohibited from using SCH assets and facilities relating to conflicted entity(ies);
 - n. Prohibited from participating in negotiations on behalf of SCH and conflicted entity(ies);
 - o. Prohibited from disclosing proprietary information belonging to SCH to conflicted entity(ies).
5. In developing a Management Plan, ORC and the RCOIC may conduct factual inquiries and consult with and receive recommendations from such persons or committees as ORC and the RCOIC deems necessary and appropriate.
 6. A completed or updated Management Plan will generally serve as such written approval.
 7. Investigator must submit FCOI to IRB of Record.
 - a. FCOI identified due to an updated disclosure after a study is approved, may result in IRB activity holds until the conflict is resolved.
 8. The IRB is responsible for reviewing the management plan and the consent form language to ensure whether the financial interest(s) and its management plan adequately protect the rights and welfare of human subjects. They may suggest that;
 - a. Additional actions be taken to minimize risks to human subjects;
 - b. Changes to the kind, amount, and level of detail of information in the consent form be provided to human subjects regarding the source of funding, funding arrangements, financial interests of parties involved in the research, and any financial interest management terms and conditions applied.
 9. For PHS-funded research, the actions detailed above (sections F and G) will be completed prior to the expenditure of any research project funds, or within 60 days of a disclosure of an SFI during the course of a research project by an existing Investigator or an Investigator new to the project.
 10. Whenever a Management Plan is implemented, ORC shall take such actions as it deems reasonable to audit and/or monitor compliance with the Management Plan, including obtaining regular reports from individuals and committees charged with oversight responsibilities in connection with FCOI management plans. This audit and/or monitoring of compliance will be conducted until the completion of the research project or until the Management Plan is no longer required.
- H. Management of Other Interests
1. When a disclosure of SFI is determined not to constitute an FCOI, or disclosure of non-SFI related to human subjects research, ORC may determine that some type of management or oversight of the interest is appropriate before certain research activities may proceed. ORC may specify additional terms and conditions to manage these other interests.
- I. FCOI Reporting to PHS Awarding Components for PHS-Funded Research

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1. ORC will submit FCOI reports to a PHS Awarding Component:
 - a. Prior to expenditure of any funds under a PHS-funded research project, if an FCOI has not been eliminated;
 - b. Within 60 days of identifying an FCOI during an ongoing research project;
 - c. Annually for any FCOI previously reported regarding an ongoing PHS-funded research project. The report shall specify the status of the FCOI (if the FCOI is still being managed or explain why it no longer exists) and if appropriate, any changes to the Management Plan. The report shall be submitted annually for the duration of the research project at the same time as the submission to NIH of the annual progress report, multi-year progress report, if applicable, or at the time of extension.
 2. Any FCOI report submitted to a PHS Awarding Component shall include the minimum elements as required by 42 CFR Part 50, Subpart F and contain sufficient information to understand the nature and extent of the financial conflict and assess the appropriateness of the Management Plan.
- J. FCOI Reporting for NSF – Funded Research
1. ORC will notify NSF of financial conflict issues that are not resolved to the satisfaction of Seattle Children's.
- K. PHS-Funded Research through Subrecipients
1. If the PHS-Funded Research or portions of it is carried out through a subrecipient, the SCRI will take reasonable steps to ensure that any subrecipient Investigator complies with 42 CFR Part 50, Subpart F by incorporating the following as part of the written agreement with the subrecipient:
 - a. Terms that establish whether this policy or the subrecipient's FCOI policy will apply to the subrecipient Investigators;
 - b. Time period(s) for the subrecipient to report all identified FCOI or for submission of all subrecipient Investigator SFI disclosures to SCRI.
- L. Publicly Accessible Information
1. This policy shall be available via Seattle Children's publicly accessible web site.
 2. For PHS-Funded Research, ORC shall make information concerning significant financial interests that meet the criteria below available to the public, upon written request for such information:
 - a. SFI was disclosed and is still held by Senior/Key Personnel (as defined in this policy);
 - b. ORC determined the SFI is related to a PHS-Funded Research project;
 - c. ORC determined the SFI constitutes an FCOI.
 3. The above information made available shall consist of the minimum elements as required by 42 CFR Part 50, Subpart F and shall be provided by written response to the requestor.
 4. The above information shall remain available for public request for at least three years from the date that the information was most recently updated.
- M. Retrospective Review of PHS-Funded Research
1. Whenever ORC identifies an SFI that was not disclosed in a timely manner or was not previously reviewed by ORC during an ongoing PHS-Funded Research project, ORC shall within 60 days:
 - a. Review the SFI;

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- b. Determine whether it is related to a PHS-Funded Research project;
 - c. Determine whether an FCOI exists;
 - d. If ORC determines an FCOI exists, ORC shall implement (at least on an interim basis) a Management Plan that specifies the actions that have been taken and will be taken to manage such FCOI.
2. Whenever an FCOI related to a PHS-Funded Research project is not identified or managed in a timely manner due to non-compliance by SCRI or an Investigator, including if an Investigator fails to comply with a Management Plan, ORC shall:
 - a. Notify the Chief Academic Officer (CAO) and the President of SCRI (see section M of this policy) via email communication;
 - b. Within 120 days of non-compliance identification, complete and document a retrospective review of the Investigator's activities and the research project. Documentation of the review will include all elements as specified by 42 CFR Part 50, Subpart F;
 - c. Based on the results of the retrospective review, if appropriate, update the previously submitted FCOI report and specify the actions that will be taken to manage the FCOI moving forward;
 - d. If bias is found, notify the PHS Awarding Component promptly and develop and submit a mitigation report. The mitigation report shall consist of the minimum elements as required by 42 CFR Part 50, Subpart F;
 - e. Submit FCOI reports to the PHS Awarding Component annually thereafter for the duration of the research project.
- N. Sanctions and Remedies for Violation of Policy
1. If ORC determines an Investigator has violated this policy, including failure to submit required disclosures or failure to comply with the requirements of a management plan, ORC shall report the violation to the Chief Academic Officer (CAO) and the President of SCRI. The CAO and President shall take reasonable steps to respond appropriately to violations, including, but not limited to:
 - a. Suspending research activity expenditures;
 - b. Administratively suspending any research study related to the FCOI;
 - c. Instituting disciplinary measures up to and including suspension or termination.
 2. If required to do so, SCRI will submit to HHS, or permit on site review of, all records pertinent to compliance with this policy and federal regulations.
 3. In the case in which it is determined that a PHS-Funded Research project whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with an FCOI that was not managed or reported, SCRI shall require the Investigator involved to disclose the FCOI in each public presentation of the results of the research and shall request an addendum to previously published presentations.
- O. Record Keeping
1. ORC shall maintain records relating to:
 - a. All Investigator disclosures of financial interests;
 - b. ORC's review and response to such disclosures;
 - c. Actions taken under this policy or retrospective reviews.
 2. For PHS-Funded Research, these records shall be maintained for at least three years from the date the final expenditures report is submitted to the PHS Awarding

Component or as required by 45 CFR 74.53(b) and 92.42(b). For all other research, these records shall be maintained for at least three years from the date of the final expenditures report.

DEFINITIONS

Compensation: means any remuneration, including, salary and payment for services not otherwise identified as salary such as consulting fees, honoraria, and paid authorship.

Covered Persons: the principal investigator and any other individual involved in the design, conduct, or reporting of funded research, under the Seattle Children's workforce (as defined in policy 10282) and if applicable, family members (see definition of family member).

Disclosure: an Investigator's provision of information about their financial interest(s) to Seattle Children's.

Equity Interest: any financial interest in the profits of, or stock of, a commercial or non-profit enterprise, a stock option, or any other ownership interest in a commercial or non-profit enterprise.

Entity: any domestic or foreign, public or private, for profit or non-profit legal entity or organization other than Seattle Children's Research Institute, any agency of the State of Washington, or the federal government.

Family Member: an Investigator's spouse, domestic partner or dependent children.

Financial Conflict of Interest (FCOI): a significant financial interest that is related to and could directly and significantly affect the design, conduct, or reporting of the Research.

Financial Interest: anything of economic or monetary value, whether or not the value is readily ascertainable, possessed by an Investigator and his/her family member (see definition above).

Institution of Higher Education: an educational institution in any state in the U.S. that meets all the following requirements:

- Admits as regular students only persons having a certificate of graduation from a school providing secondary education, or the recognized equivalent of such a certificate, or persons who meet the related requirements of federal law;
- Is legally authorized within such state to provide a program of education beyond secondary education;
- Provides an educational program for which the institution awards a bachelor's degree or provides not less than a two-year program that is acceptable for full credit toward such a degree, or awards a degree that is acceptable for admission to a graduate or professional degree program, subject to review and approval by the U.S. Secretary of Education;
- Is a public or other nonprofit institution; and
- Is accredited by a nationally recognized accrediting agency or association, or if not so accredited, is an institution that has been granted pre-accreditation status by such an agency or association that has been recognized by the U.S. Secretary of Education for the granting of pre-accreditation status, and the U.S. Secretary of Education has determined that there is satisfactory assurance that the institution will meet the accreditation standards of such an agency or association within a reasonable time.

Institutional Official: one or more persons designated by Seattle Children's Research Institute as having responsibilities and authority under this policy. For the purposes of this policy, this is the Office of Research Compliance.

Institutional Responsibilities: all work performed at or on behalf of Seattle Children's, including but not limited to: research conducted at, on behalf of, or through Seattle Children's; research consultation performed on behalf of Seattle Children's; teaching; professional practice; management duties performed on behalf of Seattle Children's; and/or service on Seattle Children's institutional committees or boards (e.g. steering committees, Institutional Review Boards, Data and Safety Monitoring Boards).

Intellectual Property (IP): as per the IPC-100 policy, IP is defined as ownership and associated right relating to scientific discoveries, technological advances, compilation, and original works. Intellectual Property includes Patents, Trademarks, Copyrights, Trade Secrets and other species such as computer software, Mask Work, printed material, or Tangible Property. The formal protections provided by Patents, Copyrights or Trademarks may be used to preserve some Intellectual Property from unauthorized use or misappropriation. Intellectual Property is created when something new and valuable has been conceived or developed, or when unusual, unexpected, or non-obvious results have been discovered with existing technology and which can be applied to some useful purpose. Intellectual Property can be created by one person or co-created by several.

Investigator: any employee of SCH or faculty member of another institution who is engaged in research at facilities owned, leased or operated by SCH and who is responsible for the design, conduct or reporting of research. Investigators typically include, but are not limited to the following roles, the Principal Investigator, Project Director, Co-investigator, and Senior/Key Personnel (see definition of Senior/Key Personnel).

Management Plan: a written plan to address a financial conflict of interest to ensure, to the extent possible, that the design, conduct and reporting of research will be free from bias.

PHS: the Public Health Service of the U.S. Department of Health and Human Services and any PHS awarding components to which authority may be delegated, including without limitation the National Institutes of Health.

PHS Awarding Component: the organizational unit of the Public Health Service that funds Research that is subject to 42 CFR 50, subpart F.

PHS-Funded Research: any research or sponsored activity for which funding is available from a PHS awarding component through a grant or cooperative agreement, however authorized, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project or research resources award. PHS-Funded Research does not include any Phase I SBIR Program application or award.

Principal Investigator (PI): any person designated with the title of "Principal Investigator" of a research or sponsored project having primary responsibility for the scientific and technical conduct, reporting, fiscal and programmatic administration, and implementation.

Reimbursed Travel: travel activity for which the travel Expenses are paid directly by the Investigator, who is then reimbursed by an entity for such travel expenses.

Research: a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research (e.g. a published article, book or book chapter) and product development (e.g. a diagnostic test or drug) and includes any activity for which PHS research funding is available.

Senior/ Key Personnel: the program director/principal investigator (PD/PI) and other individuals who contribute to the scientific development or execution of a project in a substantive, measurable way, whether or not they request salaries or compensation.

Significant Financial Interest (SFI): an investigator or family member's financial interest that reasonably appears to be related to an Investigator's Institutional Responsibilities and meets one or more of the following criteria, after accounting for any specified exclusions. Note that certain exclusions apply, in which case the interests do not need to be disclosed:

	Criteria	Exclusions
1	<p>Aggregate Reimbursed Travel or Sponsored Travel totaling more than \$5,000 received in the preceding 12 months</p> <p>Disclosure will include the following information:</p> <ul style="list-style-type: none"> • Purpose of the trip • Identity of the sponsor/organizer • Destination • Duration (start and end dates) • Amount 	<p>Travel for which expenses are paid for or reimbursed by:</p> <ul style="list-style-type: none"> • Seattle Children's Research Institute • a domestic US Federal, state or local government agency • a domestic US Institution of higher education (as defined above) • a domestic US academic teaching hospital • a domestic US medical center • a domestic US research institute affiliated with an institution of higher education <p>For example, travel which relates to institutional responsibilities paid for by NIH is excluded.</p> <p>However, travel related to institutional responsibilities paid for by a pharmaceutical company, professional association, or a <u>non-US</u>:</p> <ul style="list-style-type: none"> • government agency • institution of higher education • academic teaching hospital • medical center, research institute affiliated with an institution of higher education <p>must be reported on the COI disclosure form.</p>
2	<p>Aggregate Compensation totaling more than \$5,000 received in the preceding 12-months (e.g. salary, consulting fees, honoraria or paid authorship)</p>	<p>Compensation received from SCH, CUMG and/or UW.</p> <p>Income from seminars, lectures or teaching engagements sponsored by and/or service on advisory committees or review panels for:</p> <ul style="list-style-type: none"> • Seattle Children's Research Institute • a domestic US Federal, state or local government agency • a domestic US Institution of higher education (as defined above) • a domestic US academic teaching hospital • a domestic US medical center • a domestic US research institute affiliated with an institution of higher education <p>However, income from seminars, advisory committees or review from <u>non-US</u> entities must be reported on the COI disclosure form.</p>
3	<p>Any Equity in a non-publicly (Privately) traded entity as of the date of disclosure</p>	<p>Equity in investment vehicles where the Investigator does not directly control investment decisions (e.g. mutual funds, retirement accounts).</p>

4	Aggregate Equity in a publicly traded entity valued in excess of \$5,000 as of the date of disclosure	Equity in investment vehicles where the Investigator does not directly control investment decisions (e.g. mutual funds, retirement accounts).
5	Aggregate Equity in a publicly traded entity and Compensation and Sponsored/Reimbursed Travel received from the same entity totaling more than \$5,000 received in the preceding 12 months	<p>Equity in investment vehicles where the Investigator does not directly control investment decisions (e.g. mutual funds, retirement accounts).</p> <p>Compensation received from SCH, CUMG and/or UW.</p> <p>Income from seminars, lectures or teaching engagements sponsored by and/or service on advisory committees or review panels for:</p> <ul style="list-style-type: none"> • Seattle Children's Research Institute • a domestic US Federal, state or local government agency • a domestic US Institution of higher education (as defined above) • a domestic US academic teaching hospital • a domestic US medical center • a domestic US research institute affiliated with an institution of higher <p>However, Income from seminars, lectures or teaching engagements sponsored by and/or service agreements on advisory committees or review panels for industry or <u>non-US</u> entities must be reported on the COI disclosure form.</p>
6	Intellectual Property rights and income received from such rights in the preceding 12 months	<p>Intellectual property rights from which an Investigator has not received income.</p> <p>Please note: In some instances, intellectual property interests that are exclusions may be subject to management under the Seattle Children's Hospital Corporate Policies entitled, "Conflict of Interest and Fiduciary Duties of Decision-Makers" and/or "Anti-Kickback, Self-Referrals, and Conflict of Interest".</p>

Sponsored Research: any research project for which an application/proposal is submitted to OSR. This includes research funded by internal awards such as Center for Clinical and Translational Research Funding Programs.

Sponsored Travel: travel expenses paid directly by an entity on behalf of an Investigator and not reimbursed directly to the Investigator so that the exact monetary value may not be readily available. This does not include travel expenses paid directly by a Seattle Children's research study budget (also known as an activity).

Subrecipient: an Investigator (see definition above) either affiliated with an organization or working as an individual (e.g., consultant/collaborator) that works with Seattle Children's under a PHS-funded or proposed sub-award or subrecipient agreement, or collaborates on human subject (IRB) research or animal (IACUC) research.

Travel Expenses: financial expenses incurred for the purpose of engaging in travel activity, including but not limited to, costs for transportation, parking, food, drink, lodging and related amenities.

APPROVED BY

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RELATED POLICIES

[Seattle Children's Individual and Institutional Conflicts of Interest Policy, 10282](#)