
Section 70 - Corporate Compliance Plan

Effective Date: 1/4/2019

70.03.003

Relationships with Vendors

PURPOSE

1. St. Jude Children's Research Hospital, Children's GMP, and the St. Jude Graduate School of Biomedical Sciences (collectively "St. Jude") seek to ensure the interactions faculty and staff may have with Vendors are conducted in accordance with all applicable laws and in a manner, that minimizes conflicts of interest and the real or perceived potential to improperly influence research and clinical decision-making, or create patient safety or quality care concerns.
2. This policy establishes standards for appropriate interactions with Vendors. This policy supplements the Conflict of Interest and Commitment in Research policy (Institutional Policy 70.03.001). In the event of a conflict between this policy and the Conflict of Interest and Commitment in Research policy, the terms of this policy shall govern and control. Nothing in this policy is intended to limit the responsibility of those who have a direct role in institutional decisions to avoid conflicts of interest and to interact with non-Vendor entities on an impartial basis. St. Jude faculty and staff shall not solicit gifts, meals, travel, or entertainment from non-Vendor entities wishing to do business with St. Jude. If offered by entities that do not meet this policy's definition of "Vendor," acceptance of gifts, meals, travel, and reasonable business entertainment (e.g., attendance at sporting and cultural events) is acceptable as long as the items or events are reasonable in terms of expense and will not influence any part of a decision making process.

SCOPE

This policy applies to all St. Jude faculty and staff (collectively "Employees") and their interactions with Vendors. (Please note: It may be helpful to review this policy's definition of Vendor, listed in the Definitions section below, prior to reading the policy).

POLICY

1. St. Jude has established standards Employees who engage in relationships with Vendors must follow to minimize the possibility of such relationships creating conflict of interest concerns or improperly influencing research and clinical decision-making, or creating patient safety or quality care concerns.
2. Employees may submit a Vendor Request for Exception Form to receive compensation or other items of value the policy indicates should not be accepted. The Vendor Request for Exception Form is described in greater detail in the Procedures section below.
3. Employees' interactions with Vendors must comply with the following standards:
 - A. Gifts, Meals, and Compensation

Section 70 - Corporate Compliance Plan

Effective Date: 1/4/2019

70.03.003

Relationships with Vendors

- 1) Gifts, such as textbooks, electronic devices, flowers, entertainment, etc., may not be accepted from Vendors, with the following exceptions:
 - a) Educational materials that directly benefit patients or are intended to be used by or with patients, such as models and journal article reprints, may be accepted.
 - b) Gifts of less than \$10 value (pens, notebooks, etc.) provided by Vendors may be accepted.
 - c) Unsolicited food, such as desserts and snacks delivered to the St. Jude campus and not provided in conjunction with an on-campus event (e.g., food delivered through the mail to show appreciation) may be accepted so long as the food is made available to all Employees in an area or department.
 - d) Employees shall not enter raffles or other drawings in which Vendors give away items of value, including, but not limited to, gift certificates, software, and mobile or electronic devices.
 - e) Discounts and rebates are not gifts, but are subject to requirements in the Fraud and Abuse Compliance in Contracting policy (Institutional Policy 70.02.003).
- 2) Meals may not be accepted from Vendors, with the following exceptions:
 - a) Employees must purchase their own meals (or partake in a meal funded by the hosting St. Jude department, if applicable) when attending a Vendor education session held on the St. Jude campus.
 - b) Meals paid for directly by Vendors off campus are permitted when there is a legitimate purpose justifying acceptance of the meal. Examples of meals provided for legitimate purposes are meals offered in the course of providing approved consulting or advisory services, meals at meetings directly related to ongoing research projects, and meals provided in conjunction with educational conferences or programs (e.g., covered by a registration fee, offered to all event attendees).
 - c) Employees should decline one-on-one or small group meals with Vendor representatives engaged in sales or marketing activities.
- 3) Compensation
 - a) Employees may not accept personal compensation, such as honoraria and consulting or advisory board service fees, from Vendors.
 - b) Employees may not accept sponsored or reimbursed travel expenses, such as airfare, lodging, and transportation, from Vendors.
 - c) Approved Consulting Arrangements

Section 70 - Corporate Compliance Plan

Effective Date: 1/4/2019

70.03.003

Relationships with Vendors

- i. Consulting arrangements with Vendors that simply pay a guaranteed amount with minimal or no associated duties or deliverables or that pay excessive compensation for the services provided are prohibited.
- ii. Before signing a consulting agreement, Employees must consider whether the request for services originated from the appropriate division within a Vendor organization. For example, Vendor marketing representatives are generally not the appropriate unit to engage services that are solely scientific.
- iii. All consulting arrangements must comply with the St. Jude Faculty Handbook (if applicable) and policies 70.03.001 and 70.02.003. In addition, all consulting arrangements must:
 - (a) Be in writing;
 - (b) Describe in reasonable detail the services provided;
 - (c) Provide no more than fair-market value compensation;
 - (d) Require necessary and legitimate services that are actually rendered;
 - (e) Not involve the use of St. Jude facilities, services, or resources;
 - (f) Not prohibit publication of research results generated as a result of employment at St. Jude;
 - (g) Not be motivated (or appear to be motivated) by an improper purpose, such as to incentivize the employee to change or maintain his or her purchasing or prescribing habits;
 - (h) Not be with a for-profit company sponsoring the employee's research-related work, unless the Conflict of Interest Committee has reviewed and approved the arrangement; and
 - (i) Be disclosed to and reviewed by the Office of Technology Licensing before consulting services are rendered.

B. Donations

- 1) Vendor donations (including donations of equipment, devices, or supplies) should be directed to ALSAC as set forth in institutional policy.

C. Pharmaceutical Samples and Medical Supply/Equipment Loans

Section 70 - Corporate Compliance Plan

Effective Date: 1/4/2019

70.03.003

Relationships with Vendors

- 1) Drug samples for individual patient treatment may not be accepted from Vendors (see Pharmaceutical Services Department policy 3.09); this prohibition does not apply to drug samples or free drug used in the context of a clinical trial.
- 2) The loan of medical supplies or a product, device, or equipment for the purpose of evaluating the medical supplies, product, device, or equipment is permissible for a trial period not to exceed 90 days and the arrangement must be in compliance with policy 70.02.003.

D. Site Access by Sales and Marketing Representatives

- 1) Vendor sales and marketing representatives are not permitted in any direct patient care areas except to provide in-service training and then by appointment only. This is not intended to prevent a Vendor sales or marketing representative with an appointment to see an employee from incidentally walking through a direct patient care area.
- 2) Vendor sales and marketing representatives are permitted in non-patient care areas by appointment only. Appointments will normally be made for purposes such as:
 - a) In-service training of Employees;
 - b) Evaluation of new purchases;
 - c) Provision of useful information on drug therapy, products, and purchasing (see Pharmaceutical Services Department policy 2.12); and
 - d) Presentation of seminars that share new technical, scientific, or educational information, applications, or technologies.
- 3) Vendor representative appointment and credentialing requirements are contained in the Vendor Credentialing policy 10.06.023.
- 4) Vendor representatives who will be given access to patient information must sign a St. Jude Confidentiality Form.
- 5) Vendor representatives who will be present during any patient procedure must have permission prior to the procedure from the responsible practitioner (who must have received patient consent) and must complete a health evaluation.

E. Support for Educational and Other Professional Activities

- 1) Support for accredited continuing medical education (CME) may be accepted from Vendors as long as:
 - a) The support subsidizes attendees' tuition fees only;

Section 70 - Corporate Compliance Plan

Effective Date: 1/4/2019

70.03.003

Relationships with Vendors

- b) The program meets the accreditation or certification standards and requirements of the Accreditation Council for Continuing Medical Education (ACCME), the American Osteopathic Association, the American Medical Association, the American Academy of Family Physicians, or the American Dental Association (ADA) Continuing Education Recognition Program;
 - c) Vendors have not selected the presenter(s); and
 - d) Vendors will not directly pay the presenters(s).
- 2) Direct support (including grants) from Vendors for unaccredited or noncertified CME must not be accepted.
 - 3) Vendors may not influence the curriculum of a St. Jude-sponsored educational event in any way, including, without limitation, the planning, content, and/or execution of the event.
 - a) Any presenter at a St. Jude-sponsored educational event must disclose any financial interest that poses a conflict of interest to learners prior to the educational activity and in post-meeting publications.
- F. Vendor-Sponsored Research Projects
- 1) All Vendor support (funds, devices, drugs, etc.) received via sponsored research projects must be reviewed and approved by Clinical Trials Administration or the Grants and Sponsored Programs Office, and any other appropriate department or office, and all sponsored research agreements are subject to all applicable St. Jude policies and the Faculty Handbook.
 - 2) Disclosures of potential or actual conflicts of interest with a sponsored research project must be made to the Compliance Office per Institutional policy 70.03.001 and the Institutional Review Board, if applicable.
- G. Vendor-Sponsored Conference Attendance and Speaking Engagements
- 1) Employees may attend Vendor-sponsored programs (e.g., educational meetings, lectures, and conferences). Such events must contain objective scientific and educational information that promotes evidence-based medicine and scientific research.
 - a) Programs must be structured so as not to improperly influence purchasing or prescribing decisions.
 - b) Employees' main incentive in attending the Vendor-sponsored programs must be to further their knowledge on the subject(s) presented.
 - 2) Employees may participate as bona fide lecturers at Vendor-sponsored programs if the programs:

Section 70 - Corporate Compliance Plan

Effective Date: 1/4/2019

70.03.003

Relationships with Vendors

- a) Comply with the ACCME Standards for Commercial Support or the standards of the Accreditation Council for Pharmacy Education (ACPE) or the ADA, as appropriate, whether or not CE credit will be awarded; and
 - b) Disclose to attendees orally and/or in writing their financial relationship with the Vendor, if applicable.
 - 3) Items, such as meals, transportation, lodging, or incidentals that are included with a registration fee may be accepted.
 - 4) Employees may not accept any remuneration from Vendors to pay expenses incurred by a spouse or other guest.
- H. Speaker's Bureaus and Ghost Writing
- 1) Employees may participate in a transparent writing collaboration with attribution between academic and Vendor investigators, medical writers, and/or technical writers.
 - 2) Participation in the following activities is not permitted:
 - a) Vendor-sponsored "speakers bureaus" (i.e., contractual relationships to give talks in which the topic(s) and/or content are provided by the Vendor).
 - b) Allowing professional publications and presentations to be "ghost written" (i.e., material that is officially credited to someone other than the writer(s) of the material).
 - c) Dedicated marketing and training programs designed solely or predominantly for sales or marketing purposes.
- I. Training and Education Regarding Use of Medical Devices
- 1) To ensure Employees receive training free from inappropriate influences over their clinical and research decision-making and prescribing and purchasing decisions, the following standards shall be followed:
 - a) Attendance at educational training sessions sponsored by Vendors is permitted if the setting is conducive to the effective transmission of knowledge, such as surgical suites, specialized training centers, clinical laboratories, etc.
 - b) Attendance at training sessions at international locations is discouraged when a US location is reasonably available.
 - c) Remuneration for an employee's travel and lodging in connection with a training program may be accepted from Vendors when the requirements are clearly stated in an associated agreement.

Section 70 - Corporate Compliance Plan

Effective Date: 1/4/2019

70.03.003

Relationships with Vendors

PROCEDURE

1. procedure Employees may submit a Vendor Request for Exception Form to receive compensation or other items of value this policy indicates should not be accepted. The process Employees must follow to have their request reviewed and approved is indicated on the Form. The Vendor Request for Exception Form may be used to submit a request to receive:
 - A. Gifts, meals, and compensation;
 - B. Support for educational events and conferences, including travel expenses; and
 - C. Extended evaluation periods for medical devices, equipment, and products.
2. Monitoring and Enforcement
 - A. St. Jude physicians are strongly encouraged to register in the Centers for Medicare & Medicaid Services (CMS) Open Payments system and track any records Vendors submit to CMS on the physician's behalf. Physicians who notice an inaccuracy can dispute the information and work with applicable Vendors to resolve disputes before the information is posted on CMS' publicly accessible Open Payments website.
 - B. Department chairs, division chiefs, senior management, and the Compliance Office are responsible for monitoring compliance with this policy and are expected to enforce this policy with the support of the Conflict of Interest Committee. Alleged violations of this policy must be communicated to the respective department chair, division chief, senior manager, or to the Compliance Office. St. Jude reserves the right to impose appropriate discipline when warranted. Appropriate corrective action will be determined by the department chair, division chief, or senior manager in conjunction with the Chief Compliance Officer, Chief Legal Officer, Chief Administrative Officer, or the Chief Executive Officer.

DEFINITIONS

1. Vendor – Any pharmaceutical, medical device, medical equipment, medical supply, medical service, and bioscience company, whether or not it is currently doing business with St. Jude.

REFERENCES

1. Conflict of Interest and Commitment in Research Policy 70.03.001
2. Faculty Handbook
3. Fraud and Abuse Compliance in Contracting Policy 70.02.003

Section 70 - Corporate Compliance Plan

Effective Date: 1/4/2019

70.03.003 ***Relationships with Vendors***

4. Pharmaceutical Services Department Policy 3.09
5. Vendor Credentialing Policy 10.06.023
6. Pharmaceutical Services Department Policy 2.12
7. CMS Open Payments website (<https://www.cms.gov/openpayments/>)

FORMS AND OTHER DOCUMENTS

1. [Vendor Request for Exception Form](#), available on the Compliance Office intranet site.
2. [Vendor Request for Exception Form: Evaluation Period Greater Than 90 Days](#), available on the Compliance Office intranet site.

REFERENCED INSTITUTIONAL POLICIES

Policy #	Policy Title	Owner
10.06.014	Reimbursement of Travel Expenses	Pruitt, Page
20.10.015	Continuing Medical Education (CME)	Alessi, Jennifer
70.02.003	Fraud and Abuse Compliance in Contracting	Steuer, Katherine B
70.03.001	Conflict of Interest and Commitment in Research	Pruett, Laura

Section 70 - Corporate Compliance Plan

Effective Date: 1/4/2019

70.03.003

Relationships with Vendors

POLICY DETAILS

Title: Relationships with Vendors.docx
Policy Type: Institutional
Policy Number: 70.03.003
Section: 70 - Corporate Compliance Plan
Category: 3 - Conflicts of Interest
Policy Owner: Long, Scott
Alternate: Pruett, Laura
Sponsor: Diaz, Robyn

POLICY HISTORY

Action	Approval Date	Effective Date
New Policy	2/10/2012	2/10/2012
Reviewed	9/30/2014	10/1/2014
Revised	1/4/2019	1/4/2019

Next review date is 1/4/2022

Section 70 - Corporate Compliance Plan

Effective Date: 1/4/2019

70.03.003

Relationships with Vendors

APPROVALS

Approval	Date
Owner/Alternate - Long, Scott	1/2/2019 8:38:43 AM
Sponsor - Diaz, Robyn	1/2/2019 1:06:09 PM
Administrative Approver - Quinn, Mary Anna	1/3/2019 3:43:55 PM

Signature: Signature on file in Administration Date: 1/4/2019
Director and CEO