



<b>Roswell Park Cancer Institute</b> Policy and Procedure	<b>Date Issued:</b> 11/1/2008	<b>Number:</b> 812.1
<b>Title:</b> Standards for Vendor Relationships and Interactions	<b>Revision:</b> 3	<b>Effective Date:</b> 2/24/14
<b>Prepared by:</b> Vice President for Risk Management and Corporate Compliance	<b>Approved by:</b>  Michael B. Sexton, General Counsel	<b>Page:</b> 1 of 6

## A. GENERAL STATEMENT OF POLICY

It is the policy of Roswell Park Cancer Institute (RPCI) to establish and maintain relationships with its vendors, including pharmaceutical, biotech, medical device and hospital and research equipment, supplies and service providers (Vendors) that are compliant with legal, regulatory and ethical requirements. Interactions/relationships with Vendors may involve various members of the RPCI workforce and may occur in a variety of contexts that provide critical support for patient care, educational and research activities. It is important to ensure that such Vendor relationships and interactions do not create even the appearance of improperly influencing purchasing decisions or compromising clinical or scientific objectivity, data integrity or patient safety. This policy sets forth guidelines and procedures to help ensure that RPCI pursues relationships with Vendors that support the mission of RPCI and that comply with relevant laws and ethical standards.

## B. SCOPE

This policy and procedure applies to all members of the RPCI workforce (including RPCI and HRI employees, volunteers, trainees, researchers, and other persons whose conduct, in their performance of work for RPCI is under RPCI's direct control, whether or not they are paid by RPCI) and to all Vendors who do business with RPCI, have contracts with or under negotiation with RPCI or receive funds or referrals from RPCI.

## C. ADMINISTRATION

This policy and procedure will be administered by Senior Leadership including the RPCI Department Chairs and Department Administrators with oversight by the Vice President for Risk Management and Corporate Compliance, the Vice President of Corporate Ethics and Research Subject Protection, the General Counsel and the CEO of RPCI.

## D. POLICY / PROCEDURE

1. For purposes of this Policy, the term "Vendors" means providers and companies including pharmaceutical, biotech, medical device and hospital and research equipment, supplies and service providers who are doing business with RPCI, have current contracts with RPCI or under negotiation with RPCI, receive funds from RPCI or referrals from RPCI. This policy covers the following types of interactions/relationships with Vendors:
  - a. Gifts (including meals, entertainment and travel);
  - b. Educational grants and support for education and other professional activities;
  - c. Site Access by Sales, Marketing and other Vendor representatives; and
  - d. Honoraria and payment for consulting, research or other services.

2. Gifts (including meals, entertainment and travel).

- a. Definition: A gift includes anything of value given for free (or at a reduced amount) to an RPCI employee by a Vendor, including but not limited to money, service, loans, travel, meals, refreshments, entertainment, and discounts (including holiday/special occasion presents). A gift does not include anything for which an RPCI employee pays fair market value or anything that an RPCI employee receives as a reward or prize in a contest or event open to the public.
- b. Gifts to Individuals.
  - i. RPCI employees should never request, solicit or accept personal gifts from Vendors. This prohibition specifically includes but is not limited to gifts from Vendors involved in the competitive bid process, as well as gifts that are offered in exchange for, or based on, prescribing or providing specific services or products and, gifts that are tied to the volume or value of purchases made by anyone at RPCI.
  - ii. RPCI employees are prohibited from accepting financial remuneration or gifts from vendors in return for providing confidential information including but not limited to Protected Health Information (PHI), or in exchange for making communications to patients about a vendor's products or services on behalf of RPCI.
  - iii. Except for the occasional acceptance of a business novelty, such as a pen or notepad of little or no value, the solicitation or acceptance of a personal gift from a Vendor by an RPCI employee shall be addressed through the Institute disciplinary process. Cash or cash equivalents such as gift certificates, phone cards, etc. are not business novelties and may never be accepted regardless of value.
- c. Travel.
  - i. Except as described in the provisions governing Vendor support for educational activities (Section 3. below), RPCI employees may not accept Vendor support for RPCI-work related trips, including but not limited to trips to assess Vendor products to support purchasing decisions.
  - ii. Direct payment by a Vendor to an RPCI employee for travel and/or lodging is prohibited except when provided in connection with a bona fide personal services agreement (in compliance with Section 5. below and all other Institute policies) for which travel is necessary and the travel provided is reasonable in relation to the services rendered.
- d. Food.
  - i. Food/Meals at RPCI. Meals or other gifts of food (including lunches, snacks, etc.) directly provided by Vendors (or agents of Vendors such as research monitors) shall not be permitted anywhere in the Institute. This prohibition is not meant to preclude the use by RPCI of Vendor support or grant funds to purchase food or meals at RPCI hosted, sponsored or initiated professional and educational meetings or seminars (see section 2.d.iii. below).

- ii. Food/Meals at Vendor-hosted events (not at RPCI). Acceptance of free meals from vendors at off-site Vendor-hosted events is also prohibited except as described in the next paragraph.
  - iii. RPCI employees may attend meals or receptions hosted by Vendors in connection with professional or educational meetings (such as ASCO or ASH) as long as the events are generally open to all attendees at the meetings, are modest in value and are provided in a venue and manner conducive to professional, informational or educational networking or communication.
3. Vendor Support for Educational Activities and for Seminars and Meetings Sponsored by RPCI.
- a. Standards Applicable to Vendor Support for all Educational Activities.
    - i. All educational grants/financial support from Vendors for educational programs or activities including specific lectures and seminars, CME programs, purchases of textbooks or educational materials, scholarships to attend meetings, etc, must be processed through the Development Office of the Alliance.
    - ii. There must be a written letter of agreement for each educational grant that describes the purpose of the grant and clearly establishes that the Vendor has no control over the course content, speaker selection, or product purchased and with respect to funds for lectures, seminars and conferences, otherwise assures that the grant will be used in compliance with ACCME Standards for Commercial Support (regardless of whether or not formal CME credit is awarded) and this policy. Current ACCME Standards for Commercial Support are found at [www.accme.org](http://www.accme.org) and are attached to this policy as Appendix A.
    - iii. Staff members who are involved in a vendor or product selection process may not solicit educational grants from vendors who are under active consideration for significant purchases. RPCI staff whose job includes ongoing authority and responsibility to make or influence purchasing decisions or vendor choice should not directly solicit funds from vendors under any circumstances.
    - iv. Funds provided for a specific event or purpose may be used only for that event or purpose. If the letter of agreement permits RPCI to keep unused monies, excess funds must be used for another program or activity with the same or similar purpose.
    - v. Program or other materials must disclose RPCI's sponsorship of the event and its content and any support from a Vendor or other third party.
  - b. Seminars or meetings sponsored by RPCI. Vendor support for educational seminars or meetings sponsored by RPCI (on site or off-site) is permitted as long as the event is conducted in accordance with this policy and RPCI's Continuing Medical Education (CME) policies which were developed to ensure the independence of educational activities and are based on the ACCME Standards for Commercial Support. It is strongly recommended that support for educational conferences be sought from multiple vendors or organizations.
  - c. Educational Materials (textbooks, videotapes, etc.). In the case of Vendor funds provided for the purpose of purchasing educational materials (e.g. textbooks,

videotapes), the selection and distribution of the educational materials must be made by the appropriate Department Chair or his/her designee without input from the Vendor providing the financial support.

- d. Scholarships. Vendor support for scholarships to permit healthcare professionals in training to attend educational conferences or professional meetings may be accepted as long as the appropriate RPCI Program Director or Department Chair selects the meeting and the individuals to attend the meeting and the specific use of the funds for attendance fees, travel, lodging and meals.
4. Site Access by Sales, Marketing and other Vendor Representatives. Vendor representatives who wish to visit an RPCI Department or Physician and RPCI employees who wish to meet with Vendor representatives must comply with the following procedures.
- a. Except for scheduled training or in-service education provided at the request of an RPCI employee, Vendor representatives are not permitted to meet with Physicians or RPCI employees at RPCI off-site satellite clinics such as the Amherst Center.
  - b. The Vendor representative must schedule and confirm in advance, an appointment with an identified appropriate representative of the department or a specific physician. Except as requested by an RPCI staff member, appointments are limited to Monday through Friday, 8:00 a.m. to 4:00 p.m.
  - c. On the date/time of the appointment, the Vendor representative must sign in and obtain a pass at the information desk located on the ground floor of the hospital. The pass shall not be issued until the appointment is confirmed with the department representative or specific physician.
  - d. After he/she has obtained a pass, the Vendor representative must be escorted by an RPCI staff member to the department, physician's office, or other pre-arranged meeting place. The Vendor representative may not visit other areas of the hospital or Institute unless accompanied by an RPCI employee.
  - e. The Vendor representative may not be accompanied by associates or partners unless this is agreed to by the department representative or physician when the appointment is arranged.
  - f. When scheduling the location, day and time of meetings with Vendor representatives, reasonable efforts should be made to minimize the risk that protected health information may be seen or heard by the sales representative. Accordingly, Vendor representatives may not attend any departmental meetings or conferences where patient information is disclosed and/or discussed.
  - g. Vendor representatives are not permitted in patient care areas except to provide assistance or in-service training on devices and other equipment and then only at the request of an RPCI employee and by appointment. The following additional requirements apply when a Vendor representative is requested to be present in a patient care area:
    - i. Certification that the representative is free from any health impairment which could be of potential risk to the patient including a certificate of immunization against rubella, a certificate of immunization against measles for all personnel born on or after January 1, 1957 and ppd (Mantoux) skin test for tuberculosis;

- ii. Certification that the representative has had training in HIPAA requirements and/or has signed a confidentiality or business associate agreement as appropriate;
    - iii. Consent from the patient, if applicable;
    - iv. Such other and further procedures as required by RPCI policies, procedures and Medical Staff Rules and Regulations have been followed.
  - h. At the end of the scheduled appointment, the Vendor representative should be escorted by an RPCI staff member to the Information desk to return the pass and exit the hospital.
  - i. At all times in the Institute, the Vendor representative must have in his/her possession a pass issued as indicated above and a valid vendor identification card.
  - j. Failure to comply with this policy and procedure by a Vendor representative may result in the loss of that individual representative's visitation privileges at RPCI.
5. Honoraria and Payment for Consulting, Research or Other Services provided to Vendors.
- a. Honoraria.
    - i. Definition: An honorarium is any payment, fee or other compensation, usually given on a one-time basis, to an RPCI employee for services that are not related to the individual's official duties at Roswell Park, as a gratuity or award or honor, for services such as giving a speech, writing an article, or attending a meeting or conference. Vendor payments for lodging and travel are included in the definition of honoraria.
    - ii. Pursuant to New York State Law, RPCI employees (other than physicians and research faculty) may not accept honoraria, as defined above, from any Vendor who does business with or has contracts under negotiation with RPCI.
    - iii. RPCI physicians and research faculty members may accept an honorarium for activities within their particular discipline or field as long as acceptance of the honorarium would not constitute an impermissible conflict of interest. Faculty honoraria arrangements that exceed either \$2,000 per day or \$5,000 total (excluding travel and lodging reimbursement) for the entire conference or project must be approved in advance by the Institute CEO.
    - iv. Prior approval, reporting and disclosure of the receipt of honoraria from Vendors may be required under Institute policies [1102.1](#), [708.1](#) and the New York State Public Officers Law. Additional information about honoraria can be found in Institute Policy [125.1](#) and at [www.dos.state.ny.us/ethc/rules/Part930.htm](http://www.dos.state.ny.us/ethc/rules/Part930.htm), which provides the relevant section of the Public Officers Law (19 NYCRR 930). Additional information about conflicts of interest can be found in Institute policies [708.1](#) and [1102.1](#).
  - b. Consulting, personal service and research agreements.
    - i. A formal written agreement is required for research activities funded by Vendors and for consulting or personal service agreements between RPCI and its employees (including RPCI physicians and research faculty) and Vendors. The agreement must specify the nature of the services to be provided by RPCI and

the basis for payment for the services which must be set at fair market value as determined by the value or cost of the resources expended by RPCI and its staff in providing the service. Such agreements must be reviewed and approved by the General Counsel prior to the commencement of the activity.

- ii. Proposals by or for RPCI employees to perform services for Vendors that constitute outside employment must be reviewed and approved in accordance with the procedure set out in [Policy 218.1](#), regardless of the RPCI employee's salary grade. RPCI employees must disclose reimbursement received for outside employment on the appropriate RPCI conflict of interest form and personal services performed by RPCI employees for Vendors may not constitute an impermissible conflict of interest.
  - Payment may not be accepted for simply attending (as opposed to participating as a presenter) at a Vendor-sponsored meeting.
  - Ghostwriting or the unacknowledged, undisclosed provision of content for any professional presentation to be provided by an RPCI employee pursuant to a personal services agreement with a Vendor is prohibited.
- iii. Except in cases of pre-approved outside employment, Vendors shall issue payments directly to RPCI for services rendered by RPCI employees.

## **E. DISTRIBUTION**

This Policy and Procedure will be distributed to all Institute Managers via the RPCI internal web page and to holders of backup hard copies of the manual. Managers are responsible for communicating policy content to pertinent staff.