

 ROSWELL PARK <small>COMPREHENSIVE CANCER CENTER</small>	Roswell Park Comprehensive Cancer Center Policy and Procedure	Date Issued: 11/1/2008	Number: 812.1
Title: Standard for Vendor Relationships and Interactions	Revision: 5	Effective Date: 10/22/2018	
Prepared by: Counsel for Regulatory Compliance	Approved by: Michael B. Sexton, General Counsel	Page: 1 of 5	

A. GENERAL STATEMENT OF POLICY

It is the policy of Roswell Park Comprehensive Cancer Center (Roswell Park) 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 Roswell Park 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 Roswell Park pursues relationships with Vendors that support the mission of Roswell Park and that comply with relevant laws and ethical standards.

B. SCOPE

This policy and procedure applies to Roswell Park and Health Research Inc., Roswell Park Division (HRI) employees, volunteers, trainees, researchers, and other persons whose conduct, in their performance of work for Roswell Park is under Roswell Park's, whether or not they are paid by Roswell Park (Roswell Park Workforce Members) and to all Vendors who do business with Roswell Park, have contracts with or under negotiation with Roswell Park or receive funds or referrals from Roswell Park.

C. ADMINISTRATION

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

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 Roswell Park, have current contracts with Roswell Park or under negotiation with Roswell Park, receive funds from Roswell Park or referrals from Roswell Park. This policy covers the following types of interactions/relationships with Vendors:

- a. Gifts including meals, entertainment and travel (see also Roswell Park Policy 812.2 <https://policies.roswellpark.org/sop/read/Gifts.pdf?sop=812.2&acknowledge=1>);
- 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 (see also Roswell Park [Policy 218.1](#) on Outside Activity and [Policy 122.1](#) on A+ Time).

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

- a. The definition of the term Gift and the rules governing the acceptance of Gifts from Vendors are included in [Roswell Park Policy 812.2](#). Except as permitted under the provisions of that policy, Roswell Park Workforce Members 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 Roswell Park.

The inappropriate solicitation or acceptance of a personal gift from a Vendor by a Roswell Park Workforce Member shall be addressed through the Roswell Park disciplinary process.

- b. Except as described in the provisions governing Vendor support for educational activities (Section 3. below), Roswell Park employees may only accept Vendor support for Roswell Park -work related trips, including but not limited to trips to assess Vendor products to support purchasing decisions if such acceptance is permitted under the provisions of Roswell Park [Policy 122.1](#).
- c. Direct payment by a Vendor to a Roswell Park Workforce Member for travel and/or lodging associated with Outside Activity is prohibited except when provided in connection with a bona fide personal services agreement (in compliance with Section 5. Below, Roswell Park [Policy 218.1](#) and all other Roswell Park policies) for which travel is necessary and the travel provided is reasonable in relation to the services rendered.
- d. 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 Roswell Park. This prohibition is not meant to preclude the use by Roswell Park of Vendor support or grant funds to purchase food or meals at Roswell Park hosted, sponsored or initiated professional and educational meetings or seminars.
- e. Acceptance of free meals from vendors at off-site Vendor-hosted events is generally prohibited except as permitted under the provisions of [Roswell Park Policy 812.2](#) on Gifts.

3. Vendor Support for Educational Activities and for Seminars and Meetings Sponsored by Roswell Park.

- 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 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. Roswell Park 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 Roswell Park 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 Roswell Park's sponsorship of the event and its content and any support from a Vendor or other third party.
 - b. Seminars or meetings sponsored by Roswell Park. Vendor support for educational seminars or meetings sponsored by Roswell Park (on site or off-site) is permitted as long as the event is conducted in accordance with this policy and Roswell Park'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 Roswell Park 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 visit a Roswell Park Department or Physician and Roswell Park employees who wish to meet with Vendor representatives must comply with the following:
 - a. Except for scheduled training or in-service education provided at the request of a Roswell Park employee, Vendor representatives are not permitted to meet with Physicians or Roswell Park employees at Roswell Park 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 a Roswell Park 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 a Roswell Park 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 Roswell Park unless accompanied by a Roswell Park 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 a Roswell Park 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 Roswell Park 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 a Roswell Park staff member to the Information desk to return the pass and exit the hospital.
- i. At all times at Roswell Park, 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 Roswell Park.
5. Payment for Consulting, Research or Other Services provided to Vendors.
- a. 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 Roswell Park and its employees (including Roswell Park physicians and research faculty) and Vendors. The agreement must specify the nature of the services to be provided by Roswell Park 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 Roswell Park 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 Roswell Park 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 Roswell Park employee's salary grade. Roswell Park employees must disclose reimbursement received for outside employment on the appropriate Roswell Park conflict of interest form and personal services performed by Roswell Park 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 a Roswell Park 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 Roswell Park for services rendered by Roswell Park employees.

E. DISTRIBUTION

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

Standards for Commercial Support: Standards to Ensure Independence in CME Activities

Standard 1: Independence

Standard 1.1 A CME provider must ensure that the following decisions were made free of the control of a commercial interest. (See www.accme.org for a definition of a "commercial interest" and some exemptions.) (a) Identification of CME needs; (b) Determination of educational objectives; (c) Selection and presentation of content; (d) Selection of all persons and organizations that will be in a position to control the content of the CME; (e) Selection of educational methods; (f) Evaluation of the activity.

Standard 1.2 A commercial interest cannot take the role of non-accredited partner in a joint provider relationship.

Standard 2: Resolution of Personal Conflicts of Interest

Standard 2.1 The provider must be able to show that everyone who is in a position to control the content of an education activity has disclosed all relevant financial relationships with any commercial interest to the provider. The ACCME defines "'relevant' financial relationships" as financial relationships in any amount occurring within the past 12 months that create a conflict of interest.

Standard 2.2 An individual who refuses to disclose relevant financial relationships will be disqualified from being a planning committee member, a teacher, or an author of CME, and cannot have control of, or responsibility for, the development, management, presentation or evaluation of the CME activity.

Standard 2.3 The provider must have implemented a mechanism to identify and resolve all conflicts of interest prior to the education activity being delivered to learners.

Standard 3: Appropriate Use of Commercial Support

Standard 3.1 The provider must make all decisions regarding the disposition and disbursement of commercial support.

Standard 3.2 A provider cannot be required by a commercial interest to accept advice or services concerning teachers, authors, or participants or other education matters, including content, from a commercial interest as conditions of contributing funds or services.

Standard 3.3 All commercial support associated with a CME activity must be given with the full knowledge and approval of the provider.

Standard 3.4 The terms, conditions, and purposes of the commercial support must be documented in a written agreement between the commercial supporter that includes the provider and its educational partner(s). The agreement must include the provider, even if the support is given directly to the provider's educational partner or a joint provider.

Standard 3.5 The written agreement must specify the commercial interest that is the source of commercial support.

Standard 3.6 Both the commercial supporter and the provider must sign the written agreement between the commercial supporter and the provider.

Standard 3.7 The provider must have written policies and procedures governing honoraria and reimbursement of out-of-pocket expenses for planners, teachers and authors.

Standard 3.8 The provider, the joint provider, or designated educational partner must pay directly any teacher or author honoraria or reimbursement of out-of-pocket expenses in compliance with the provider's written policies and procedures.

Standard 3.9 No other payment shall be given to the director of the activity, planning

committee members, teachers or authors, joint provider, or any others involved with the supported activity.

Standard 3.10 If teachers or authors are listed on the agenda as facilitating or conducting a presentation or session, but participate in the remainder of an educational event as a learner, their expenses can be reimbursed and honoraria can be paid for their teacher or author role only.

Standard 3.11 Social events or meals at CME activities cannot compete with or take precedence over the educational events.

Standard 3.12 The provider may not use commercial support to pay for travel, lodging, honoraria, or personal expenses for non-teacher or non-author participants of a CME activity. The provider may use commercial support to pay for travel, lodging, honoraria, or personal expenses for bona fide employees and volunteers of the provider, joint provider or educational partner.

Standard 3.13 The provider must be able to produce accurate documentation detailing the receipt and expenditure of the commercial support.

[Standard 4: Appropriate Management of Associated Commercial Promotion](#)

Standard 4.1 Arrangements for commercial exhibits or advertisements cannot influence planning or interfere with the presentation, nor can they be a condition of the provision of commercial support for CME activities.

Standard 4.2 Product-promotion material or product-specific advertisement of any type is prohibited in or during CME activities. The juxtaposition of editorial and advertising material on the same products or subjects must be avoided. Live (staffed exhibits, presentations) or enduring (printed or electronic advertisements) promotional activities must be kept separate from CME. For print, advertisements and promotional materials will not be interleaved within the pages of the CME content. Advertisements and promotional materials may face the first or last pages of printed CME content as long as these materials are not related to the CME content they face and are not paid for by the commercial supporters of the CME activity. For computer based, advertisements and promotional materials will not be visible on the screen at the same time as the CME content and not interleaved between computer 'windows' or screens of the CME content. (Supplemented February 2014; the information that follows previously appeared in ACCME policies. No changes have been made to the language.) Also, ACCME-accredited providers may not place their CME activities on a Web site owned or controlled by a commercial interest. With clear notification that the learner is leaving the educational Web site, links from the Web site of an ACCME accredited provider to pharmaceutical and device manufacturers' product Web sites are permitted before or after the educational content of a CME activity, but shall not be embedded in the educational content of a CME activity. Advertising of any type is prohibited within the educational content of CME activities on the Internet including, but not limited to, banner ads, subliminal ads, and pop-up window ads. For computer based CME activities, advertisements and promotional materials may not be visible on the screen at the same time as the CME content and not interleaved between computer windows or screens of the CME content. For audio and video recording, advertisements and promotional materials will not be included within the CME. There will be no 'commercial breaks.' For live, face-to-face CME, advertisements and promotional materials cannot be displayed or distributed in the educational space immediately before, during, or after a CME activity. Providers cannot allow representatives of Commercial Interests to engage in sales or promotional activities while in the space or place of the CME activity. (Supplemented, February 2014; the information that follows previously appeared in ACCME policies. No changes have been made to the language.) For Journal-based CME, None of the elements of journal-based CME can contain any advertising or product group messages of commercial interests. The learner must not encounter advertising within the pages of the article or within the pages of the related questions or evaluation materials.

Standard 4.3 Educational materials that are part of a CME activity, such as slides, abstracts and handouts, cannot contain any advertising, corporate logo, trade name or a product-group message of an ACCME-defined commercial interest.

Standard 4.4 Print or electronic information distributed about the non-CME elements of a CME activity that are not directly related to the transfer of education to the learner, such as schedules and content descriptions, may include product-promotion material or product-specific advertisement.

Standard 4.5 A provider cannot use a commercial interest as the agent providing a CME activity to learners, e.g., distribution of self-study CME activities or arranging for electronic access to CME

activities.

[Standard 5: Content and Format without Commercial Bias](#)

Standard 5.1 The content or format of a CME activity or its related materials must promote improvements or quality in healthcare and not a specific proprietary business interest of a commercial interest.

Standard 5.2 Presentations must give a balanced view of therapeutic options. Use of generic names will contribute to this impartiality. If the CME educational material or content includes trade names, where available trade names from several companies should be used, not just trade names from a single company.

[Standard 6: Disclosures Relevant to Potential Commercial Bias](#)

Standard 6.1 An individual must disclose to learners any relevant financial relationship(s), to include the following information: The name of the individual; The name of the commercial interest(s); The nature of the relationship the person has with each commercial interest.

Standard 6.2 For an individual with no relevant financial relationship(s) the learners must be informed that no relevant financial relationship(s) exist.

Standard 6.3 The source of all support from commercial interests must be disclosed to learners. When commercial support is "in-kind" the nature of the support must be disclosed to learners.

Standard 6.4 'Disclosure' must never include the use of a corporate logo, trade name or a product-group message of an ACCME-defined commercial interest.

Standard 6.5 A provider must disclose the above information to learners prior to the beginning of the educational activity.

Source URL:

<http://www.accme.org/requirements/accreditation-requirements-cme-providers/standards-for-commercial-support>