

	Roswell Park Comprehensive Cancer Center Policy and Procedure	Date Issued: 3/1/2000	Number: 218.1
Title: Outside Activity and Honoraria	Revision: 10	Effective Date: 3/11/2024	
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A. GENERAL STATEMENT OF POLICY

No employee of Roswell Park Comprehensive Cancer Center (Roswell Park) or Health Research Inc., Roswell Park Division (HRI) shall engage in any Outside Activity which (i) interferes or is in conflict with the proper and effective performance of the employee's duties and responsibilities at Roswell Park or HRI; (ii) brings discredit to or causes unfavorable criticism of Roswell Park or HRI; and/or (iii) assumes or usurps an opportunity that should rightly belong to Roswell Park.

B. SCOPE

This policy and procedure applies to all employees of Roswell Park and HRI.

C. ADMINISTRATION

This policy and procedure will be coordinated through the Office of the Senior Vice President for Human Resources (HR) in conjunction with the Ethics Officer.

D. POLICY / PROCEDURE

1. **Definitions**

- a. "Covered Employee" shall mean any Roswell Park or HRI employee who meets any one of the following criteria: (i) is a licensed, credentialed health care provider (*e.g.*, Physicians, Advanced Practice Providers, Pharmacists); (ii) is designated by the Roswell Park HR Department as a Policy-Maker under New York State (NYS) regulations; (iii) is at salary grade 24 and above; (iv) proposes to perform an Outside Activity for a Vendor (See Policy 812.1 at Section D.5.a.ii); or (v) proposes to perform an Outside Activity for a foreign entity.
- b. "Outside Activity" shall mean any non-Roswell Park or HRI employment (including self-employment) or provision of professional services including consulting, non-Roswell Park teaching, clinical activity (*e.g.*, moonlighting at another hospital), speaking as a service to a commercial entity (*e.g.*, speaking on behalf of a pharmaceutical company), expert witness services, holding elected or appointed public office, or serving as a director or officer for a for-profit or not-for profit entity, whether or not contemplated in an offer letter or employment agreement. Outside activity includes services for which an Honorarium is to be paid to the Roswell Park or HRI employee.
- c. "Honorarium" shall mean any payment, which may take the form of a fee or any other

- compensation, made to an employee of Roswell Park or HRI in consideration for a service performed that is not part of their official duties at Roswell Park or HRI. Such service includes, but is not limited to, delivering a speech, writing or publishing an article, or participating in any public or private conference, convention, meeting, or similar event. Honorarium shall also include payment for expenses incurred for travel, lodging, and meals related to the activity performed.
- d. "Service Payment" shall mean any payment of money, reimbursement of expenses, or other compensation made by a non- Roswell Park or HRI organization or individual in consideration for any professional activity or service performed by a Roswell Park or HRI employee. Such compensation shall include the cost of travel and expenses.
 - e. "Expense Payment" shall mean, for purposes of this policy, a payment or reimbursement made by Roswell Park or HRI for the cost of attendance, registration, travel, food, or lodging related to Professional Activity Time (A+ Time).
 - f. "Interested Source" shall mean any person or entity who on their own behalf, or on behalf of an entity, satisfies any one of the following:
 - i. is regulated by, negotiates with, seeks to contract with or has contracts with, or does other business with: (i) the Roswell Park/HRI employee, in their official capacity;(ii) Roswell Park or HRI; or (iii) any other New York State Agency when Roswell Park or HRI is to receive the benefits of the contract; or
 - ii. lobbies or attempts to influence actions, decisions, or policies of Roswell Park or HRI (including an entity or individual required to be listed on a statement of registration pursuant to §1-e(a)(1) of article 1-A of the Legislative Law); or
 - iii. is the spouse or unemancipated child of any individual satisfying the requirements of section (D.1.f.ii.) above; or
 - iv. is involved in any action or proceeding, in which administrative and judicial remedies thereto have not been exhausted, and which is adverse to either: (i) the Roswell Park or HRI employee in their official capacity; or (ii) Roswell Park or HRI; or
 - v. has received or applied for funds from Roswell Park or HRI at any time during the previous 12 months up to and including the date of the proposed or actual receipt of the Honorarium, Service Payment, or Expense Payment.
 - g. "Outside Activity Committee" is the committee that reviews applications for approval of outside activity and/or honoraria on behalf of and as designee of the President and CEO of Roswell Park and shall be composed of at least the following members: Vice President HR (or designee), Ethics Officer (or other member designated by the Chief Legal Officer), Compliance Officer, and Director of Technology Transfer and Commercialization (or designee).
 - h. "Policy Maker" shall mean a Roswell Park or HRI employee who holds a position that is determined by the Roswell Park HR Department to be a policy making position and, as for Roswell Park employees, is reported to the New York State Commission on Ethics and Lobbying in Government pursuant to the Public Officers Law. Roswell Park and HRI employees may contact HR with questions regarding their policy maker status.
 - i. "Service Payment" shall mean any payment of money, reimbursement of expenses, or other compensation made by a non-Roswell Park or HRI organization or individual in consideration for any professional activity or service performed by a Roswell Park or HRI employee. Such payment shall include covering the cost of travel and expenses.

2. **Approval for Outside Activity and Honoraria**

a. Who is Required to Obtain Approval

- i. **Covered Employees:** Covered Employees are required to obtain prior approval from the Outside Activity Committee to accept Honoraria and to participate in Outside Activities, regardless of whether they will receive compensation for the Outside Activity. This requirement applies whether or not the employee's offer letter of employment agreement explicitly or implicitly contemplates the employee performing outside activity while employed at Roswell Park or HRI.
- ii. **Policy Makers:** After receiving internal approval through the Outside Activity Committee, Policy Makers must also obtain prior approval from the New York State Commission on Ethics and Lobbying in Government (COELIG) using COELIG's Outside Activity Request form, which can be found on COELIG's website for the following types of Outside Activities:
 - a. any job, employment, or business venture that generates or is expected to generate more than \$5000 in compensation annually; or
 - b. holding an elected or appointed public office; or
 - c. serving as a director or officer of a for profit entity (regardless of compensation); or
 - d. serving as a director or officer of a not-for-profit entity when compensation is more than \$5000 annually.
- iii. **President and CEO Of Roswell Park:** After notifying the Outside Activity Committee via the Outside Activity system, the President and CEO of Roswell Park must seek prior approval from COELIG for the following activities:
 - a. providing a service for which Honoraria has been offered, *unless* the Outside Activity Committee in collaboration with the Office of General Counsel and Compliance determines that the service is exempt under 19 NYCRR 930.7; or
 - b. performing a job, employment, or business venture that generates or is expected to generate \$1000 or more per year; or
 - c. holding elected or appointed public office (as an Outside Activity); or
 - d. serving as a director or officer of a for profit entity regardless of compensation; or
 - e. serving as a director or officer of a not for profit entity that generates or expected to generate \$1,000 or more annually (Note: COELIG approval to serve as a director or officer of a not for profit entity that generates or is expected to generate between \$0 and \$999 annually is not required, but the President and CEO must notify COELIG in writing prior to commencing service).

b. Reporting Honoraria

- i. Any Covered Employee who is required to file a financial disclosure statement with COELIG shall report any Honorarium in excess of \$1000 (or all Honoraria the aggregate total of which exceed \$1000 received from a single source) in their financial disclosure statement for the applicable year.

3. **Procedure to Obtain Approval**

- a. Applications for obtaining approval from the Outside Activity Committee under this policy may be accessed on-line via the employee's personal i2 page by clicking on the

"My Outside Activity" link under the Related Links section.

- b. The application shall contain the following information, as applicable:
 - i. The name of the employee.
 - ii. The identity of the outside employer, if applicable, and nature of that employer's business.
 - iii. A detailed description of the services to be performed by the employee including the dates and locations where the Outside Activity will be performed.
 - iv. The amount of compensation or Honorarium, and when applicable, an itemization of the amounts to be paid for personal services, registration, travel, lodging and meals, etc.
- c. A copy of any written agreement to be signed by the employee in connection with the Outside Activity or Honoraria must be uploaded to the employee's application and include the Standard Provisions and academic responsibility paragraph described in the "Outside Activity Contract Requirements" attached as Exhibit A to this Policy.
- d. Completed applications will be electronically routed to the office of the Senior Vice President of HR (or designee) and must include the endorsement of the requesting employee's Department Chair/Head/Principal Investigator.
- e. The Department of HR will initially receive and review each application for completeness and shall proceed as follows:
 - i. All incomplete applications will be returned to the applicant.
 - ii. All applications for review of expert witness engagements and honoraria will be forwarded to the Ethics Officer (or their designee) for review and decision.
 - iii. All other applications will be forwarded to the members of the Outside Activity Committee for review and determination by majority vote.
- f. The Outside Activity Committee shall make its determination based on its interpretation of whether the proposed outside activity is in accordance with the applicable provisions of the New York State Public Officers Law, COELIG Advisory Opinions, pertinent Roswell Park policies and procedures, and regulations governing employee conduct and other factors including, but not limited to (i) whether there appears to be a significant conflict as defined in Roswell Park policy; (ii) a physician-applicant has other relationships with the same entity or related entities; (iii) the business in question is in competition with a service provided at Roswell Park/HRI; or (iv) the business in question is a referral source to or from Roswell Park/HRI. The Conflict-of-Interest Committee may be consulted, as necessary and appropriate.
- g. The Outside Activity Committee may approve the Outside Activity and/or Honorarium provided the following conditions are met:
 - i. An amount equal to a maximum of 50% of an FTE employee's gross salary may be earned from outside sources annually (excluding equity interests and stock dividends), with no more than 25% of gross Roswell Park/HRI salary earned from any single outside source.
 - ii. Roswell Park/HRI personnel, equipment, and time are not used in preparing for or performing the Outside Activity. (Note: If an agreement requires the use of Roswell Park/HRI resources, it should be restructured as an agreement with Roswell Park/HRI for the employee's services.)
 - iii. Roswell Park/HRI funds are not used to pay the Roswell Park/HRI employee's attendance, registration, travel, lodging, or meal expenses related to the Outside Activity.

- iv. If the Outside Activity or services for which Honoraria has been offered is to be performed during the Roswell Park/HRI employee's official workday, they must charge leave accruals (other than sick leave) to perform the Outside Activity.
- v. If the Outside Activity, compensation for Outside Activity, or Honorarium is offered by or on behalf of an Interested Source, all of the following criteria must be met:
 - a. it is not reasonable, under the circumstances, to infer that the offer of Outside Activity, the compensation, or Honorarium was intended to influence the Roswell Park/HRI employee in the performance of their official duties.
 - b. the offer of Outside Activity, the compensation, or Honorarium could not under the circumstances be reasonably expected to influence the Roswell Park/HRI employee in the performance of their official duties.
 - c. the offer of Outside Activity, compensation, or Honorarium is not, under the circumstances, intended as a reward for any official action on the Roswell Park/HRI employee's part.
 - d. the Outside Activity Committee determines that there is no attempt to conceal the fact that an Interested Source is involved in the Outside Activity or payment of the Honorarium.
 - e. performing the Outside Activity and/or accepting the Honorarium does not violate New York State Public Officers Law section 74, the federal or NY State anti-kickback laws or self-referral laws. In that connection, for example, acting as a paid consultant for a pharmaceutical company may be permissible under certain conditions including that a time-limited contract is in place that outlines the specific deliverables, tasks, responsibilities, and compensation consistent with the expertise provided.
- h. All determinations by the Outside Activity Committee shall be reported to the Conflict-of-Interest Committee.
- i. If the Outside Activity Committee approves the application, it shall include a statement on the approval indicating that the application has been approved in accordance with the conditions set forth in this policy and a citation to applicable regulations including 19 NYCRR 930.5 (for Honoraria) and 19 NYCRR part 932 (for Outside Activity), if applicable.
- j. Following the determination of the Outside Activity Committee, the Outside Activity administrator will send an email to the employee with a copy of the Committee's decision. The approval email will include any stipulations outlined by the Committee that must be followed. A copy of the approved application will also be emailed to the employee. All approvals/denials will be kept in the outside activity database.
- k. Generally, approvals are for a maximum of one (1) year period. However, an approval for Outside Activity is only valid until such time as there is a material change in the employee's Roswell Park/HRI responsibilities or in the Outside Activity, at which time a new application for approval must be submitted. The Roswell Park/HRI employee who is engaging in approved Outside Activity must reapply for approval through their i2 "My Outside Activity" link after the approved term has expired or if there is a material change in the employee's responsibilities or the approved Outside Activity. A material change includes, for example, an increase in the outside activity compensation or time to be devoted to the outside activity, or the outside entity becomes an Interested Source.

- l. Each request for approval of Outside Activity will be reviewed and decided upon on its own merits, considering such factors as the type of work, type of business, and duration of the employment.
- m. Roswell Park/HRI reserves the right in all cases to review the employee's time, accruals, Roswell Park e-mail and telephone activity, etc. to ensure that Roswell Park/HRI resources, time, equipment, or personnel have not been inappropriately utilized in connection with approved Outside Activity.

4. **General Rules for all Outside Activities**

- a. For full-time Roswell Park or HRI employees, Roswell Park or HRI shall be the primary employer. Each employee's responsibilities at Roswell Park/HRI must be the major focus of the employee's energies, efforts, and talents.
- b. Before agreeing to engage in any Outside Activity, a Roswell Park or HRI employee should consider whether the Outside Activity violates any of the statements in the General Statement of Policy above. The employee should consult with their supervisor or the Ethics Officer if they have any questions or concerns in this regard.
- c. When performing Outside Activity, the Roswell Park or HRI employee must make it clear that they are not representing Roswell Park in any capacity.
- d. In the event that a Roswell Park or HRI employee is acting as a clinical instructor on behalf of a professional school using Roswell Park as a clinical site, the employee may be permitted to perform clinical instruction during otherwise normal working hours (but still must use personal time accruals and not A+ Time); may use Roswell Park equipment or resources as are required in the normal course of doing the instructing; and must wear an identifying badge indicating that they are acting on behalf of the professional school for which the outside employment has been approved.
- e. No Roswell Park or HRI employee may engage in any activity in which the employee's ability to provide an unbiased view is limited or curtailed in any way (sometimes referred to as a speakers' bureau). To that end, employees may not participate in an Outside Activity or accept any Honorarium if the arrangement has any of the following characteristics: 1) the company has the contractual right to dictate or control the content of the presentation or talk; and/or 2) the company creates the slides or presentation material and has final approval of the content and edits; and/or 3) the Roswell Park or HRI employee is expected to act as a company's agent or spokesperson for the purpose of disseminating company or product information.
- f. Ghostwriting or the unacknowledged, undisclosed provision of content for any professional presentation to be provided by a Roswell Park or HRI employee as Outside Activity is prohibited.
- g. No Honoraria or other remuneration may be accepted to attend a sales presentation, to attend conferences where recreation or marketing are the primary focus, or for activities which are part of the physician or research faculty's Roswell Park/HRI duties.
- h. Some employees with certain titles (research scientist, cancer research scientist, research physician, research psychiatrist, psychiatrist) may be exempt from the NYS Honorarium requirements, provided that the service performed is within the subject matter of their official academic or research discipline. The Ethics Officer or designee will approve honoraria under one of the three categories below:
 - i. Category 1: Applicant is Not Exempt under 19 NYCRR 930.7
 - a. No Roswell Park resources (personnel, equipment, computer, email etc.) can be used for the activity.

- b. You must not seek reimbursement from Roswell Park/HRI for any expenses related to this activity.
- c. You may not use A+ Time for time away from the Institute to engage in this activity. You must charge accruals (other than sick time).
- ii. Category 2: Applicant is Exempt but Honoraria is Primarily for a Commercial Purpose (*e.g.*, advisory board for pharma company)
 - a. You must not seek reimbursement from Roswell Park/HRI for any expenses related to this activity.
 - b. You may not use A+ Time for time away from the Institute to engage in this activity. You must use leave accruals (other than sick time).
- iii. Category 3: The Applicant is Exempt and the Activity is Primarily for a Public Benefit Purpose
 - a. Unless you have exceeded your A+ time allotment, you may use A+ Time for time away from Roswell Park to engage in this Activity. If you have exceeded your A+ Time allotment, you must charge accruals (other than sick time).

5. **Additional Rules for Expert Witness Engagements:**

- a. Expert witness engagements may not exceed five in number per year.
- b. To avoid conflicts of interest, expert witness testimony should generally not be provided in cases pending in the eight Western New York counties or in Monroe County.
- c. Many professional and medical specialty societies have adopted guidelines for expert witness engagements. Roswell Park and HRI physicians and employees are encouraged to consult such guidelines when deciding on whether to testify as an expert witness.
- d. Expert witnesses are expected to be impartial and should not adopt a position as an advocate or partisan in the legal proceeding.
- e. Compensation for the expert witness should be reasonable and commensurate with the time and effort necessary to prepare for the engagement.

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.

OUTSIDE ACTIVITY CONTRACT REQUIREMENTS

If you are seeking approval to accept Honoraria or participate in an Outside Activity that involves a contract, you must upload an *acceptable* contract to your Outside Activity application. Your application will be considered incomplete until the acceptable contract is uploaded. If you are unsure whether the outside entity will require a contract – ask. Most companies requesting consulting services, including participation on advisory boards, will require a contract.

What is an Acceptable Contract?

An outside activity contract is acceptable only if it includes the “Academic Responsibility” paragraph below and the attached Roswell Park Standard Consulting / Speaking Agreement Provisions. You may request a copy of the Standard Provisions from the Outside Activity Committee Administrator.

Academic Responsibility: The Roswell Park Cancer Institute Corporation Standard Consulting / Speaking Agreement Provisions (“Standard Provisions”) are attached to this agreement as Appendix [INSERT APPENDIX NUMBER PROVIDED BY OUTSIDE COMPANY] and are incorporated herein by reference. [NAME OF CONSULTANT] and [NAME OF COMPANY] agree to abide by such Standard Provisions and further agree that if any provision in this agreement is inconsistent with the Standard Provisions, the Standard Provisions shall govern and prevail.

What if I upload a contract without the Standard Provisions?

Your application will be returned to you as incomplete.

What if the Outside Company requests Revisions?

The Committee will consider an outside entity’s requests for revisions, but substantive revisions are rarely accepted, and your application will be delayed. If the Committee has insufficient time to review your application due to a request for substantive revisions, your application may be denied as untimely.

Where should I send the Revisions?

The revisions should be made in a Word version of the document and appear in redline. Submit the redline by email to the Outside Activity Committee Administrator – currently Vivian Scoma Vivian.Scoma@roswellpark.org

DO NOT submit revisions to any individual committee member or to the Legal Department. Doing so will significantly delay the Committee’s decision.

Does the Committee’s approval of revisions mean my application will be approved?

No. Acceptability of a contract is only one of many factors the Committee must consider when reviewing an Outside Activity application. Uploading an acceptable contract triggers Committee review, not approval.

What must I do after the application is approved and the contract signed?

You must submit a copy of the fully signed contract to the Outside Activity Committee Administrator. Failure to do so is a violation of Roswell Park policy and may result in delay or denial of future outside activity applications. The Committee has no obligation to remind you to submit the signed contract.

EXHIBIT [INSERT EXHIBIT LETTER/NUMBER]

ROSWELL PARK CANCER INSTITUTE CORPORATION
STANDARD CONSULTING / SPEAKING AGREEMENT PROVISIONS

- a) It is the policy of Roswell Park Cancer Institute Corporation ("Roswell Park") that these Standard Consulting / Speaking Agreement Provisions ("Standard Provisions") must be attached to any written agreement ("Agreement") to provide consulting or speaking services ("Services") between an employee, student, or member of the professional staff or faculty ("Consultant") of Roswell Park and any organization ("Company").
- b) Services shall not involve any use of the funds, personnel, facilities, materials, confidential information or other resources of Roswell Park.
- c) Neither the name of Roswell Park, nor any variation thereon, nor adaptation thereof may be used in any advertising, promotional or sales literature, or other publicity without the prior written approval of Roswell Park.
- d) Consultant's rights, title and interest in inventions, discoveries and developments conceived or reduced to practice in the performance of the Services made solely or jointly with Company employees or agents ("Consulting Inventions") may be assigned to the Company, so long as the provisions in Paragraph 5 below are not applicable. Consultant shall disclose to Roswell Park's Office of Technology Transfer and Commercial Development, in confidence, all Consulting Inventions which are related to Consultant's research, clinical, or educational activities at Roswell Park in order to provide Roswell Park an opportunity to assess, together with Company, whether the invention is subject to the provisions of Paragraph 5 below.
- e) Notwithstanding Paragraph 4 above, Company agrees and understands that Consultant has a pre-existing obligation to assign to Roswell Park, all of Consultant's rights in intellectual property which arise or are derived from Consultant's employment at Roswell Park or which utilize the funds, including funding from any outside source awarded to or administered by Roswell Park, personnel, facilities, materials, or other resources of Roswell Park including resources provided in-kind by outside-sources. Company has no rights by reason of the Agreement in any publication, invention, discovery, improvement or other intellectual property, whether or not publishable, patentable or copyrightable that is subject to Consultant's obligations to Roswell Park. Company also acknowledges and agrees that it will enjoy no priority or advantage as a result of the Services created hereunder in gaining access, whether by license or otherwise, to any proprietary information or intellectual property of Roswell Park. Other than the inventions assigned to Company pursuant to Paragraph 4 above, Company shall have no rights or interests in any other inventions, discoveries or developments owned by or assignable to Roswell Park.
- f) Nothing in the Agreement shall be construed to restrict or limit the duties Consultant is performing or may perform in the course of, or incidental to, Consultant's employment at Roswell Park, including but not limited to research sponsored by a third-party commercial entity.
- g) Each party to the Agreement acknowledges (i) that the Consultant is entering into the Agreement, and providing Services to the Company, in the Consultant's individual capacity and not as an employee or agent of Roswell Park, and (ii) Roswell Park is not a party to the Agreement and has no liability or obligation hereunder.
- h) Consultant shall control the final content of any presentations and any materials presented by or attributed to Consultant ("Presentation Materials"). Consultant agrees that in performance of the Services under the Agreement any of Consultant's Presentation Materials will be objective, balanced and scientifically rigorous. Any Presentation Materials created by Consultant as a direct result of performance of Services cannot be edited by Company in any way to alter the scientific reliability and relevance. Nothing in the Agreement is intended to, nor shall be construed to

constitute, the giving or granting of permission or license to use the Presentation Materials for:
(a) any activity which constitutes sales or marketing of any particular product, service, device, technology or process; or (b) any activity directed at the general public or which can reasonably be described as medical advice or care.

i) By signing the Agreement, the parties to the Agreement agree to abide by these Standard Provisions, and further agree that if any provision in the Agreement is inconsistent with these Standard Provisions, these Standard Provisions shall govern and prevail.