

Ministry-wide	Setting: Organization-wide	Areas/Dept: All	
Title: Conflict of Interest and Disclosure Process (CC-701)			
Category/Chapter:			
Compliance			

#### **DEFINITIONS:**

- 1. A Conflict of Interest occurs when an OSF employee is in a position to make or influence a decision or take an action on behalf of OSF that results in personal gain for the employee (or an Immediate Family Member) as a result of the employee's business dealings, other financial interests (including gifts) or personal interests. Such circumstances can include a financial or personal interest that compromises:
  - a. his or her Fiduciary duty or job responsibilities at OSF;
  - b. his or her professional judgment in the delivery of patient care;
  - c. his or her scientific integrity in the conduct of Research; or
  - d. the services, operations or businesses of OSF.
- 2. **Industry Interactions** are any activities between an OSF employee and an employee or other representative of a pharmaceutical, biotechnology, medical device or other health care-related company. These activities include, but are not limited to:
  - a. compensated presentations;
  - recommending products, services or supplies to patients, employees or OSF employees;
  - c. consulting;
  - d. onsite training, Research, procedure-oriented education, Continuing Medical Education (CME), Graduate Medical Education (GME) and non-CME educational activities: and
  - e. receipt of Gifts, Business Courtesies or Contributions.
- 3. **Vendor** refers to any outside source, entity or business (or its subsidiaries, employees or agents) or individual that:
  - a. provides products or services to OSF;
  - b. otherwise does business with OSF, or desires to do business with OSF;
  - c. desires to influence, in some manner, OSF patient care or business decisions;
  - d. is in the process of negotiating a transaction or arrangement with OSF; or
  - e. offers or provides health care-related compensation or funding of any kind to employees or researchers.
- 4. Other Terms capitalized in this policy are defined in Addendum A.

#### **PURPOSE:**

- To provide general guidance and standards for interactions between OSF employees and Vendors in order to maintain professional objectivity in such interactions, and to avoid Conflicts of Interest or the appearance of conflicts.
- 2. To encourage transparency, protect the rights and welfare of our patients, and maintain public confidence in the integrity of OSF by managing, reducing or eliminating any actual or apparent Conflicts of Interest.

#### **POLICY:**

- 1. Integrity, Leadership, Trust and Stewardship are four of the foundational OSF Values. All OSF employees have a duty to act honestly and with integrity, and a duty to make decisions on behalf of, and in the best interest of, OSF and its patients.
- Consistent with the OSF Mission and Values, it is expected that individuals in positions
  of making or influencing decisions regarding Vendor arrangements and any business
  transactions on behalf of OSF or its patients will act in good faith in fulfilling their
  responsibilities.
- 3. OSF seeks to ensure that all OSF employees' relationships with industry remain (1) principled, (2) protective of the integrity of medical education, Research and clinical decision-making, (3) capable of withstanding governmental scrutiny, and (4) able to uphold public expectations for the OSF Mission, including the reputations of physicians and other employees alike.
- 4. Any Industry Interaction in which the intent of a Vendor is to influence patient care or business decisions is automatically considered a Conflict of Interest and is avoided.
- 5. Conflicts of Interest generated by pharmaceutical, biotechnology, medical device or other health care-related industry activities are resolved consistent with obligations to patient care and safety, and consistent with the business and other interests of OSF.
- 6. Compliance with this policy will also help ensure that OSF meets applicable Federal and State laws and regulations and the standards of The Joint Commission, and that OSF employees practice good business ethics with respect to actual or apparent Conflicts of Interests in health care, education and Research.
- 7. To enable OSF to manage, reduce or eliminate Conflicts of Interests, designated employees and other individuals who work at OSF facilities and who are engaged in making or influencing decisions on behalf of OSF or its patients (as outlined in this policy) are required to disclose, at least on an annual basis, all Significant Financial Interests and relevant Personal Interests related to their respective work responsibilities.
- 8. An employee may have a Significant Financial Interest or relevant Personal Interest that is not necessarily a Conflict of Interest.
- 9. Whether or not they are specifically designated to disclose, all employees are subject to the provisions of this policy, and if appropriate, will disclose any interests that could result in a Conflict of Interest.
- 10.OSF will take reasonable measures to protect the confidentiality of an individual's disclosed information and limit the flow of this information on a need-to-know basis for the sole purpose of compliance with this policy.

#### **Examples of Individuals Designated to Disclose**

11. The following categories of individuals are subject to the disclosure provisions of this policy and have been designated to disclose at least annually:

- a. Officers and executives of the OSF Ministry;
- b. Key Employees, as defined in the IRS Form 990;
- Individuals charged with purchasing, procurement and contracting decisionmaking (or whose decisions influence purchasing and contracting or the "channeling" of patients) at any level;
- d. Investigators and Key Personnel in Research (Also see Ministry Compliance policy, *Conflict of Interest and Disclosure Process for Researchers (CC- 705)*, and also applies to Research activities at OSF);
- e. OSF-employed physicians;
- f. Any other designated individuals or groups as deemed appropriate by their work responsibilities or as required by law.

# **Examples of Conduct that May Lead to a Conflict of Interest**

- 12. Below are examples of conduct or situations that may lead to the appearance of, or an actual or apparent Conflict of Interest.
  - a. Engaging in conduct that (a) violates any OSF policy, (b) is opposed in any way to the OSF Mission and Values, (c) threatens the integrity of the OSF Mission and Values, (d) creates or could create a public misperception of the OSF Mission and Values, or (e) jeopardizes patient safety or well-being; (employees, for example, may not engage in Research activity that involves embryonic stem cells derived from direct abortions.)
  - b. Accepting Gifts, Business Courtesies and other items offered by Vendors;
  - c. Receiving inappropriate payments, Contributions or other inducements from Vendors:
  - d. Applying undue pressure or otherwise leveraging one's position in an effort to promote, press or force the selection of a Vendor (or the continued engagement of a Vendor) or the hiring of a prospective employee (or any terms of employment):
  - e. Influencing a purchasing or procurement decision where there are personal gains or benefits involved;
  - f. Soliciting other OSF employees for political, financial or other personal gain for oneself or on behalf of relatives or other outside parties;
  - g. Disclosing or using proprietary or confidential OSF information, such as financial data; patient information; payer information; business, operations or marketing strategic plans, for one's personal or business purposes, or to the detriment of OSF, even if unintentionally;
  - h. Using OSF resources or assets for one's personal gain or benefit, or for personal business purposes;
  - i. Having Significant Financial Interests in a Vendor or in an entity that is in competition with the services or products that OSF provides or plans to provide;
  - j. Engaging in Compensated Activities or any outside activity that distracts from duties as an OSF employee or leads to preoccupation with other jobs, scheduling issues or activities performed during paid OSF time on behalf of other employers or clients;
  - k. Testifying as an expert witness against OSF or another OSF employee in a legal case or any matter involving OSF, unless subpoenaed.

#### **Examples of Allowable Activities That Further OSF's Mission**

- 13. Certain outside activities, whether compensated or not, may be desirable, if they further the OSF Mission, or promote goodwill or community relations on behalf of OSF, so long as the activities are without Conflict of Interest or the appearance of conflict, or involve a conflict that is being managed to minimize the effect on OSF. The activities are to have direct approval from senior management, unless it is widely understood or implicit by the employee's position that the employee is empowered as an 'agent' of OSF to engage in such activities on behalf of OSF.
- 14. Examples of activities that further the OSF Mission include:
  - a. Speaking at seminars, conferences or lectures that are not sponsored by industry:
  - b. Serving on government or other public agencies, advisory boards or review panels.
- 15. Any situation of doubt related to a potential Conflict of Interest are to be discussed with management and the Ministry Compliance and Risk Management Division (hereafter referred to as "Ministry Compliance") before engaging in any conduct or transaction that may create a Conflict of Interest. If an employee is not already subject to Disclosure, the completion of an electronic Conflict of Interest Disclosure questionnaire may be required. The employee would then also be subject to the requirements of the Disclosure Process.

### OSF Guidelines for Activities or Events that May Lead to a Conflict of Interest

16. The following OSF guidelines or limitations have been established for activities or events that may lead to a Conflict of Interest.

# Summary of Guidelines for Gifts, Business Courtesies, Contributions and Educational Activities

- 17. Employees contemplating accepting Gifts, Business Courtesies or Contributions from Vendors are to be made aware that these individuals or organizations may intend to influence employees' decisions in their favor. Acceptance of these types of offerings may inadvertently create feelings of obligation, a desire to reciprocate or a loyalty to a party other than OSF, and may create a Conflict of Interest.
- 18. Any offer with the intent to influence OSF decisions is prohibited, and Gifts, Business Courtesies or Contributions are not accepted from Vendors who are, or will be, in the OSF bidding process or in proximity to the renewal process of a contract, because of the appearance of a Conflict of Interest.

#### Specific Guidelines for Gifts

19. OSF serves our patients, residents and visitors without the need for Gifts, tips or gratuities. Employees have the responsibility of serving all patients and residents equally and are not to solicit or accept Gifts from patients, residents, visitors or Vendors. (Refer to Ministry HR policy, Gifts, Tips, and Contributions (107), for information on acceptance of Gifts from patients.) Vendor Gifts are to be refused, returned to the Vendor, or turned over to the Foundation, who will acknowledge the Gift. In limited circumstances, employees may be allowed to accept Gifts from

Vendors, but OSF places restrictions on such Gifts. The objective of limiting and disclosing Gifts is avoidance of an actual or apparent Conflict of Interest.

- 20. To determine whether Gifts offered by Vendors are acceptable, OSF has established the following specific guidelines:
  - a. <u>Gifts Given with Intent to Influence</u> Gifts given with the intent to influence an employee's patient care or business decisions are always impermissible and are refused.
  - b. <u>Cash Gifts</u> Gifts of cash or cash equivalents (such as gift cards, certificates, vouchers, checks or coupons) to an individual employee are always impermissible and are to be refused, returned to the gifting source, or given to the Foundation.
  - c. <u>Year-End Holiday Perishable Gifts</u> Gifts of food, candy or flowers that can be shared with an entire department or unit are permissible during the end-of-year holiday season if the gifts are equal to or less than \$50 from each Vendor.
    - i. Examples of allowable end-of-year seasonal Gifts that are approximately equal to \$50 include a meat, cheese and cracker tray, a two-pound box of chocolates or a small floral arrangement.
    - ii. However, perishable Gifts that are greater than \$50 are subject to Disclosure by the department head or Manager as part of his or her Disclosure requirements.
    - iii. If the Gift exceeds a \$50 retail value in a given year, the Gift should be graciously acknowledged, and then the Vendor is advised that in future years, the Gifts may not exceed a \$50 retail value.
    - iv. Alcohol is not a permitted Gift.
  - d. <u>Tickets to Events</u> Vendors may offer tickets or invitations to attend sporting, cultural or social events as a gesture of appreciation for business with OSF. Careful consideration is to be given before accepting such Gifts, which may inadvertently create feelings of obligation to reciprocate and may create a Conflict of Interest.
  - e. Gifts paid by Vendors are to be reasonable and infrequent, with respect to any particular Vendor or industry, as a whole, and are subject to Disclosure if exceeding \$50 per Vendor in a calendar year.
  - f. If an invitation is extended to a spouse, the full retail value for both the employee and the spouse is disclosed.
  - g. <u>Patient Education-Based Gifts</u> Infrequent, modest Gifts of educational value for use with patients (e.g., objective, evidence-based writing or teaching materials, anatomical models and reference books) that are not offered with the intent to influence OSF patient care or business decisions and that are presented to a department or unit (not to an individual) are acceptable and do not need to be disclosed.
    - i. The department head or Manager makes the decision whether to accept the Gift on behalf of the department or unit.
    - ii. Efforts are made to remove or cover any identifying Vendor information.
    - iii. Electronic or multi-media Gifts, such as iPods or cellular telephones, are not acceptable, as they may be used for personal use.
  - h. <u>Nominal Value Gifts</u> Other Gifts of nominal value, such as pens, pads of paper, water bottles and coffee cups, are also acceptable.

 Medication Samples – For those OSF offices or facilities that choose to dispense medication samples received from Vendors, the OSF Medical Group Sample Medication Policy provides guidance.

### Specific Guidelines for Business Courtesies

- 21. Business Courtesies paid or subsidized by a Vendor must be appropriate for the relationship with OSF, of a business nature or of an objective, evidence-based scientific or educational nature, and of a nature and value such that OSF would have normally reimbursed the expense. The recipient may not seek reimbursement from OSF for permissible expenses paid by a Vendor.
  - a. <u>Business Courtesies Offered as Incentives or Intent to Influence</u> Business Courtesies offered to an employee as an opportunity for the Vendor to influence OSF patient care of business decisions are always prohibited and are to be avoided or refused.
  - b. <u>Frequency</u> Business Courtesies paid by Vendors must be reasonable and infrequent.
  - c. <u>Business Courtesies from \$50 to \$1,000</u> Business Courtesies (including business Meals outside OSF facilities) exceeding \$50 per Vendor in a calendar year (that do not fall under any previously listed guidelines) must be disclosed.
  - d. <u>Discussion of Business Courtesies Exceeding \$1,000</u> Business Courtesies exceeding \$1,000 per Vendor in a calendar year are to be discussed with an employee's Manager with respect to avoiding a Conflict of Interest or the appearance of a conflict, in advance of accepting the courtesy. Disclosure is required. Business Courtesies exceeding \$1,000 may be considered allowable without prior discussion when the Business Courtesies are widely understood to be part of executive leadership responsibilities. Such Business Courtesies are subject to the same Disclosure requirements.
  - e. <u>Training</u> Business Courtesies offered by Vendors for training (including travel) on a product or device that OSF had purchased or is considering purchasing are permissible. Such training (including travel) is to be coordinated with Ministry Facilities Management Engineering or Supply Chain Management. Business Courtesies offered for training (including travel) on a product or device in which a physician or an employee is personally interested are to be initially reviewed and pre-approved by management.
  - f. <u>Non-CME or Other Activities</u> Business Courtesies, including trips paid or subsidized by Vendors that include entertainment, meals, socializing, golf outings, etc., for non-CME activities that, in reality (or in large part), are marketing efforts (or are for the purpose on the Vendors' part of maintaining a relationship with OSF) are subject to the dollar limits and other restrictions on Business Courtesies.
  - g. <u>Spouses Accompanying Employees on Trips</u> When spouses accompany employees for Vendor-paid or subsidized events, conferences, etc., their expenses, such as travel, lodging, meals, entertainment, etc., are to be paid by the employee. Where the Vendor has paid for the spouse to accompany the employee or sporting or cultural events, the employee's disclosure will include the expenses for both; it is not necessary to break out separate costs for the same hotel room.
  - h. <u>Meals</u> Meals provided and paid by Vendor representatives and brought into an OSF facility (whether owned or leased by OSF) are not allowed, even when

offered as a convenience to employees attending meetings or educational sessions sponsored or conducted by Vendor representatives.

- i. <u>Exceptions</u> Restrictions on acceptance of meals does not apply to employee-paid meals, meals that are paid by an OSF facility or site on behalf of employees, or Vendor-sponsored dinner tables at Foundation events.
- ii. <u>Outside Business Meals</u> Business Meals paid by a Vendor outside OSF facilities or sites, such as a business luncheon or dinner, are allowable, as necessary for OSF business reasons, and are expected to be reasonable and infrequent, with respect to any particular Vendor or industry, as a whole. Outside Meals paid by Vendors for an entire staff, department or a group of OSF employees are not allowed even as part of a meeting or training session.
  - 1) Disclosure of all Meals is to be made for any amount over \$50 per Vendor in a calendar year. Outside Meals may not be accepted from any Vendor who is attempting to influence OSF patient care or business decisions, and are not to be accepted from Vendors who are, or will be, in the OSF bidding process, because of the appearance of a Conflict of Interest.
  - 2) <u>Value of Meal and Employee's Responsibility</u> The employee has an affirmative responsibility to request from the Vendor the actual cost or a reasonably accurate estimate of the cost of an outside Meal provided or paid by the Vendor. When the value of an outside Meal cannot be accurately estimated, the employee should presume that the value of each Meal exceeds \$50, per person, for purposes of disclosure. Disclosure of Meals must be made for any amount over \$50 per Vendor in a calendar year.
- iii. <u>Meals at Outside Events</u> Meals paid by Vendors and included as part of an employee's business or educational conference fees are acceptable, subject to the guidelines for Business Courtesies.
- iv. <u>Meals for Spouses</u> It is not appropriate to include spouses in outside business Meals provided or paid by Vendors, unless there is a legitimate business reason for including them.
  - This provision does not apply to certain OSF positions, such as
    officers, executives and senior leaders, who are serving as
    representatives of OSF while attending with a spouse certain social,
    community or public events involving dinners or other Meals provided
    or paid by Vendors.
  - 2) In these situations, the Disclosure requirements would apply to both Meals. When a spouse accompanies an employee on a trip paid by a Vendor for the employee's permitted business purposes, the spouse's Meals are to be paid by the employee.

#### Specific Guidelines for Contributions /Donations

22. To provide continuity and to avoid duplication of effort, all fundraising projects and requests for support from individuals, corporations, foundations or other entities are to be initiated through the Foundation or through departments or individuals that have been authorized by senior management to do so.

- a. <u>Unsolicited Offers from Vendors</u> When receiving unsolicited offers or donations, employees, departments or units are to advise Vendors that they may not personally accept donations and that they have been instructed to forward donations to the Foundation immediately. The Foundation will acknowledge the donation.
- b. <u>Permissible Contributions Not Related to Fundraising for OSF</u> Reasonable industry Contributions, grants or other funds may be presented to a facility or department and are to be held by the Foundation so long as:
  - The funds are designated for a specific educational conference or program sponsored by a professional society, or OSF, not by industry or a Vendor; and
  - ii. Industry or the Vendor does not specify or interfere with the employees chosen by the department head or Manager to participate; and
  - iii. The department head or Manager who accepted the Contribution discloses receipt of such on his or her individual Conflict of Interest disclosure form.

# Specific of Guidelines for Educational Activities

- 23. Department heads and Managers are responsible for enabling staff to differentiate between:
  - a. Objective, evidence-based, scientific Industry Interactions that are ultimately beneficial to patients and to OSF; and
  - Various commonly-employed industry marketing strategies intended to influence decisions made by an OSF provider for patient care, or the business and other interests of OSF.
- 24. <u>Examples of Commonly-Employed Industry Marketing Strategies</u> latter may include, but are not limited to, participation in advisory boards, journal clubs, peer groups, detailing programs (including lunches) and dinner lectures. ("Detailing" programs typically focus exclusively on a given Vendor's offerings.) Industry Interactions may not be limited to discussion of the program sponsors' products or services, and Employees are to not be paid for participating in such discussions. In general, the programs in which employees participate may not involve unethical practices.
  - a. <u>CME/GME Activities</u> The primary mission of accredited clinical training programs is to support objective, scientific, evidence-based, patient-focused, competent and responsible clinical care. The training for Continuing Medical Education (CME) will meet the standards for objective, scientific, evidence-based educational content and will meet the Accreditation Council for Continuing Medical Education (ACCME) Standards for Commercial Support.
    - i. Graduate Medical Education (GME) is to provide an organized educational program of guidance and supervision of residents, facilitating the residents' professional, personal and ethical development, while ensuring safe and appropriate care for patients. GME will be provided by sponsoring institutions that are in substantial compliance with the Accreditation Council for Graduate Medical Education (ACGME) Institutional Requirements, and the sponsoring institutions ensures that their ACGME-accredited programs are in substantial compliance with institutional, common and specialty-specific program requirements.
    - ii. A Vendor's support of an employee's attendance at CME or GME programs is considered a type of Business Courtesy when the Vendor covers or

- subsidizes the cost of the employee's participation, including conference fees and travel expenses. Business Courtesy guidelines for Disclosure requirements apply.
- iii. Monetary Contributions offered directly to employees by industry sources for CME or GME support may not be earmarked for certain employees. Grants or other funds are to be turned over to the Foundation to hold for a given department. (See 'Specific Guidelines for Contributions' under #18.)
- iv. The disbursement of grants or other educational funds contributed by industry sources to the Foundation is the responsibility of the department head or Manager who selects the employees to attend.
- b. <u>Non-CME or Other Activities</u> The continual stream of developing therapeutic information from academic and commercial sources are to be critically evaluated. Discretion is necessary to determine whether non-CME educational or other activities present only (potentially biased) industry-based information or industry information for marketing purposes, rather than provide objective, scientific, evidence-based educational content. Activities that, in reality (or in large part), are marketing efforts are to be avoided.
  - Industry support for such activities is subject to the OSF Conflict of Interest Disclosure requirements outlined in *Business Courtesies* and *Contributions*, above.
  - ii. If industry support for such activities is offered to an employee, and is, therefore, subject to the OSF Conflict of Interest Disclosure requirements, the department head or Manager is responsible for initially reviewing and verifying that a proposed activity has objective educational merit, or is for appropriate business-related purposes, and then providing pre-approval for attendance in instances in which there is no actual or apparent Conflict of Interest.
  - iii. Educational portions of a conference or training program are to constitute the substantial majority of time, whereas social events sponsored by or connected with industry supporters are to be of modest value (and are subject to Business Courtesy and Meal guidelines under #17.).
  - iv. Practical courses not offered through professional societies will be viewed as industry marketing or speaker's bureau activities.

#### **Summary of Guidelines for Personal Interests or Activities**

- 25. Examples of personal interests or activities that may present an actual or apparent Conflict of Interest include, but are not limited to:
  - a. An employee who applies undue pressure or otherwise leverages his or her position in an effort to promote, press or force the selection of a Vendor (or the continued engagement of a Vendor) or the hiring of a prospective employee (or any terms of employment);
  - b. An employee who influences a purchasing or procurement decision where there are personal gains or benefits involved;
  - c. An employee who serves in an unpaid capacity on an industry board or advisory committee;
  - d. An employee who discloses or uses proprietary or confidential OSF information for his or her personal or business purposes, or to the detriment of OSF, even if unintentional;

- e. An employee who uses OSF resources or assets for his or her personal gain or benefit, or for personal business purposes;
- f. An employee who has institutional affiliations, academic pressure or personal relationships that may influence his or her decisions, judgment or conduct; or
- g. An employee's opportunities for advancement or recognition for his or her contributions, if the employee allows such opportunities to influence his or her treatment decisions or treatment recommendations to patients.

### **Summary of Guidelines for Ownership Interests**

- 26. Ownership interest in a publicly-traded Vendor when an employee's or an Immediate Family Member's cumulative equity interest is valued at \$10,000 or more, or 5% or more, whichever is less, of the Vendor is subject to the Conflict of Interest Disclosure requirements.
- 27. If the Vendor's business is directly or indirectly related to the employee's professional or business responsibilities at OSF, and the ownership interest is determined to be an actual or apparent Conflict of Interest, then a customized Management Plan to manage, reduce or eliminate any actual or apparent Conflict of Interest is required.
- 28. Similarly, any ownership interest in a privately-held Vendor (including the employee's own business) is subject to the Disclosure requirements. If the Vendor's business is directly or indirectly related to the employee's professional or business responsibilities at OSF, and the ownership interest is determined to be an actual or apparent Conflict of Interest, then a customized Management Plan to manage, reduce or eliminate any actual or apparent Conflict of Interest is required.
- 29. Ownership interest in any entity that is obviously unrelated to an employee's role at OSF, such as a restaurant or dry cleaning business typically would not be considered a Conflict of Interest (although using OSF work time and resources to operate one's own business would be considered a Conflict of Interest).
- 30. Also, competing directly with OSF in the purchase or sale of property, property rights, interest or services is prohibited.

# **Summary of Guidelines for Compensated Activities Outside OSF Employment**

- 31.OSF does not wish to impose restrictions on Compensated Activities outside OSF employment so long as the activities do not present actual or apparent Conflicts of Interest. Resolving any Conflicts of Interest is done to protect the rights and welfare of OSF patients and to protect the reputation and the strategic and business interests of OSF.
- 32. Any offer of a Compensated Activity are not to be accepted from Vendors who are, or will be, in the OSF bidding process or in proximity to the renewal process of a contract, because of the appearance of a Conflict of Interest.
- 33. Outside Compensated Activities are to meet all OSF requirements that may relate to those activities, including, but not limited to, the requirements of Ministry HR policies, Confidentiality (105), Attendance (602), Medical Examinations (203) and Solicitation and Distribution (111).

- 34. If, a facility or department has more restrictive limits or disclosure requirements, they will monitor and enforce the more stringent requirements within their division by designated management staff.
- 35. Additionally, the involvement of other employees, residents or trainees in the Compensated Activities of an employee or Immediate Family Member must be avoided.

# General Guidelines for Compensated Activities Outside OSF Employment

- 36. To determine whether Compensated Activities are or may lead to Conflicts of Interest, OSF has established the following general guidelines:
  - a. <u>Compensated Activities Involving Health Care Products or Services and Exceeding \$1,000, or \$10,000 Cumulatively</u> Disclosure is required when compensation from Compensated Activities involving health care products or services exceeds \$1,000 per Vendor in a calendar year, or \$10,000 cumulatively that year from all Vendors.
    - In addition to Disclosure, the employee is required to discuss the outside Compensated Activity with his or her department head or Manager and receive pre-approval before undertaking the activity.
    - ii. The department head or Manager utilizes the guidelines under 'General Criteria For Evaluating Disclosures And Determining Actual Or Apparent Conflicts Of Interest' in this policy for reviewing the compensated activity.
    - iii. Otherwise, if it is determined to be a Conflict of Interest through the Disclosure Process, then management, reduction or elimination of the Conflict of Interest will be required.
    - iv. The criteria in sections c. (i-iv), and d.(i-iv) below are also met.
  - b. <u>Compensated Activities When Representing OSF</u> Disclosure is required when compensation from one or more Compensated Activities in which an employee is representing OSF as its agent and which benefits OSF exceeds \$1,000 (for a single activity or cumulatively for all such activities) in a calendar year. Generally speaking, however, such an activity is not likely to be considered a Conflict of Interest so long as the employee has approval for the activity from his or her department head or Manager or implicitly by virtue of his or her OSF executive position. The employee may prepare on OSF time and may use reasonably necessary OSF resources. It is strongly recommended that the employee convey the compensation for all such activity to the Foundation.
  - c. <u>Compensated Activities Involving "Moonlighting" Related to Employee's OSF Work Responsibilities</u> When compensation is received from one or more outside jobs related to the employee's OSF job responsibilities ("moonlighting"), disclosure is not required, and any such outside job is not considered to be a Conflict of Interest so long as:
    - i. The outside job does not detract in any way from the business operations or strategic plans of OSF; and
    - ii. The outside job does not prevent the employee from making decisions at OSF that are in the best interests of OSF and its patients; and

- The employee does not run the risk of using or disclosing OSF proprietary or confidential information in the course of the outside activity; and
- iv. The employee is not representing OSF; and
- v. The criteria in the next section are met.
- d. <u>Compensated Activities Completely Unrelated to Employee's OSF Work Responsibilities</u> When compensation is received from one or more outside jobs that are completely unrelated to the employee's OSF work responsibilities, disclosure is not required, and any such outside job is not considered to be a Conflict of Interest so long as:
  - i. The outside job does not interfere in any way with the employee's job performance, including the responsibilities specified in his or her employment contract, if applicable; and
  - ii. The outside activity does not involve behavior that violates any OSF policy, conduct that is opposed in any way to the OSF Mission and Values, or behavior that jeopardizes patient safety or well-being; and
  - iii. The employee discusses any concerns with his or her department head or Manager as to whether his or her outside job may be considered a Conflict of Interest and whether his or her outside job may present any scheduling conflicts.
  - iv. If the criteria above are not met, or if there are concerns on the part of the employee's department head or Manager that there may be a Conflict of Interest, the department head or Manager may contact the Ministry Compliance for guidance. The employee may be asked to complete a disclosure, but there is no presumption of prohibited activity or wrongdoing.

# Specific Guidelines for Certain Compensated Activities Outside OSF Employment Consulting

- 37. Consulting services may not violate the OSF Mission and Values. (For example, an employee will not provide consulting services involving embryonic stem cells derived from a direct abortion.)
- 38. Consulting services are clearly defined, with an actual need for the services to be provided.
- 39. Payment to an employee is reasonable and consistent with fair market value for the employee's time and expertise.
- 40. Payment to an employee is not based on the volume or value of business that is generated for the outside source.
- 41. Payments to an employee do not involve ownership interests or in-kind compensation.
- 42. The time committed by an employee to his or her consulting services is in compliance with the terms of his or her work responsibilities or employment contract with OSF.
- 43. Serving as a consultant to a government agency or an entity working on behalf of the government is encouraged by OSF and, although subject to the Conflict of Interest Disclosure requirements, is unlikely to lead to a Conflict of Interest.

#### **Authorship**

- 44. Authorship credit is intended to promote accountability and demonstrate evidence of independence, based on specific peer-review standards or on the International Committee of Medical Journal Editors (ICMJE) authorship criteria, which include, among other criteria, the need for an employee to make "substantial" contributions and have actual involvement, as well as the requirement that the employee retain the right to publish.
- 45. Independence is not possible when an outside entity has full or partial control of any aspect of publication. A Conflict of Interest occurs when an employee has a competing interest that could influence, or could create the appearance of influencing, patient care or other OSF interests. (See also 'Presentations and Disseminating Information', below.) By definition, ghostwriting, where a publication bears an employee's name, but the employee is not the actual writer or had a minor role in the authorship, cannot meet such criteria, and, as such, is an example of an impermissible Conflict of Interest.

# **Presentations and Disseminating Information**

- 46.OSF is committed to objectivity and intellectual rigor in the transmittal of medical information. Therefore, clinical information disseminated in any form cannot be controlled, in whole or in part, by an industry source.
- 47. If an OSF physician, clinician or other OSF employee is asked by an industry source to make a presentation or other means of information dissemination (including publications and patient education), there may not be financial ties between the physician/clinician/employee and the industry source.
- 48. An OSF presenter may use an OSF logo, or the logo of an entity affiliated with OSF, on slides or similar materials if the presenter is representing OSF as approved by his or her department head or Manager (or as part, as is widely understood, of his or her job responsibilities).
- 49. A limited number of industry-prepared slides may be used if:
  - a. The slides represent sound scientific data or information and were prepared in accordance with the standards required by the FDA to prevent off-label use; and
  - b. The slides were imbedded into the OSF presenter's own work and prominently identify the industry source for each slide; and
  - c. The OSF presenter specifies that the content of the presentation reflects his or her own views, not the views of industry; and
  - d. The OSF presenter provides a fair and balanced assessment of the therapeutic options in an effort to promote scientific discourse; and
  - e. Any actual or apparent Conflict of Interest has been disclosed and resolved through the OSF Conflict of Interest Disclosure Process; and
  - f. When presenting at a conference held by a professional society (or the equivalent), any Conflict of Interest has been resolved with reference to the professional society's guidelines.
- 50. An example of an impermissible Conflict of Interest related to presentations is participation by an employee in an industry-sponsored or industry-supported speaker's

bureau in which industry (or a specific Vendor) provides training on making presentations and opportunities to present.

# **Intellectual Property**

51. Intellectual Property rights, including patents, copyrights, trademarks, licensing agreements and royalty arrangements, especially rights in pharmaceutical, biotechnology, device manufacturer or health care-related technology products or services, that provide personal gain to an employee may be considered an actual or apparent Conflict of Interest and are subject to the Conflict of Interest Disclosure requirements.

### **Expert Testimony**

52. An OSF employee may not testify as an expert witness against OSF or another OSF employee in a legal case or any matter involving OSF, unless subpoenaed.

#### Research

- 53. Refer to Ministry Compliance policy, *Conflict of Interest and Disclosure Process for Researchers (CC-705).*
- 54. Research support from a Vendor in which an employee or an Immediate Family Member has a Significant Financial Interest, or Research involving Intellectual Property that is currently owned (or is expected to be owned) by a Vendor, is subject to the Conflict of Interest Disclosure requirements and, in general, is prohibited or, at a minimum, requires a customized Management Plan to manage, reduce or eliminate any actual or apparent Conflict of Interest.
- 55. An agreement with any outside entity that provides for exclusive or limited access to Research data is not allowed.
- 56. Any arrangement that involves any form of scientific misconduct is prohibited.

#### **Board Membership**

57. A paid membership on the governing board or an advisory board of a competitor or Vendor of OSF, or a leadership role or other position (including an employment relationship) with a competitor or Vendor may well be an actual or apparent Conflict of Interest and is subject to the Conflict of Interest disclosure requirements.

#### **Summary of Guidelines for Personal Interests or Activities**

- 58. Examples of personal interests or activities that may present an actual or apparent Conflict of Interest include, but are not limited to:
  - a. An employee who applies undue pressure or otherwise leverages his or her
    position in an effort to promote, press or force the selection of a Vendor (or the
    continued engagement of a Vendor) or the hiring of a prospective employee (or
    any terms of employment);
  - b. An employee who influences a purchasing or procurement decision where there are personal gains or benefits involved;
  - c. An employee who serves in an unpaid capacity on an industry board or advisory committee:

- d. An employee who discloses or uses proprietary or confidential OSF information for his or her personal or business purposes, or to the detriment of OSF;
- e. An employee who uses OSF resources or assets for his or her personal gain or benefit, or for personal business purposes;
- f. An employee who has institutional affiliations, academic pressure or personal relationships that may influence his or her decisions, judgment or conduct; or
- g. An employee 's opportunities for advancement or recognition for his or her contributions, if the employee allows such opportunities to influence his or her treatment decisions or treatment recommendations to patients.

# **Summary of Guidelines for Ownership Interests**

- 59. Ownership interest in a publicly-traded Vendor when an employee's or an Immediate Family Member's cumulative equity interest is valued at \$10,000 or more, or 5% or more, whichever is less, of the Vendor is subject to the Conflict of Interest Disclosure requirements. If the Vendor's business is directly or indirectly related to the employee's professional or business responsibilities at OSF, and the ownership interest is determined to be an actual or apparent Conflict of Interest, then a customized Management Plan to manage, reduce or eliminate any actual or apparent Conflict of Interest is required.
- 60. Similarly, any ownership interest in a privately-held Vendor (including the employee's own business) is subject to the Disclosure requirements. If the Vendor's business is directly or indirectly related to the employee's professional or business responsibilities at OSF, and the ownership interest is determined to be an actual or apparent Conflict of Interest, then a customized Management Plan to manage, reduce or eliminate any actual or apparent Conflict of Interest is required.
- 61. Ownership interest in any entity that is obviously unrelated to an employee's role at OSF, such as a restaurant or dry cleaning business typically would not be considered a Conflict of Interest (although using OSF work time and resources to operate one's own business would be considered a Conflict of Interest).
- 62. Competing directly with OSF in the purchase or sale of property, property rights, interest or services is also prohibited.

# General Criteria For Evaluating Disclosures And Determining Actual Or Apparent Conflicts Of Interest

- 63. The following criteria are among the factors that may be considered by a department head or Manager or by the Ministry Compliance in determining whether a Conflict of Interest exists. Not all criteria will be applicable to every situation.
  - a. Does the outside activity involve conduct that violates any OSF policy? Is it opposed in any way to the OSF Mission and Values? Does it jeopardize or have the potential to jeopardize patient safety or well-being?
  - b. Does the outside activity detract, in any way, from the best interests of OSF patients or the business operations or strategic plans of OSF?
  - c. Does the outside activity interfere in any way with the job performance of the employee, including any mandatory overtime requirements?

- d. Does the outside activity have the potential to influence the employee's decisionmaking on behalf of OSF?
- e. Is the party providing Gifts or paying the OSF employee a Vendor or a competitor of OSF, especially in instances in which the employee has the ability to influence the decision to engage or retain the Vendor or other party or to influence patient care or business decisions?
- f. Does the employee run the risk of using or disclosing OSF proprietary or confidential information in the course of the outside activity?
- g. Is there any false or implied representation of OSF or any of its operating units? Is a prominent disclaimer necessary to the effect that the employee is not representing OSF?
- h. Is the outside activity prepared, provided or presented on the employee's own time? Are any OSF resources, including facilities, equipment, materials and OSF employees' time, being used without management approval for the outside activity?
- i. Does the outside activity involve the development or promotion of a commercial product or service that is opposed to or in competition with the business interests or strategic direction of OSF? If so, then has the activity been approved by OSF senior management?
- j. Is an outside activity involving professional services clearly defined? Is there an actual need for the services, as opposed to artificial or superficial reasons on the part of an outside source such that it appears that the arrangement is intended simply to influence the employee?
- k. Is the compensation for the outside activity reasonable and consistent with "fair market value," considering the services to be provided, such that it appears that the compensation is intended simply to influence the employee?
- I. Is compensation for the outside activity based on the volume or value of business that is generated for the outside source?
- m. Is the employee being compensated for an outside activity involving health care products or services through receipt of any kind of ownership interest, including stock or stock options, or by receipt of a Fiduciary or leadership appointment, such as a director, officer or partner role?
- n. If the outside activity involves a presentation or other dissemination of information, then is the content of the presentation controlled, in whole or in part, by an outside source? Are there financial ties to an outside source that may influence the work or work product (such as published findings)?
- o. Does the outside activity inappropriately prevent or inhibit independence in any way, especially with respect to Research or patient care?

### PROCESS:

- 1. The following information describes the online Disclosure Process, including the process for reviewing and evaluating Disclosures, and, as applicable, for managing, reducing or eliminating actual or apparent Conflicts of Interest.
- 2. If an individual is required to disclose, a complete and accurate Disclosure is required, whether or not the individual in question believes that there is a possibility of a Conflict of Interest.

#### **Disclosure Schedules**

- 3. The following schedules for Disclosures apply:
  - a. <u>Annual:</u> All designated individuals complete and submit an online Disclosure form annually. Employees will typically have until the end of the calendar year to update their electronic disclosure questionnaire for incidental disclosures.
  - b. Incidental Disclosures:
    - i. Any changes in Significant Financial Interests or relevant Personal Interests that occur after the annual Disclosure are to be disclosed at the time of or subsequent to the event, but may be made at any time during the calendar year, so long as the changes are disclosed at least annually.
    - ii. Examples of reportable changes include, but are not limited to, a new consulting arrangement, the purchase or inheritance of stock in a pharmaceutical, biotechnology or medical device company, and the cessation of payments from an outside entity.
  - c. <u>Project-Related Disclosure:</u> For certain projects involving one or more Vendors, employees may be asked to provide a focused disclosure for any personal or financial potential or actual relationship between the Vendor and the employee, such as for a Research or Product Review Committee project.
  - d. Third-Party Disclosure:
    - i. If an individual observes an employee's activity or actions that appear to be a Conflict of Interest, the individual is encouraged first to direct that employee to this policy and other applicable policies, and then use the chain of command to express concern.
    - ii. The Manager contacts Ministry Compliance to discuss situations involving potential Conflicts of Interest and the possible need for Disclosure.
    - iii. The individual may call the OSF Integrity Line at 1-800-547-2822.
    - iv. The identity of the person raising an issue through the Integrity Line remains confidential to the extent possible, and employees reporting in good faith to the Integrity Line are protected from retaliation under Ministry HR policy, *Whistleblower Protection* (130).
    - v. Disclosures will be reviewed by Ministry Compliance.

#### **How to Disclose**

4. All Disclosures are made by completing the online Disclosure form. Instructions for logging in are provided in the introductory notification email sent to each individual who has been designated to disclose. Additional instructions are then provided online for completion of the electronic questionnaire form. OSF policies and supporting documents are available on the website for reference. For a Third-Party Disclosure, follow the instructions provided under "Third Party Disclosure," above.

#### **Disclosure Attestation Statement**

5. Upon completion of the online Disclosure questionnaire, the employee will attest that he or she has read, understands and agrees to comply with the OSF Conflict of Interest policies and that he or she has made all Disclosures to the best of his or her knowledge.

#### **Review and Evaluation of Disclosure**

6. Once an employee has responded to the Disclosure questionnaire, it will be reviewed

and evaluated by designated staff in the Ministry Compliance, and if actual or apparent Conflicts of Interest are identified in the Disclosure, the individual will be informed of the status of the review process, including the need for additional information, the need for a Management Plan or the need for further review by the Conflict of Interest Committee. A notification will be sent after review of the Disclosure if no actual or apparent Conflicts of Interest exist.

## **Request for Reconsideration**

7. OSF is committed to fairness and recognizes that there may be circumstances in which facts are incomplete or misunderstood. Therefore, OSF will honor a request for reconsideration by an employee who is asked to eliminate or manage actual or apparent

## Noncompliance with Policy

8. Noncompliance with this policy may incur administrative action, up to and including termination of employment or loss of specific privileges, such as participation in education or Research activities. Employees not complying with this policy are subject to the Positive Discipline process. (Refer to Ministry HR policy, *Positive Discipline* (601).)

#### REFERENCES:

Confidentiality (105). Ministry Human Resource policy retrieved May 2014.

Gift, Gratuities and Contributions (107). Ministry Human Resource policy retrieved May 2014.

Membership in Professional or Other Organizations (108). Ministry Human Resource policy retrieved May 2014.

Education, Training and Development (109.) Ministry Human Resource policy retrieved May 2014.

Conflicts of Interest (110). Ministry Human Resource policy retrieved May 2014.

Solicitation and Distribution (111). Ministry Human Resource policy retrieved May 2014.

Political Campaign Activity (129). Ministry Human Resource policy retrieved May 2014.

Whistleblower Protection (130). Ministry Human Resource policy retrieved May 2014.

Employment of Relatives (204). Ministry Human Resource policy retrieved May 2014.

Medical Examination (203). Ministry Human Resource policy retrieved May 2014.

Positive Discipline (601). Ministry Human Resource policy retrieved May 2014.

Attendance (602). Ministry Human Resource policy retrieved May 2014.

OSFMG Sample Medication Policy. OSFMG/Ambulatory policies retrieved May 2014.

This policy is in effect for OSF Healthcare System, OSF Healthcare Foundation and all OSF Healthcare System subsidiaries and affiliates, except as limited in the header or body of this policy. For purposes of this policy, the terms "subsidiaries" and "affiliates" mean facilities or entities wholly owned or wholly controlled by OSF Healthcare System. Specifically, this policy applies to:

		Name as listed with Medicare:
$\boxtimes$	OSF St. Mary Medical Center	ST MARY MEDICAL CENTER
$\boxtimes$	OSF Saint Francis Medical Center	SAINT FRANCIS MEDICAL CENTER
$\boxtimes$	OSF Saint James – John W. Albrecht Medical Center	SAINT JAMES HOSPITAL
$\boxtimes$	OSF St. Joseph Medical Center	ST JOSEPH MEDICAL CENTER
$\boxtimes$	OSF Saint Anthony Medical Center	SAINT ANTHONY MEDICAL CENTER
$\boxtimes$	OSF St. Francis Hospital & Medical Group	ST FRANCIS HOSPITAL
$\boxtimes$	OSF Holy Family Medical Center	OSF HEALTHCARE SYSTEM
$\boxtimes$	OSF Saint Elizabeth Medical Center	Ottawa Regional Hospital & Healthcare Center
$\boxtimes$	OSF Saint Luke Medical Center	OSF HEALTHCARE SYSTEM

Approved By: Board of Directors	Revision Approval Dates: 06/2014; 02/2011
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Responsible Party: Ministry Compliance and Risk Management Division	Review Dates:
Original Approval Date: 10/2010	Rescinded Date:
Original Effective Date: 01/01/2010	

### **ADDENDUM A**

#### **DEFINITIONS**

**Business Courtesies** are activities or items of value that are provided to individuals by outside entities (or employees or agents of outside entities) at no or subsidized cost to the individual, presumably to participate in business-related activities. Examples may involve educational activities, such as continuing medical education (CME) programs, professional or Vendor-sponsored conferences, roundtable discussions and advisory meetings. Business Courtesies include Vendor-paid travel, lodging, meals, professional membership fees and entertainment, such as hospitality activities, golf outings and sporting or cultural events.

**Conflict of Interest** exists in circumstances in which an OSF employee has a financial or personal interest that compromises (1) his or her Fiduciary duty or job responsibilities at OSF, (2) his or her professional judgment in the delivery of patient care, (3) his or her scientific integrity in the conduct of Research, or (4) the services, operations or businesses of OSF. A Conflict of Interest occurs when an OSF employee is in a position to make or influence a decision or take an action on behalf of OSF that results in personal gain for the employee (or an Immediate Family Member) as a result of the employee's business dealings, other financial interests (including Gifts) or personal interests.

Compensated Activities may involve another job, a consulting arrangement, a speaking engagement, participation in a speaker's bureau, promoting products or services, commercial product or service development, serving on a community or advisory board, or holding a Fiduciary or leadership position in another company (including one's own). Compensated Activities may or may not need to be disclosed depending on the nature of the activity. (Typically, "moonlighting" that meets certain criteria does not need to be disclosed.)

**Compliance Division** is the office of the Corporation's Corporate Administration that is responsible for developing standards and coordinating functions related to Conflict of Interests.

**Conflict of Interest Committee** is the group of individuals that is responsible on behalf of OSF for reviewing and managing reported or identified actual or apparent Conflicts of Interests. The OSF Conflict of Interest Committee is authorized by the Corporation's Board of Directors.

**Contributions** are a type of Gift that involves a donation by a Vendor to OSF or to an OSF employee, who then contributes the donation to OSF or uses the Contribution for another specific purpose.

**Disclosure** is the means through which individuals inform OSF of financial or personal and related outside interests so that OSF may determine if an actual or apparent Conflict of Interest exists.

**Disclosure Process** is the process used by OSF to gather, review and evaluate financial and personal Disclosures, identify Conflicts of Interest, develop Management Plans, communicate with key individuals, and manage the overall Conflict of Interest process.

**Fiduciary** describes the role or responsibility of a person to whom property or authority is entrusted for the benefit of another. Fiduciary service relevant to a Conflict of Interest includes an individual's membership on an advisory or governing board (including a Board of Directors) for any outside entity, whether for-profit or not-for-profit. All outside Fiduciary service is to be disclosed to determine whether an actual or apparent Conflict of Interest exists.

### <u>ADDENDUM A</u>

#### **DEFINITIONS**

**Foundation** refers to the OSF HealthCare Foundation or to the charitable foundation established by any OSF Facility or Operating Unit.

**Gifts** refer to items offered or provided by Vendors. Examples of Gifts include cash (or cash equivalents, such as gift cards, certificates, vouchers, checks or coupons), gratuities, Business Courtesies, Contributions, or free or discounted: clothing, jewelry, tickets to events, educational items, patient care items, iPods, cellular phones, or other electronic media, and loans.

Immediate Family Member of an individual refers to the spouse, siblings, children and parents of an individual, including their spouses, as well as step-parents, step-siblings and step-children and children by adoption. It may also refer to any individual, although not related by blood, marriage or adoption, with whom one has a personal relationship (with a close, long-time friend, for example) or business relationship (with a partner in a business venture outside OSF, for example) that may create a workplace Conflict of Interest.

Industry Interactions are any activities between an OSF employee and an employee or other representative of a pharmaceutical, biotechnology, medical device or other health care-related company. These activities include, but are not limited to, consulting; compensated presentations; participation in speaker's bureaus; authorship or ghostwriting; acting as an expert witness; marketing of new drugs, devices or other health care products; demonstrating new devices or other health care products for other employees; recommending products, services or supplies to patients, employees or OSF employees; onsite training, Research, procedure-oriented education, Continuing Medical Education (CME), Graduate Medical Education (GME) and non-CME educational activities; and receipt of Gifts, Business Courtesies or Contributions.

**Investigator** includes the Principal Investigator (PI) and any other person responsible for the design, conduct or report of Research, regardless of the source of funding.

**Key Employees** are OSF employees who are deemed to be "Key Employees" for purposes of the IRS Form 990.

**Key Personnel** are people listed as such on Research applications and Institutional Review Board (IRB) application documents, representing individuals who make a substantial contribution to a Research project.

**Management Plan** is a documented communication assigned to an individual that prescribes the course of action that must be taken to manage, reduce or eliminate an actual or apparent Conflict of Interest and thus allow an activity (such as purchasing, Research or education) to proceed. Management Plans will be acknowledged in writing by the individuals to whom the plans are assigned, and the individuals are required to come into compliance with the plans. Management Plans are catalogued, tracked, monitored and audited through the online Disclosure system.

A typical **standard** Management Plan may require Disclosure of the Conflict of Interest to all relevant parties (with respect to Research, for example, to patients, human subjects (and their family members, when appropriate), sponsors, journal editors and reviewers, and attendees at conferences). Standard Management Plans may be developed and assigned routinely by Ministry Compliance.

### **ADDENDUM A**

#### **DEFINITIONS**

A **customized** Management Plan may be developed and assigned to individuals by Ministry Compliance, the OSF Conflict of Interest Committee or the Ministry's Board of Directors, as needed. A customized Management Plan may disallow an individual from participation in a particular activity (such as involvement in a Research study, or decision-making with respect to the purchase of medical equipment), or may require that an actual or apparent conflict be eliminated (by complete or partial divestiture of a company's stock, for example) before certain activities may occur at OSF (such as serving as an Investigator on a Research study).

**Manager** is the individual who administers an employee's performance evaluation or who makes decisions on behalf of an employee's unit or department.

**Meals** refers to food provided by Vendor representatives and brought into an OSF facility, or business Meals paid by Vendor representatives and provided outside OSF facilities. Typically, Meals refers to food that contains more than a single edible item, such as entrees or food platters. Nominal food items, including single food items, such as cookies and candy, are not Meals. The cost of Meals for purposes of Disclosure includes beverages, appetizers, deserts, tax and tip.

**Non-Compliance** is the accidental or deliberate failure to follow OSF policies related to Conflicts of Interest, Disclosure requirements, terms of a Management Plan or other instructions of Ministry Compliance or the OSF Conflict of Interest Committee.

**Personal Interests** arise out of relevant activities that may not have a direct financial component, but may present an actual or apparent Conflict of Interest. Such interests may involve the employee or his or her Immediate Family Members. A Personal Interest is not necessarily a Conflict of Interest.

**Research** is any systematic investigation involving human subjects that is designed (in whole or in part) to develop or contribute to generalizable knowledge or the results of which are intended to be later submitted to, or held for inspection by, the Food and Drug Administration (FDA) as part of an application for a Research or marketing permit.

**Significant Financial Interests** are monetary arrangements with individuals, businesses or other entities with which OSF has a transaction or arrangement, or is considering or negotiating a transaction or arrangement. A Significant Financial Interest is not necessarily a Conflict of Interest. Examples of Significant Financial Interests include:

**Debt Interests:** Holding of debt or debt securities by an individual or Immediate Family Member in any company or entity engaged in any business or attempting to do business with OSF, including Research.

**Equity Interests:** Ownership by an individual or Immediate Family Member of stock, stock options or other proprietary interests in any company or entity that furnishes goods or services to OSF, or leases or sells real estate or equipment to OSF, or is engaged in any business or is attempting to do business with OSF, including Research. Significant Financial Interests do not include investments in mutual funds or retirement plans, such as 401(k) or 403(b) plans, where there is no individual control over fund selections.

**Publicly Traded Companies:** Cumulative equity interest valued at \$10,000 or more, or 5% or more, whichever is less, of the business entity as determined by reference to publicly listed prices.

#### ADDENDUM A

#### **DEFINITIONS**

**Non-Public Companies:** Any ownership interest in any company or entity whose value cannot be determined by reference to publicly listed prices (for example, privately-held and start-up companies).

**Position:** Any position held by an individual or Immediate Family Member as an officer, director or trustee, manager, medical director, employee or former employee of any company or entity that that furnishes goods or services to OSF, or leases or sells real estate or equipment to OSF, or is engaged in any business or is attempting to do business with OSF, including Research.

Compensation: Receipt by an individual or Immediate Family Member of any cumulative remuneration within the calendar year, or anticipation of payment in that calendar year, in excess of \$1,000 (or \$10,000 that year from all Vendors) for services rendered by the individual or Immediate Family Member to a Vendor. Compensation includes receipt of, or the right or expectation to receive, any income from such business, whether in the form of a fee (e.g., consulting), salary, allowance, forbearance, forgiveness, interest in real or personal property, dividends, royalties derived from the licensing of Technology, rent, capital gain, real or personal property, or any other form of compensation, or any combination thereof. Compensation also includes an agreement or other arrangement whereby an individual or Immediate Family Member will receive future remuneration by the company or entity for services to be rendered.

**Intellectual Property:** The individual or Immediate Family Member has a financial relationship or interest involving Intellectual Property rights (e.g., a patent, copyright or trademark yielding any royalties, milestone payments or other cash flows from such rights), and the outcome of a Research study could influence the value of the Intellectual Property.

**Technology** includes the technology-related aspects of any diagnostic, therapeutic, medical or surgical procedure and of any process, method, compound, drug or device.

**Vendor** refers to any outside source, entity or business (or its subsidiaries, employees or agents) or individual that (1) provides products or services to OSF, (2) otherwise does business with OSF, (3) desires to do business with OSF, (4) desires to influence, in some manner, OSF patient care or business decisions, (5) or is in the process of negotiating a transaction or arrangement with OSF, or (6) offers or provides health care-related compensation or funding of any kind to employees or researchers.