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With Industry Alliances for Medical Advances, Organizations Face More Elaborate Conflicts

By Nina Youngstrom

A new chapter was written on the management of conflicts at Moffitt Cancer Center when a pharmaceutical company licensed technology developed by CEO Alan List, M.D., who is also a researcher and practicing physician. The deal meant big dollars for the CEO personally and a considerable investment in clinical trials at Moffitt using the new technology, but it presented all kinds of challenges for the Tampa, Florida, institution. List, who would normally negotiate a transaction of this scale, had to stay out of it, and so did the people who would have taken over because they report to him.

"We call this an institutional conflict of interest because he was the CEO and because of the significance of the deal with Moffitt," said Donnetta Horseman, chief compliance officer at Moffitt. "We had to firewall him completely from this entire deal."

The pharma company touches so many things that required oversight. Moffitt's foundation accepts unrestricted grants from the drug manufacturer and they co-sponsor education events. Multiple research projects were underway at Moffitt that are funded by the pharmaceutical company, and Moffitt purchases a lot of its medications for use with patients. And there's the potential for a clinical conflict if the CEO prescribes drugs made by this company when there are cheaper or more efficient alternatives.

"Every way you can imagine there could be a conflict, that conflict existed," she said at the Health Care Compliance Association's Compliance Institute April 16 and in an interview.

Although managing the conflicts "made my head hurt," Horseman said, it was time to establish the necessary processes and procedures. "We are on the forefront of developing vaccines and technology to treat and try to cure cancer, and the only way to do that is through industry partnerships and alliances," she said. "We have to figure out a way to get controls in place and manage institutional conflicts and reputational risks. Partnering to help us develop new technologies is how we will accomplish our mission and vision." Moffitt has since addressed similar conflicts because of its work with pharmaceutical, device and biotech companies. "It's a delicate balancing act between maintaining relationships and having it not appear as if we are biased toward these particular companies," she noted.

For starters, Moffitt has established an institutional conflict of interest policy and committee with representatives from various departments, including a "disinterested" board member from the corporate compliance committee, a member of the center's Patient and Family Advisory Council and an external representative from an unaffiliated academic medical center. It has a separate charter and committee to review institutional and business-related conflicts.

Institutional Conflict-of-Interest Policy

Moffitt Cancer Center in Tampa, Florida, has established an institutional conflict-of-interest policy and committee to manage the conflicts that arise as it works more closely with pharmaceutical, biotech and device companies on advancing treatments, says Chief Compliance Officer Donnetta Horseman. Contact Horseman at donnetta.horseman@moffitt.org.

Policy Statement

It is the policy of the Center to ensure that all transactions between industry partners and Workforce members are held to the highest ethical standards in an atmosphere of transparency and high integrity. The Center recognizes collaborations with industry partners play an integral role in advancing scientific endeavors, enhancing the Center's mission and promoting commercial development of Center innovations. This policy strives to protect the integrity of transactions between the Center and industry partners impacting research, clinical care, intellectual property commercialization, education funding and charitable donations.

Purpose

This policy defines specific guidelines to reduce and manage any potential or actual conflicts of interest or bias on the part of the institution for all transactions between the Center and industry partners. Transactions that pose potential risks are subject to review, oversight, and, when appropriate, management. The existence of actual bias will not be permitted and any conflict that creates actual bias will be eliminated. This policy is designed to maintain the highest possible ethical standards, adhere to all applicable state and federal regulations, maintain the primacy of the Center's mission and protect the reputation of the Center and its faculty and staff.

Scope

This policy applies to leaders, faculty, Clinicians and staff.

Stakeholders:

Procedures

A. **Institutional Conflict of Interest ("ICOI") Committee**

The ICOI Committee ("Committee") shall review and manage potential institutional conflicts. The Committee shall look at the totality of the circumstances surrounding the disclosure and make a case-by-case, individualized determination of how to best manage, reduce or eliminate the conflict of interest.

If a member of the ICOI Committee is involved in the transaction(s) under review by the Committee, or if the member's impartiality is in some other way compromised, the member shall not participate in the review of that particular ICOI.

To manage, reduce or eliminate an ICOI, the Committee may require, but is not limited

to requiring, any of the following actions:

a. Any of the research-related management controls as defined in the Conflicts of Interest in Research Policy.

b. Review of the COI by the Clinical Ethics Committee

c. Disclosure of the COI to patients

d. Disclosure of the COI to educational event participants

e. Disclosure of the COI to the public via press releases and/or the website

f. Designation of a safe harbor protocol for Workforce members to report concerns related to the conflict. Safe harbor reporting options include, but are not limited to, reporting concerns directly to the Compliance Office, calling the Compliance Hotline or contacting an external member of ICOI Committee designated as the safe harbor.

B. **Identification of Significant Financial Interests ("SFI")**

1. Research

a. When the Center holds a direct or indirect SFI, either as primary site or non-primary site for Research, it is presumed that the center shall not conduct such Research until such SFIs have been managed, reduced or eliminated.

b. The Center will identify individuals within each department who shall promptly disclose Institutional SFIs to the Compliance Office by completing and submitting a Conflict of Interest Disclosure Statement.

c. Institutional conflicts of interest involving Research may be reviewed by the ICOI Committee and Research Conflict Committee, as necessary.

d. To manage, reduce or eliminate an ICOI related to Research, the ICOI Committee and/or Research Conflict Committee may require, but are not limited to requiring, any of the following actions:

i. Independent review of the results of the study

ii. Disclosure to research team members (such as students, staff or other faculty members)

iii. Designation of a safe harbor with whom the research team members can report concerns

iv. Disclosure to research participants in the informed consent document

v. Disclosure to other centers participating in multi-site trials

vi. Disclosure in public presentations and/or publications of scientific results

vii. Annual certification of compliance with the COI management plan

2. Clinical Decision Making

a. A clinical conflict of interest may exist when a Clinician has a personal financial relationship with an industry partner with which the Center also has an ICOI, and that relationship could influence the decision making of the Clinician, or affect a patient's decision and/or consent to the use of the company's product or to participate in a clinical research study.

b. Full Disclosure of financial relationships is required when Center Staff have personal financial relationships with industry partners that produce, manufacture or distribute products which may be used in the care of patients. Products include medical devices, implants, pharmaceuticals, biologics, diagnostics or other medical products.

c. The Compliance Office, in conjunction with the ICOI Committee, will assess for the breadth and scope of the relationship, the dollar value of the relationship or interest, the actual usage of the product(s) and justification for any predominate usage, as well as off-label use of the company's products.

d. Center staff must also disclose any significant financial interest when developing, authoring and/or maintaining pathways for the Clinical Pathways Program. The Compliance Office will collaborate with the Clinical Pathways Program to provide information related to Staff financial interests with industry partners and assist in developing management plans as necessary.

e. The Clinical Ethics Committee may review financial relationships to determine whether the clinical conflict should be disclosed to patients and/or the patient's family.

f. The Compliance Office shall monitor the Center for Medicare and Medicaid Services Open Payment database for accuracy of reporting by Industry as per standard processes.

3. Purchasing/Procurement

a. The Compliance Office shall maintain a listing of companies with identified institutional conflicts of interests. The Chief Financial Officer or designee shall provide a report of all purchases made by the Center of such company products to the Compliance Office on a quarterly basis.

b. The Compliance Office shall review the list to determine if the procurement of products introduces actual or perceived bias and will review such issues

with the ICOI Committee and make recommendations to manage the conflict.

4. Office of Innovation and Industry Alliances

a. The Innovation Office will notify the Compliance Office of any sponsored research collaborations or license agreements being negotiated with companies that may pose a conflict of interest.

b. The Innovation Office will notify the Compliance Office if any Innovation Office staff member or intern has a financial interest with industry partners that may pose a conflict of interest.

5. Education

a. All institutionally supported educational events will adhere to the Accreditation Council for Continuing Medical Education (ACCME) standards to ensure the Center is protected from any actual or perceived bias in these activities.

b. The Chairperson of an education event planning committee will assess institutional and individual conflicts among planning committee members to ensure that conflicted committee members recuse from portions of the discussion which pertain to the conflict as determined by the committee chairperson.

6. Foundation: Industry Gifts and Gratuities

a. The Compliance Office will provide a listing of industry partners that have an identified SFI or conflict of interest with the Center. The Foundation will notify the Compliance Office of any gifts from companies that have an identified institutional conflict of interest.

b. The Compliance Office will assess the breadth and scope of the gift to determine if management controls are required.

C. **Reporting**

1. A summary of Institutional SFIs, actions taken by the ICOI Committee and all active and archived management plans will be reported to the Corporate Compliance Steering Committee and Joint Corporate Compliance Committee of the Board on an annual basis.

2. The ICOI Committee and Compliance Office shall forward approved Conflict of Interest Management Plans to any other committees or Offices as required for additional reporting.

D. **Noncompliance**

1. If the ICOI Committee and/or Compliance Office determines that there has been noncompliance with the disclosure requirements and/or terms of any management plan issued pursuant to this Policy, the responsible party or parties may be subject to disciplinary action in accordance with Center policies.

2. This Policy supplements but does not replace other conflict of interest policies of the Center. All leaders, faculty, Clinicians and staff are required to comply with all applicable conflict of interest policies and procedures.

3. Any individual who has concerns regarding Institutional Conflicts of Interest shall report their concerns directly to the Compliance Office or through the Center's anonymous Compliance Hotline. The Compliance Office shall promptly review and respond to any concerns that it receives and take appropriate corrective action as necessary.

References

42 CFR Part 50 , Subpart F

45 CFR Part 75

Accreditation Council for Continuing Medical Education

Specifically to manage the sale of the CEO's technology and the aftermath, a special group that included the general counsel and board chair was created. The deal was reviewed and approved by the corporate compliance committee, which examined the fair-market value and distributions to the CEO and principal investigators on research using the new technology, among other things.

The conflict was also put in front of the patient advisory council which was asked whether patients would want to know if their provider had a significant financial interest in a pharmaceutical company. Members of the council said they thought there should be transparency, with the information available on Moffitt's website, but that patients shouldn't be informed one on one, Horseman said. The patients are fighting cancer, and their provider's financial interest in their medication wasn't a priority, according to the council.

Purchasing from the pharmaceutical company is monitored. "In institutional conflicts, we have finance send us a report of all purchases every three months from the pharmaceutical company," Horseman explained. "We look for spikes or trends that look different. If all of a sudden we see a spike, we want to make sure it's legitimate and not related to the institutional conflict."