

Report on Medicare Compliance Volume 27, Number 30. August 27, 2018 Cheat Sheet: Moffitt's Summary of Its Conflict Management Plan

By Nina Youngstrom

| Category | Management Controls |
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| Research | a. Pre-clinical |
| a. Pre-Clinical | 1. Independent review of the results of the study; |
| b. Clinical | 2. Disclosure to research team members (such as students, staff or other faculty members); |
| | 3. Designation of a safe harbor with whom the research team can report concerns; |
| | Compliance with journal requirements relating to disclosure of the institutional financial interests including disclosure to the publisher upon submitting article(s) pertaining to the results of the study; |
| | 5. Disclosure in presentation(s) related to the results of the study; and |
| | 6. Annual certification of compliance with the COI management plan (as appropriate). |
| | b. Clinical |
| | 1. If the Center has 30% or greater of the total accrual, an external audit may be arranged; |
| | 2. Disclosure to research team members; |
| | 3. Designation of a safe harbor with whom the research team can report concerns; |
| | 4. Disclosure to research subjects in the informed consent document; |
| | 5. Disclosure to other centers participating in multi-center trials; |
| | 6. Disclosure in public presentations and publications of scientific results; and |
| | 7. Annual certification of compliance with the COI management plan (as appropriate). |

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| Clinical Decision Making | Significant financial relationships (compensation greater than \$25,000) of Staff will be reviewed by the Clinical Ethics Committee for a determination of disclosure to patients or the patient's family. Staff cannot serve on Speakers Bureaus or other activities for ABC Company where (1) ABC Company has the right to dictate or control the content of the presentation or talk; (2) ABC Company creates the slides or presentation material and has final approval of the content and edits; or (3) the presenter is expected to act as an agent of ABC Company or spokesperson for the primary purpose of disseminating ABC Company's product or information. Staff must disclose significant financial relationships when developing (authoring) & maintaining pathways for the Clinical Pathways program. |
| Purchasing/ Procurement | On a quarterly basis, the CFO/designee will provide a report of all purchases of ABC Company Products to Corporate Compliance for review. Management plans will be issued as appropriate. Members of the P&T Committee possessing financial interest with ABC Company should recuse from discussion related to ABC Company Products. |
| Innovation Office/ Business Development | Individuals involved in institutional decisions concerning the purchase of or approval of medications or equipment, or the negotiation of other contractual relationships with industry, must disclose all financial interest (e.g., equity ownership, compensated positions on advisory boards, a paid consultancy or other forms of compensated relationship) in ABC Company. Compensation cannot exceed \$25,000 in a 12-month period. Innovation Office will notify Corporate Compliance if any Innovation Office Staff Member or Intern has a significant financial interest in ABC Company. Open Payment database will be monitored for accuracy. |
| Other a. Education b. Foundation c. Reporting | a. Education: Institutionally supported educational events will adhere to the Accreditation Council for Continuing Medical Education (ACCME) standards. In addition to addressing the Institutional conflict, the Chairperson of the planning committee will assess all individual conflicts among committee members. If the Chairperson has a financial COI with ABC Company, the Compliance Office will review the conflict. b. Foundation: Donations, gifts or other contributions (in cash or in kind) from ABC Company totaling more than \$500,000 will be reviewed by Corporate Compliance to assess the breadth and scope of the gift and determine if management controls are required. On a quarterly basis, the Foundation will report a summary of all gifts to Corporate Compliance. c. c. Reporting: Compliance with the Master Plan will be reported to the ICOI Committee, Research Conflict Committee, the Compliance Committee & the Conflict Committee of the Board annually. |

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