

HCCA 2022 Research Compliance Conference MANAGING CONFLICT OF INTEREST RISK IN ACADEMIC MEDICAL CENTERS June 8, 2022

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Conflicts of Interest

- “Conflict of interest affects virtually every aspect of medicine, including research, teaching, and clinical care.” JAMA editorial 2018
- “Conflicts of interest can influence action, but they are not acts and do not constitute a breach of duty” Marc A. Rodwin Professor of Law, Suffolk University Law School (2017)
- “Doctors and druggists wash each others’ hands-and always have” - Chaucer, Canterbury Tales
- “If I, taking care of everyone’s interests, also take care of my own, you can’t talk about conflict of interest.” Silvio Berlusconi
- <https://ori.hhs.gov/education/products/ucla/chapter4/default.htm>
- (Teaching the Responsible Conduct of Research in Humans)

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Why Should We Care About Conflicts of Interest?

- Organizational systems and processes-governance expectations
- Physician duty to patients and independent judgment
- Unconscious bias/ reciprocity
- Reputation for Integrity/Transparency
- Compliance culture/ consistency
- Legal requirements

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COI Cultures- The Palio of Siena



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Palio Culture - The University of Maryland Medical System

- UMMS spent \$500,000 to purchase 100,000 copies of “Healthy Holly” (a book series self-published by Baltimore’s now ex-Mayor Catherine Pugh) to donate to Baltimore school children, while she was a trustee of UMMS, a private, not-for-profit health system with 11 hospitals and \$2 billion in annual revenues.
- UMMS’s 2015 IRS 990—Schedule O monitoring and enforcement policy: the **general counsel** “reviews the responses...” to determine whether a conflict exists and consults with the audit committee in appropriate cases. In addition, there is a requirement that in all invitations for bids, proposals, or solicitations for offers, the vendor, supplier, or contractor must disclose any “actual or potential transaction with any organization officer, director, or employee.”
- The Baltimore Sun reported on March 13, 2019, that a third of the UMMS’s board received payments from the system “through contracts with their businesses.”
- The CEO, COO, chief compliance officer, and general counsel “left” their positions in June, 2019 and UMMS announced a new conflict of interest policy on May 31, as required by a new Maryland state law passed after the Baltimore Sun stories. The policy lays out specific responsibilities for the new chief compliance officer.
- July 2019-new Corporation Conflicts of Interest Policy October 2019-UMMS advertising for new chief compliance officer

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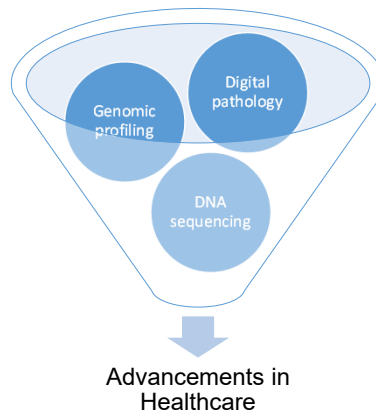
Conflict of Interest (COIs): Core Concepts

- Treatment and public health advances through scientific discovery.
- Research in healthcare will require external funders.
- Researchers and physicians will provide valuable expertise and guidance for government and private for-profit research, review, and development efforts.
- Researchers and research institutions must work with government and industry partners to evaluate and bring innovations to public.
- Institutions must balance innovation with ensuring the integrity and objectivity of clinical care, research, charitable and education missions and activities.
- Need to explain why conflicts matter

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New Opportunities (& Different Types of COIs)

Greater utilization of **data** and **samples** and application of **digital discoveries** and AI in healthcare



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New Risks (& Different Types of COIs)

- Sunshine Act reporting
- Whistleblower access and culture
- Matching programs/data journalism
- Senator Grassley's subpoenas
- Accessible 990 data
- Conference and publication reporting
- <http://retractionwatch.com/>
- Foreign influence

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Operational Challenges for Major Academic Medical Centers on Conflicts of Interest

- Written policy, state law requirements
- Need to address full range of conflict of interest issues and reporting for board members, officers, employees, physicians with privileges
- Reviewing, reporting process on Schedule O of annual IRS 990 (hint: counsel need to review conflict language before submission)
- Whose job should it be (counsel, compliance, audit committee, compliance committee, secretary) (Hint: not a process general counsel should be responsible for)
- Consequences of failure to respond/report
- Systems for capturing conflict reporting
- Record of Recusals-minutes and other decision documents

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CONFLICT OF INTEREST DISCLOSURE AND REPORTING CHALLENGES

- Generally resented by reporters and by collectors
- Compliance process:
 - Who are reporters? Do they report for others (e.g., family members)
 - Training
 - Who does collection? How? What systems? Who maintains/ accesses records?
 - Verification process?
 - External reporting and certification
 - Auditing and monitoring?
 - Evaluation and amelioration-at what points?
 - How effective are disclosure requirements?
- Ten years later: a review of the US 2009 institute of medicine report on conflicts of interest and solutions for further reform (BMJ Evidence-Based Medicine 2022;27:46-54.) –easily detected conflicts not disclosed in published work

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Senior Leadership Responsibility for COI

- Compliance- Caremark board and officer duties-
 - Caremark affirmative duty to be proactive: officers and directors have to install a system to provide reasonable assurance of compliance with law, that monitors and reports on compliance issues
- Systems to provide reasonable assurance of compliance with law
 - In re Wells Fargo & Co. S'holder Derivative Litig., 282 F.Supp. 3d 1074, 1082 (N.D. Cal. 2017) (fraudulently opened accounts)
 - Marchand v. Barnhill, 212 A.3d 805, 824 (Del. 2019) (ice cream company)
 - Caremark standards applied to nonprofits-Attorney General v. NRA; Attorney General v. Diocese of Buffalo; Attorney General v. St. Clare's Corporation

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Psychiatry Conflict of Interest Headlines - Senator Grassley

- 2008-Joseph Biederman-Harvard, Mass. General (atypicals for children)(current Mass. General website visited 1/20/20: "Dr. Biederman's work is supported by multiple federal and pharmaceutical industry grants.") (still at Mass. General)
- 2008-Alan Schatzberg, Stanford-\$4.8 million in stock options, reported as \$100,000+ (still at Stanford)
- 2008-Charles Nemeroff, Emory (\$960,000 from GSK, reported \$35,000);resigned and went to University of Miami School Medicine; now (May 2022) at Dell Medical School, UT Austin
- Impetus for Sunshine law, new (2011) NIH regulations

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Physician Payments Sunshine Act-2010

- Part of Obamacare
- 9/30/2014 –first Open Payment Program reporting (openpaymentsdata.cms.gov)
- 1/21/2022- currently reporting 2020
- [paymentshttps://openpaymentsdata.cms.gov/](https://openpaymentsdata.cms.gov/)
- Dollars for Docs (Pro Publica)
- <https://projects.propublica.org/docdollars/>
 - Many payments –royalties on devices
 - One Ca. ophthalmologist received \$20.7 million in “promotional speaking/other”

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COI Recent Public Issues

- Harvard-Professor Charles Lieber-December 2021 conviction
- University of Kansas –Prof. Feng Tao-DOE and NSF contracts-failure to disclose employment with Chinese University-convicted April 2022
- University of Arkansas-Professor Ang-failure to disclose interests in patents-guilty plea January 2022
- University of Florida-Professor Yang-2021 indictment

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How to Address Conflicts of Interest?

- 1) ignore
- 2) tolerate and trust judgment
- 3) train, tolerate, trust judgment
- 4) permit but require internal disclosure
- 5) permit but require public disclosure
- 6) manage (systems, thresholds, reporting, review, decide)
- 7) test and discipline
- 8) prohibit

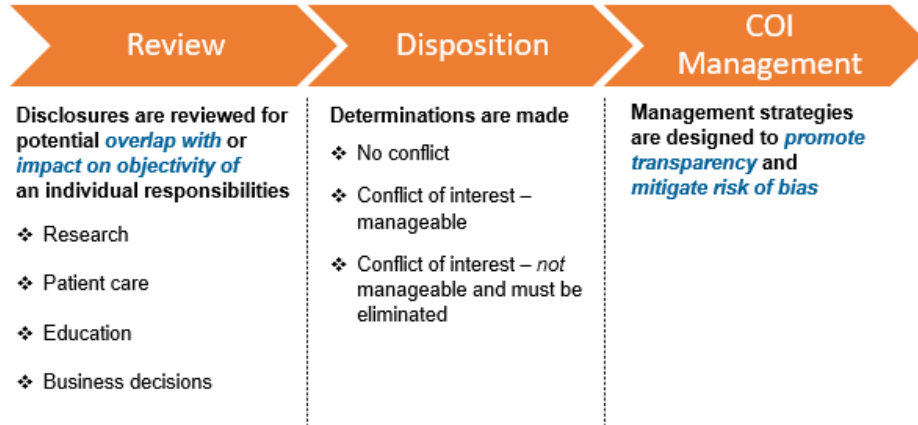
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DOING COI RIGHT - THE MSK WAY

- April 2019-new MSK New and Enhanced Conflict of Interest Principles approved
- September 2019-new policies-attached-Conflict of Interest and Commitment
- Next slides detail approach

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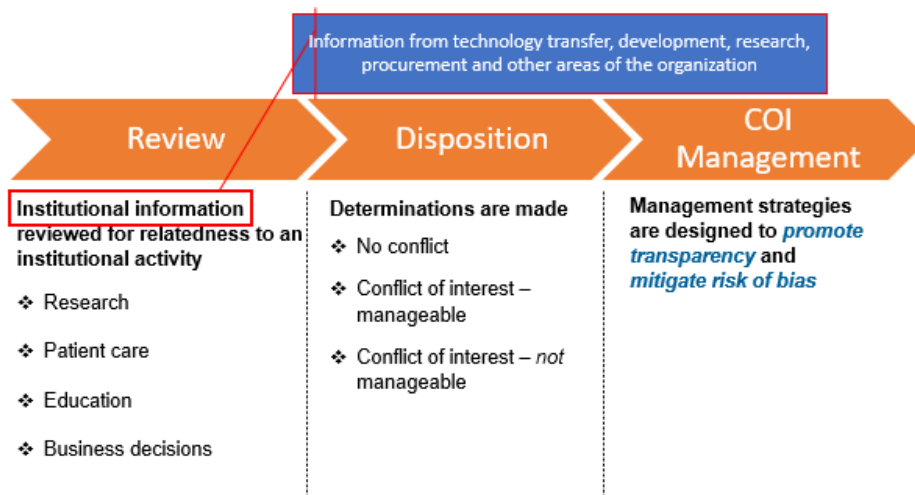
Individual Conflicts: High-Level Process



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Institutional Conflicts: High-Level Process



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Compelling Circumstances Standard

Per MSK policy and standards, MSK will not conduct interventional human subjects research at MSK when MSK has a financial interest in the product, technology, or company being evaluated -- or allow a significantly conflicted individual to lead such research -- absent *compelling circumstances*

Factors Considered

One or more criteria may be met and/or considered to make a determination that the research may proceed despite institutional interests or significant individual interests, taking into account the extent to which interests could impact research objectivity or human research subject rights and welfare AS WELL AS the extent to which study design, structure, or management strategies can protect against this

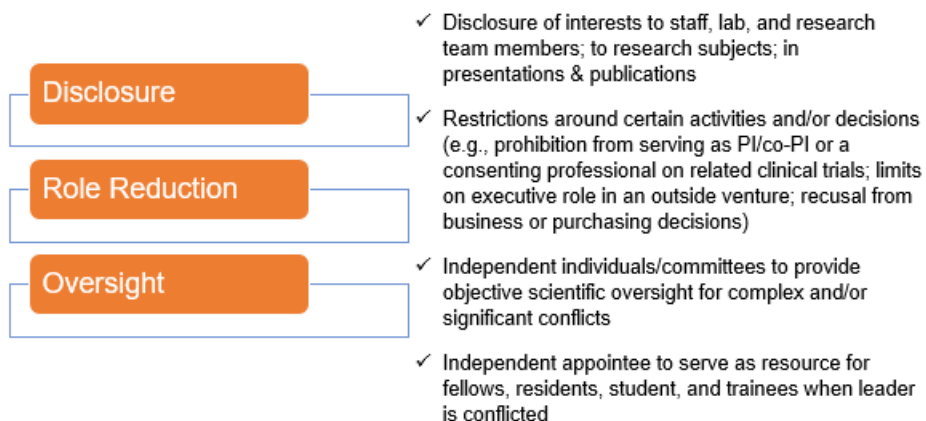
- Correlation of conflict to aims of research
- Nature and extent of the conflict
- Nature of the research and risk level to patients
- Specialized or unique expertise
- Patient benefit and need
- Special facilities and equipment
- Research advancement
- Controls against bias or risk



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COI Management Strategies

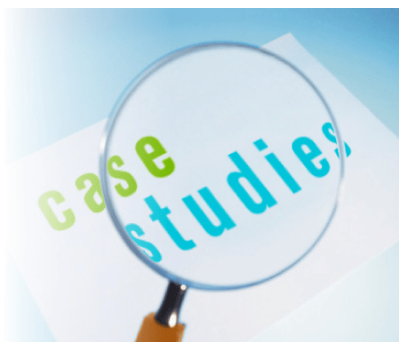


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Scenarios & Considerations

- Technology developed at the institution being studied in clinical research
- IP licensed by institution to a spin-off company
- Researcher/inventor involvement in spin-off company
- Spin-off company funding of research at the institution



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Foreign Influence & COI

- Continued scrutiny and concerns from federal agencies related to foreign influence – on an ongoing basis, across a broad range of areas (with a focus on China)
- Over the last several years, the federal government has issued a variety of executive orders, guidance, and policies
- NIH requirements related to updated biosketch and other support format pages and instructions (effective January 25, 2022.) (NIH NOT-OD-21-073; NOT-OD-21-110)
- Government reports directing federal agencies and research institutions to implement various reforms (NSPM-33 and subsequent OSTP guidance)



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Key References

Reference	Description	URL
NSPM-33 (2021) Presidential Memorandum on United States Government-Supported Research and Development National Security Policy	Report strengthens and standardizes requirements for disclosure of information related to potential conflicts of interest and of commitment from individuals with significant influence on America's R&D enterprise	Link
JCORE Report (2021) Recommended Practices for Strengthening the Security and Integrity of America's Science and Technology Research Enterprise	Recommendations for academic institutions to address foreign influence concerns, touching on topics related to conflict of interest, conflict of commitment, data and intellectual property theft, etc.	Link
OSTP Guidance for Implementing NSPM-33 (2022) Guidance to Federal Departments and Agencies Regarding Implementation of National Security Presidential Memorandum 33	Highlighting 5 core areas where detailed guidance development focused: (1) Disclosure Requirements and Standardization (2) Digital Persistent Identifiers (3) Consequences for Violation of Disclosure Requirements (4) Information Sharing (5) Research Security Programs	Link



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Key Concepts (in Context of “Disclosure”)

COI Disclosure

- Individual external activities and financial interests
- Disclosed as part of annual COI disclosure process
- Reviewed by *institution* in context of COI and COC
- COIs reported to sponsor if/as required

Other Support

- Support/resources made available for an individual's research
- Provided (“disclosed”) as part of research grant funding process – typically provided at JIT, and updated thereafter (substantive updates) annually at RPPR
- Reviewed by *sponsor* in context of scientific, budget, and commitment overlap (historically; now also considered under lens of foreign influence)

Foreign Component

- Performance of any significant scientific element or segment of a project conducted outside of the U.S.
- NIH prior approval required



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NIH Updates of Note (to date)

- Expanded reporting of certain relationships and support in Other Support and Biosketch
 - Positions and appointments
 - In-kind resources
 - Certain consulting arrangements
- Submission of certain types of agreements/documents
 - Foreign appointments, activities, and resources
- Consideration of certain relationships outside of SFI definition to be considered in FCOI context



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NSPM-33 Requirements of Note

- Expanded disclosure requirements
 - In realms of Other Support, financial interests, and non-financial relationships and activities
 - Conflict of commitment
- Establishment of a [research security program](#) (if institution has over \$50 million in federally-funded research re. science and engineering)
- Oversight and enforcement guidance for federal agencies
- Other requirements and restrictions for federal agencies and employees



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Special Note on Conflict of Commitment

- External activities that do not necessarily constitute financial interests
- Various government reports now formally defining and “grouping” conflict of commitment with conflict of interest, including specification of requirements that indicate new required institutional collection, review, and federal reporting obligations associated with conflict of commitment information

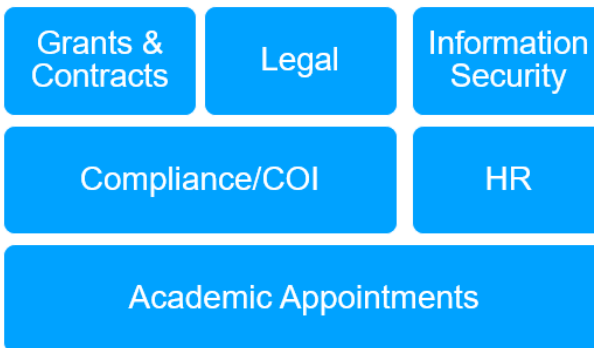


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Navigating the Current Landscape in Practice

- Updates to COI disclosure questions to gather additional information
- Coordination and information sharing among various offices & processes



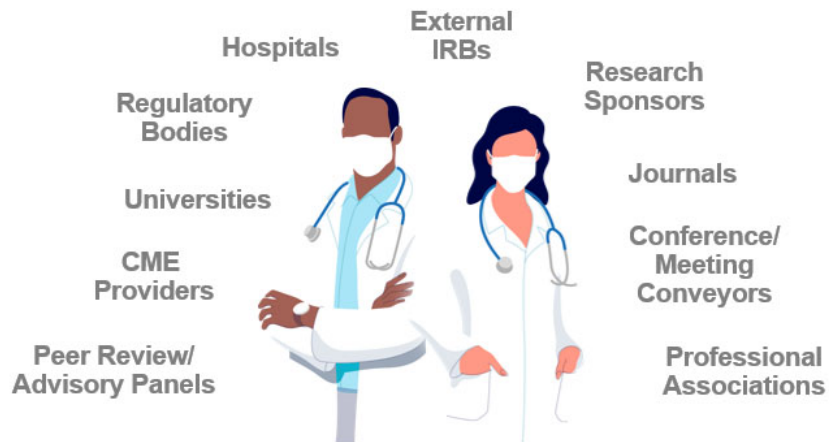
Process Points
Grant submissions
COI reviews
External agreement reviews
Onboarding new employees
Vetting students/visitors
Risk-based monitoring
Security plans
Investigations



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Disclosure Universe for Faculty/Physicians



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Disclosure Harmonization: Initiatives

Action

- Memorial Sloan Kettering Cancer, Association of American Medical Colleges, American Society of Clinical Oncology, Council of Medical Specialty Societies, and JAMA hosted a symposium in 2019 on *Harmonizing Financial Disclosures in Biomedical Journals*
- The *final report* of recommendations has been published (1/2021)
- <https://www.aamc.org/media/46506/download?attachment>

Concepts

- Commitment to **harmonization** and **reducing the burden** of various disclosure requirements + points
- Harmonized disclosure framework
- Single “source of truth” for financial interests and relationships



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Continuing Education Conflicts of Interest

- Accreditation Council for Continuing Medical Education (“ACCME”) Standards of Integrity and Independence in Accredited Medical Education CE-1/7/2020 (formerly “Standards for Commercial Support (ACCME.org)
- Individual presenters required to disclose “all financial relationships,” to accredited Continuing Education provider, regardless of amount, with “ineligible entities” regardless of relevance to their presentation. Includes known financial relationships of spouse or partner.
- “All financial relationships with ineligible entities” for the prior 12 months.
- CE provider decides what disclosures are necessary to learners.

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2011 Disclosure and Management of Federal Financial Conflict of Interest Regulations, as amended in 2016

- 42 CFR 50.603-apply to institutions that apply for or receive NIH funds
 - Investigator training once every four years
 - Institution responsible for soliciting and reviewing disclosures for each investigator who is planning to participate in or is participating in NIH research.
 - Institution must have designated official responsible for reviewing disclosures (can be committee)
 - Institution must post fcoi policy on publicly available website.
 - Institution must impose fcoi policy on subrecipients
 - Examples: Drexel University (Drexel.edu/research/compliance); Jefferson.edu (only accessible internally)

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HHS/OIG Audit 03-19-03003 of NIH (9/2019)

- 2011 Financial Conflicts of Interest regulations
- HHS/OIG Audit
 - NIH has limited policies in place to require institutions to report all sources of research support, financial interests, and affiliations
 - 1875 institutions received NIH funding in FY 2018
 - 1013 did not have FCOI policies posted on their websites
 - Sample of 90 nonposted, 41 did not have policies
 - Recommendations: ensure posting; enhance NIH monitoring programs; implement procedures to assure that entities have policies
 - NIH reporting mechanism- signature of the Authorized Organization Representative (AOR) representing that “there is in effect at the Institution an up-to-date, written and enforced administrative process to identify and manage Financial Conflicts of Interest (FCOI)”

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How Do Other People Handle Conflicts

- University of Pennsylvania Guidelines for Interaction with Industry
 - No gifts, meals, services, subsidies from drug or device firms
 - No medication samples from Industry representatives
 - Sample medication voucher program ok
 - Reimbursement for travel to present findings if company funds research.

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The New York Cookbook NPCL 715(f) Requirements (officers, directors, key persons)

- Not-for-Profit Corporation Law (“NPCL” 715(f))
- Written policy adopted by board
- Applies to directors, officers, and key persons
- The Policy must require that each officer, director and key employee submit to the Secretary of the Corporation prior to initial election to the board, and annually thereafter, a written statement identifying possible conflicts of interest.
- Disclosure of conflicts is required; the requirement of disclosure to the Secretary can be satisfied by disclosure to the Secretary’s designee as custodian (e.g., the compliance officer), if set forth in the conflict of interest policy.
- The Secretary must provide a copy of the completed statements to the chair of the audit committee or the chair of the board.
- Oversight based on IRS 990 submission

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Financial Conflicts of Interest and the IRS 990

- IRS Governance Check Sheet 2009 (Form 14114) for use by Revenue Agents-look for-
- Written policy
- Written annual disclosures of conflicts
- Record of Recusals
- Have actual or potential conflicts been disclosed
- Whether the written policy has been followed

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Form 990 Review - by Counsel or Compliance Officer?

- Part VI, Section B, of the Governance, Management, and Disclosure Section of the 990:
- “Did the organization have a written conflict of interest policy (12a). If no, go to line 13.”
- If yes on 12a go to line 12b: “Were officers, directors, or trustees, and key employees required to disclose annually interests that could give rise to conflicts?”
- If yes on line 12b, go to line 12c: “Did the organization regularly and consistently monitor and enforce compliance with the policy?” “
- If yes, describe in Schedule O how this is done.”

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IRS 990 Instructions (2019) If "Yes" on Part VI line 12c, “describe in Schedule O how this is done.”

- Line 12c. “, describe on Schedule O (Form 990 or 990-EZ) the organization's practices for monitoring proposed or ongoing transactions for conflicts of interest and dealing with potential or actual conflicts, whether discovered before or after the transaction has occurred.”

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Form 990 Review - Language from Filed 990s

- “The organization has a conflict of interest (COI) policy that addresses the consideration of potential conflicts of interest by the board of directors, committee members, key employees, and their relatives. As per the policy, such persons must make disclosure of any potential conflicts of interest and must abstain from voting on any action in which they have an interest. On an annual basis, all members are required to sign an annual conflict of interest form...” Hacienda HealthCare 990 Schedule O for 2016.
- Statement does not represent that the organization “regularly and consistently monitors and enforces compliance with the policy...” nor does it represent how monitoring and enforcement are done.

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Conclusion: Operational Challenges for Major Academic Medical Centers on Conflicts of Interest

- Written policy, state law requirements
- Need to address full range of conflict of interest issues and reporting for board members, officers, employees, contractors, physicians with privileges
- Whose job should it be (Consequences of failure to respond/report)
- Systems for capturing conflict reporting
- Record of recusals-minutes and other decision documents
- Records of conflicts decisions

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For Further Reading: JAMA THEME ARTICLE 2017 JAMA. 2017;317(17)

- 23 separate articles covering:
- Academia/Academic medical centers
- Medical education
- Medical practice and research
- Industry payments to physicians and industry funding of and collaboration with researchers
- Guideline panels
- Professional associations
- Disclosures to patients
- Roles of journals and authors

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For Further Reading

- **2019 Instructions for Form 990 Return of Organization Exempt From Income Tax (irs.gov)**
- **Conflicts of Interest Policies Under the Not-for-Profit Corporation Law**
- **New York Charities Bureau (www.charitiesnys.com)**
- **https://www.irs.gov/pub/irs-tege/governance_check_sheet.pdf**

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Thank you for your attention!

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