

**Managing Conflicts of Interest at the
IRB and Institutional Level:
INSTITUTIONAL CONFLICTS
OF INTEREST**

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**TO MAINTAIN THE PUBLIC
TRUST . . .**

Institutional officials must

- **Make decisions and policies for the institution that are free from improper bias or conflict of interest**
- **Be able to document that they have done so**

COMPETING INTERESTS

The institution has interests in

- **Its financial gain from external entities – donors, research sponsors, companies, Board and Officer investments**
- **Its own academic and clinical missions and the policies that support them – allocations of space, money, people; review and approval processes; monitoring, auditing, compliance, and discipline**
- **Its reputation**
- **Its research integrity**
- **The safety and welfare of its human subjects**

**INSTITUTIONAL CONFLICT OF
INTEREST (ICOI)**

When the financial interests of the institution, or of an institutional official acting in his/her official capacity, or of IRB members, might affect or appear to affect

- **Any phase of its research mission -- conduct, review, oversight and compliance, outcome**
- **Finances and economic status of the institution**
- **Missions of the institution**
- **Appropriate vendor relationships**
- **Employment practices**

POTENTIAL ICOI (RESEARCH)

When the institution (or institutional officials who manage or oversee research or IRB members):

- **Might get royalties from the sale of the product that is to be investigated**
- **Holds any equity through licensing its technology to a non-publicly traded research sponsor (e.g., startup company)**
- **Holds ownership interests >\$100K through licensing its technology to a publicly-traded research sponsor**
- **Gets a significant gift from a potential research sponsor**

POTENTIAL ICOI (RESEARCH) (2)

When an institutional official who has research responsibility has a

- **Significant financial interest in the research sponsor or the product to be investigated**
 - **Equity interest**
 - **Consulting relationship**
 - **Honoraria, gifts**
 - **Service as officer, board member**
- **Purchasing relationship with the research sponsor (vendor)**

RULES AND REGULATIONS ON ICOI

- Various regulations and statutes govern ICOI in finance, employment, Board duties, etc. (IRS, SEC, corporate law . . .)
- No federal regulations on ICOI in research
- Excellent guidance for institutions engaged in human subject research, adaptable to broader application:
 - *Protecting Subjects, Preserving Trust, Promoting Progress II: Principles & Recommendations for Oversight of an Institution's Financial Interests in Human Subjects Research*
AAMC Task Force on Financial Conflicts of Interest in Clinical Research, October 2002

HYPOTHETICAL CASE 1:

Department Chair

- Chair of the Department of Pathology has a startup company that proposes to sponsor the research of Dr. Doe, Asst Professor of Pathology
- Chair's authority raises this to an ICOI
 - Issues with internal as well as external perceptions
- Some options (consider basic science v. clinical research)
 - Prohibit the sponsorship
 - Transfer oversight of Dr. Doe to another Dept Chair for evaluation, salary, promotion, space, resources considerations, research oversight

HYPOTHETICAL CASE 2:

Department Chair

- Department Chair has an extensive consulting relationship with a company that proposes to sponsor the Chair's research – personal COI. Chair assigns the project to Asst Prof Doe as PI but will remain involved
- Arguably an ICOI, since the authority of Chair could influence the outcome
 - Plan: Remove the Chair from the project; require an unbiased expert to review the manuscript and data
 - Argument: Young professors benefit from the Chair's advice and mentoring
 - Basic v. clinical considerations in management

HYPOTHETICAL CASE 3:

EVP, DEAN, COO

- EVP/Dean/COO invests \$50K to take institutional equity in Dr. Path's startup company to develop vaccines (in good but short-sighted faith!)
- Suggestion: Limit financial oversight and investment to Board, institutional CFO (per AAMC advice)
 - But medical EVPs and Deans may not want to turn over their discretionary accounts to Board and CFO for management and investment
 - Blanket rules do not fit every institution

HYPOTHETICAL CASE 3:

EVP, DEAN, COO (2)

- Suggested options
 - Establish an external holding company to manage institutional equity holdings
 - Have an institutional committee outside the control of the EVP/Dean/COO make or review all further decisions related to the investment
 - Prohibit such investments entirely
- Investment was a short-sighted decision because . . .

HYPOTHETICAL CASE 4:

Tech Transfer Officer and Boss

- Dr. Path asks institution to license the vaccine technology that he generated to his company
 - ICOI because institution has equity in company, would receive royalties
 - ICOI because Dr. Path is a conflicted institutional officer
- Institution has duty to ensure that the technology is transferred in the way that is most likely to benefit the public
- Plan: Have the technology independently evaluated for value and for other markets
 - By whom?
 - Who pays?

HYPOTHETICAL CASE 5:

EVP, DEAN, COO

- Institution licenses its vaccine technology to Prof. Doe's company, in which the institution holds equity. Institution will receive royalties from the sale of the vaccine
- Company proposes to sponsor clinical research at institution to test the vaccine
- Options
 - Set up a management plan for disclosures, research and data oversight, and oversight of patient involvement that puts EVP, DEAN, COO at arm's length AND
 - Have an external review board monitor the management plan

HYPOTHETICAL CASE 6:

SERVICE CHIEF

- Dr. Smith routinely recommends the surgical sutures, stents, and other devices purchased by the hospital. Dr. Smith is compensated >\$10K as a consultant for the suture company, as a speaker for the stent company, and holds >\$20K stock in the device company.
 - ICOI with the institutional vendor policy
 - Prior disclosure by all who influence purchasing

A FEW SIMPLE RULES

- Separate the roles of administrators who oversee and make institutional decisions about research from those who oversee investments and technology transfer
- Have established policies and procedures for the identification, disclosure, review, and management or elimination of potential ICOI
- Have an ICOI Committee with some external members, high-ranking independent internal members (not COI Committee)
- Make use of external committees, *ad hoc* or standing, routinely or in certain cases, if feasible

A FEW SIMPLE RULES (2)

- Have good communication among the ICOI Committee, COI Committee(s), Tech Transfer Office, and IRB
- Disclose, disclose, disclose
- Require IRB members to disclose potential conflicts of interest and recuse or divest if appropriate