

American Health Lawyers Association

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Talking Points

- **Introduction**
- **Primary and Secondary Interests**
- **NIH-Funded Research**
- **FDA Oversight**
- **Institutional Review Boards**
- **Questions**



Conflict of Interest

“A conflict of interest is a set of circumstances that creates a risk that professional judgment or actions regarding a primary interest will be unduly influenced by a secondary interest.”

Institute of Medicine

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Types of Primary Interests

- **Examples of Researchers' Primary Interests**

- Improve health
- Save lives
- Develop new technologies
- Advance knowledge
- Discover cures

- **Examples of IRBs' Primary Interests**

- Ensure integrity of research data
- Protect human subjects
 - Ensure informed consent
 - Ensure risks to subjects are minimized
 - Ensure risks are reasonable in relation to benefits

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Types of Secondary Interests

- **Examples of Researchers' Secondary Interests**

- Financial gain
- Academic promotion
- Publication
- Prestige

- **Examples of IRBs' Secondary Interests**

- Financial gain
- Favors for friends and colleagues
- Hospital politics

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Types of Risk

- **Harm human subjects enrolled in clinical trials**
- **Corrupt data**
- **Bias results**
- **Bias how results are presented**
- **Gain marketing approval for unsafe or ineffective drugs, biologics, or medical devices**
- **Harm public health**

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NIH-Funded Research

National Institutes of Health: Conflicts of Interest In Extramural Research (OEI-03-06-00460, January 2008)

Background

- 80% of NIH budget goes to fund extramural research
- \$24 billion in grants awarded to over 3,000 grantee institutions

Federal Regulations

- Grantees must identify financial conflicts of interest
- Grantees must report financial conflicts to NIH
- Grantees must manage, reduce, or eliminate conflicts

Findings

- NIH could not account for all financial conflict-of-interest reports
- 89% of conflict-of-interest reports lacked information about:
 - the nature of the conflict
 - how the conflict would be managed, reduced, or eliminated

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NIH-Funded Research Continued

National Institutes of Health: Conflicts of Interest In Extramural Research (OEI-03-06-00460, January 2008)

Findings (cont.)

- NIH rarely follows up on conflict-of-interest reports
- NIH does not routinely verify grantee institutions' compliance with Federal regulation – oversight relies on grantees' assurances

OIG's Recommendations to NIH

- Increase oversight to ensure grantee institutions comply with Federal regulations
- Require grantee institutions to provide greater details about:
 - the nature of researchers' conflicts
 - how the conflicts will be managed, reduced, or eliminated
- Maintain a database with all conflict-of-interest reports

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NIH-Funded Research Continued

Follow-up

- NIH developed a new Web-based system to track financial conflicts of interest
- NIH will require grantees to use a newly developed electronic system to report conflicts

Additional OIG work coming soon

- Explore the nature of researchers' financial conflicts
- Explore how grantee institutions handle financial conflicts
 - Disclosure
 - Reduction
 - Elimination

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FDA Oversight

The Food and Drug Administration's Oversight of Clinical Investigators' Financial Information (OEI-05-07-00730, January 2009)

Background

- Sponsors submit pretrial applications to FDA before starting clinical trials
- Sponsors submit marketing applications after completing clinical trials

Federal Regulations

- Sponsors must collect financial information from clinical investigators before trials begin
- Sponsors need not submit financial information to FDA until the marketing application

Findings

- 42% of FDA-approved marketing applications were missing financial information
- For 31% of marketing applications, FDA did not document review of financial information
- 20% of marketing applications disclosed financial interests for which neither FDA nor the sponsor took action

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FDA Oversight Continued

The Food and Drug Administration's Oversight of Clinical Investigators' Financial Information (OEI-05-07-00730, January 2009)

OIG's Recommendations to FDA

- Ensure that sponsors submit complete financial information for all clinical investigators
- FDA reviewers should consistently review financial information and respond to disclosed conflicts
- Require sponsors to submit financial information during the pretrial application process

Follow-up

- FDA now requires marketing applications to include:
 - a complete list of clinical investigators
 - disclosure of the nature of financial conflicts or certification to the absence of any financial conflicts

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Institutional Review Boards

• **OIG Report**

Institutional Review Boards: The Emergence of Independent Boards

(OEI-01-97-00192, June 1998)

• **GAO Investigation**

Human Subjects Research: Undercover Tests Show the Institutional Review Board System Is Vulnerable to Unethical Manipulation (GAO-09-448T, March 26, 2009)

• **Congressional Hearing**

House Committee on Energy and Commerce,
Subcommittee on Oversight and Investigations
(March 26, 2009)

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Bogus Research Protocol Submitted to 3 Independent IRBs

• Study Protocol

- **Purpose:** Investigate effect on wound healing
- **Study population:** Women undergoing abdominal surgery
- **Methods:** Administer 1 liter of investigational solution into peritoneal cavity

• IRB Review

– Protocol rejected by two IRBs

Reviewer comments: “absolute junk”

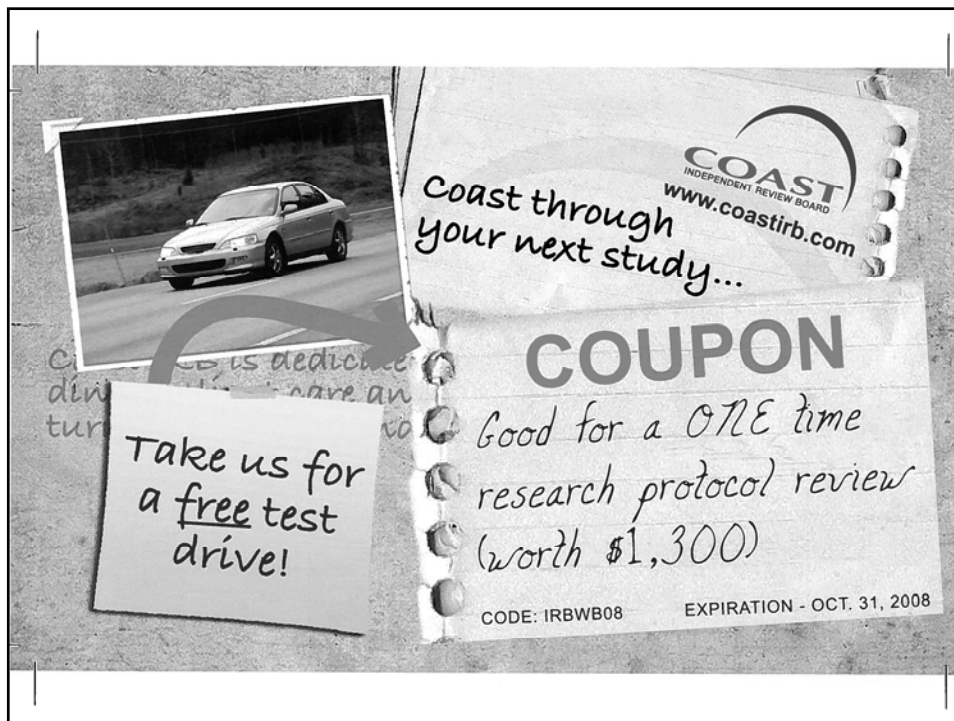
“the most dangerous thing I’ve ever seen”

– Protocol approved by Coast IRB

With coupon for discount off of next review

Note: Coast IRB is out of business effective June 30, 2009

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GAO's Bogus IRB

**E-Z Reviews IRB
1234 Phulovit Lane SE
Chetesville, AZ**

Staff: April Phuls, Timothy Wittless, Alan Ruse

- E-Z Reviews IRB website offered "Fast approvals guaranteed"
- IRB successfully registered with HHS and obtained listing in HHS database
- Actual researchers submitted clinical trial protocols to bogus IRB for review

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GAO's Bogus Medical Device Company

**Phake Medical Devices
2232 Wounded Limb Drive
Paynesville, SC**

Senior Official: Dr. Vincent N. Feelgood

- Bogus company successfully registered with HHS
- Obtained a Federalwide Assurance

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