Research Compliance Office

Conflict of Interest: Investigator and Institutional

Kristin Frazier
IRB Education
October 2008
Federal and AAHRPP Requirements

- FDA: Sponsors must disclose investigator financial interests to the FDA in marketing applications 21CFR 54

- Organization has and follows written policies and procedures to identify, manage, and minimize individual conflicts of interest of investigators. The Organization works with the IRB regarding conflicts of interest, when appropriate AAHRPP Element 1.3.G

- Organization is developing written policies and procedures for recognizing and managing institutional conflicts of interest AAHRPP Element 1.3 H
Stanford Requirements: Investigator COI (RPH 4.1 and 4.2)

- Where the faculty member is participating in research involving human subjects, and has any financial interest in the sponsor (or a member of the immediate family has such an interest), that interest must be disclosed on an ad hoc basis, regardless of its value.

- COIC members include:
  - Rich Popp, Chair
  - Harry Greenberg
  - Helen Bronte-Stewart
  - Dan Bernstein
  - Ron Levy
  - David Spiegel
  - Stan Cohen
  - Mark Blumenkranz
  - Mildred Cho
  - Ed Engleman
  - Al Lane
  - Rabbi Shelly Marder (public member)
COIC Review

- Stanford follows the AAMC guidelines:

- A **significant financial** interest is any financial interest/relationship involving
  - Income over $10,000/year
  - Equity over $10,000 in a publicly traded company
  - Any equity in a privately held company
Investigator Requirements: eProtocol Section 12

- Disclose any potential conflict of interest (with sponsor, vendor, subcontractor):
  - Consulting arrangement, management responsibility, equity holdings
  - Financial relationship: honoraria, income, or stock/stock options
  - Advisory Board member
  - Gift Fund recipient
  - Ownership or royalty interests in intellectual property in protocol

- Applies to PD, investigators and research staff who:
  - recruit, select, consent or treat participants, plan to analyze data, plan to serve as an author on a paper originating from the research or is an immediate family member (spouse, domestic partner, dependent child) of any of the above
IRB Staff notify PDs to contact COI Manager when COI is disclosed in eProtocol.

COI Manager provides IRB Staff with Action Report Form (containing disposition of COI review) and PDs are copied.

Action Report includes:
- Assessments of disclosed interests
- Suggested consent form language
  - Modification of PD’s proposed consent form language
  - Management plan
Stanford Requirements: Institutional Conflict of Interest (ICOI)

- Investigators disclose, *if to their knowledge*, Stanford has ownership or royalty interests in any intellectual properties utilized in the protocol.

- ICOI at Stanford is addressed by:
  - Office of the Dean of Research
  - Office of Technology Licensing (OTL)
  - COIC
IRB Managers forward protocols to OTL, in which PDs have indicated the University has financial interests in the company; and

RCO Intake Staff sends new protocols to OTL when a manufacturer is listed in the drug and device section in eProtocol

Director of OTL refers these protocols to the COIC and Dean of Research for review
Actions on ICOI

The Dean of Research could:

- Require divesting of Stanford’s equity OR
- Require modifications to the research so Stanford (and/or any department) does not benefit by the results of research OR
- Prohibit the research

Case-by-case assessment if royalties result from exclusive technology licensing rights
IRB Member Review

- IRB Managers project Action Report Form during review of protocol in the meeting
- Considerations in reviewing Action Report:
  - Does the consent form language adequately reflect the disclosure?
  - Does the management plan (if any) appear to mitigate (or eliminate) COI?
  - Confirm changes are made to the protocol application and consent form, as applicable