

Financial Conflicts of Interests: Revised Federal Regulations and Institutional Compliance

Washington State Institutional Review Board

June 21, 2012 Meeting

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Summary

- New responsibilities on institutions
- Effective Sep 26, 2011; compliance NLT Aug 24, 2012
- Applies to institutions with PHS (SAMHSA, HRSA, AHRQ, NIH) funding
- Specific requirements related to review, approval and oversight of research

Definitions

- Financial conflict of interest means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research
- Institution means any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that is applying for, or that receives, PHS research funding
- Investigator means the “ . . . PI and *any other person, regardless of title or position*, who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding, which may include, for example, collaborators or consultants”

Definitions

- SIGNIFICANT financial interests are interests that reasonably appear to be related to an investigator's institutional responsibilities AND that exceed certain thresholds or value (e.g., \$5000 in remuneration within 12-month period preceding disclosure of FCOI; equity interests in either publicly or non-publicly traded entities)

Common Financial Interests

- Outside (publicly traded entity) salary, honoraria, consulting fees
- Certain compensation for seminars, lectures, etc.
- Ownership interests (e.g., stock, stock options) other than in the institution
- Intellectual property rights (patents, licenses)

Core Changes

- Lowers the threshold from \$10,000 to \$5,000 for disclosure of compensation for services or equity interest in a publicly traded company, with a \$0 threshold for disclosure of equity in a non-publicly traded company
- Investigators must disclose all significant financial interests related to their institutional responsibilities (rather than only those related to the PHS-funded research)
- Investigators must complete mandatory training before undertaking PHS-funded research ; renewal every 4 years
- Management of the financial conflict of interest

IRB-Related Requirements

- Disclosure of financial conflicts of interest directly to research subjects
- Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest
- Modification of the research plan
- Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research

HRRS Actions

- Review of Washington State Agency policies and WSIRB procedures for revisions, modifications or interpretation
- HRRS Pre-IRB review practices to assess financial conflicts of interest
- Inclusion of financial conflicts of interest assessment in IRB review, deliberation and determinations
- Outreach to constituents and communities of interest
- Education and training

Notes

- Link to U.S. Government Printing Office publication of DHHS Final Rule, Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors:
<http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf>
- Link to related FAQs published at DHHS:
http://grants.nih.gov/grants/policy/coi/coi_faqs.htm
- We gratefully acknowledge Jeff Cheek, UW Research Compliance and Operations, from whose presentation, *New PHS regulations on financial conflicts of interest and changes to UW policy (GIM-10)*, some content for this slide deck was adapted