Financial Disclosure and Conflict of Interest

Education for Investigators
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Note: This presentation is an overview of the Public Health Service (PHS) and University of Kentucky (UK) regulations. Each Investigator is advised to read the regulations in their entirety; links to the regulations are provided on the Resources slide.
Resources

• PHS Regulation (42 CFR § Part 50)

• NIH FAQs

• NIH Tutorial

• UK Policy 7:2
  – http://www.uky.edu/regs/Administrative/ar7.2.htm

• Effective August 24, 2012
Background

• PHS and the National Science Foundation (NSF) issued conflict of interest policies in 1995.

• They were virtually identical.

• UK policy was established to mirror the two federal policies.

• UK policy is applicable to all research, regardless of funding source.
What changed?

• PHS issued a revised regulation that is effective 8/24/2012.

• Grantees must comply to remain eligible to apply for and receive PHS funding and to continue performing on active grants.

• UK policy was updated to be consistent with the revised regulation.

• UK policy is applicable to all Investigators.

• A few requirements are applicable to PHS funded research only.
Purpose of Financial Conflict of Interest Regulations

**PHS 42 CFR / 50.601**
To promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded by PHS will be free from bias resulting from Investigator financial conflict of interest.

**University of Kentucky AR 7:2**
This regulation sets forth policies and procedures to ensure that the personal financial interests of an Investigator do not compromise the objectivity with which research is designed, conducted, and reported or the welfare of human research subjects.
Who must disclose?

• Each Investigator on a sponsored project proposal, award, or institutionally-sponsored research must disclose.

• “Investigator” means the project director, principal investigator/program director, co-investigator, collaborator, senior/key personnel, faculty associate, and any other person, regardless of title or position, who is responsible for the design, conduct, reporting, or proposing of research or other sponsored activity.
What must be disclosed?

• Each Investigator must disclose all significant financial interests (SFI) that are related to his/her institutional responsibilities.

• Financial interests are aggregated for the Investigator, his/her spouse, and dependent children.
What must be disclosed? (Continued)

• “SFI” means one or more of the following:
  – For a publicly traded entity, remuneration and equity interest exceeding $5000 in value received in the 12 months preceding disclosure.
  – For a non-publicly traded entity, remuneration exceeding $5000 in value received in the 12 months preceding disclosure OR any equity interest.
  – Non-publicly traded entities include non-profit organizations such as associations, foundations, institutions of higher education, federal, state, local governments. Specifically excluded is income from seminars, lectures or teaching from federal, state, local government, institution of higher education, academic teaching hospital, medical center or research institute affiliated with institution of higher education.
  – Intellectual property rights and interests upon receipt of income from an entity other than UK.
Remuneration

• “Remuneration” means all salary & wages, including professional income from non-UK faculty practice plans, consulting fees, speaking fees, payment for services (e.g. honoraria, paid authorship, travel reimbursement, gifts), licensing revenue, royalties for books, publications or reports, or equity interests.

• Excluded - UK salary, royalties paid through UK, and equity interest in publicly traded mutual funds or retirement programs the investment of which is not under the control of the Investigator or family member.
Financial Disclosure Procedures

• UK has an on-line Financial Interest Disclosure Statement at MyUK, Enterprise Services, Workflow.

• A disclosure is required annually in March of each year.

• If an Investigator is new and has not completed an annual disclosure, it must be completed prior to submission of a proposal.

• The Disclosure Statement has 5 questions with one additional question for PHS Investigators.

• Investigators may access their Disclosure history at any time.
Revising a Disclosure Statement

• Investigator must revise a Disclosure Statement within 30 days of discovering or acquiring a new SFI (e.g. through purchase, marriage, or inheritance).

• Examples:
  – If you disclosed $10,000 in consulting income from ABC company and receive an additional $2,000 consulting payment during the year, report this on the next annual disclosure (same type of SFI).
  – If you disclosed $10,000 in consulting income from ABC company and subsequently received royalty income of $2000, you must update your disclosure to include the royalty income within 30 days (new type of SFI).
  – If your dependent child receives a gift of $7,000 worth of stock in a company related to your institutional responsibilities, you must update your disclosure within 30 days.
Review Procedures

• Disclosure Statements will be reviewed using a secure web-based system with restricted access.

• The review will be conducted by the Institutional Official (IO) or those to whom the IO has given specific written delegation.

• Reviewers will assess whether or not an SFI is related to the Investigator’s research and if an SFI is a Financial Conflict of Interest (FCOI).
Review Procedures (Continued)

• “Related to” means the SFI could be affected by the research or is in an entity whose financial interest could be affected by the research.

• An FCOI exists if the IO reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the research.
Review Procedures (Continued)

• If an FCOI appears to exist, the IO will notify the Investigator and dean or director and seek their review and input.

• The Investigator and dean or director will review the Disclosure Statement, make one of the following determinations and communicate it to the IO:
  – No FCOI exists
  – An FCOI exists but the SFI has been eliminated
  – An FCOI exists and a proposed management plan is provided
Management of FCOI

• If the Investigator and dean or director determine no FCOI exists, the IO may:
  – Agree with the determination that there is no FCOI
  – Disagree and ask the parties to propose a management plan
  – Refer the matter to the Research Conflict of Interest Committee (RCOIC) for review and comment

• All management plans are referred to the RCOIC which may:
  – Accept the proposed plan
  – Amend it
  – Formulate a new plan

• The RCOIC recommends a plan to the IO.

• The IO makes a final decision and informs the Investigator and dean or director.
Reporting

• The Investigator must submit annual and final reports which outline the actions taken to meet the conditions in the management plan.
Enforcement

• It is violation of the regulation to:
  – Intentionally provide incomplete or erroneous information on the disclosure form
  – Fail to make any required disclosure
  – Fail to provide information needed for a review

• Sanctions may be imposed for violation, including:
  – Being prohibited from submitting proposals
  – Having active sponsored projects suspended
  – Suspension
  – Termination of employment
  – Notification to funding agencies

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Training

• Before engaging in research, each Investigator must complete the training in this presentation.

• New Investigators planning to join an active research project must complete training before participating.

• Training must be repeated:
  – Every four (4) years
  – If an Investigator is found to be noncompliant with the regulation
  – If the regulation substantially changes
Training (Continued)

• If you are a PHS Investigator, click on the Continue to the PHS Only Information button below.

• If you are not a PHS Investigator, click on the Continue to the Training Conclusion button below.
*Applicable to PHS Only*

Reimbursed or Sponsored Travel

- Remuneration which must be disclosed includes reimbursed or sponsored travel (i.e. paid on behalf of the Investigator rather than being reimbursed) of any amount.

- Excluded:
  - Travel reimbursed or sponsored for spouse and dependent children
  - Travel paid from a UK account
  - Reimbursed or sponsored travel paid by a Federal, state, or local government agency, an institution of higher education [as defined at 20 U.S.C. 1001(a)], an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education
*Applicable to PHS Only*

**Reports to PHS**

- Prior to expending funds, UK must report to PHS any FCOI pertaining to the project; reports are due annually for the duration of the project.

- **Elements reported:**
  - Award #
  - PI
  - Investigator with FCOI
  - Name of entity, nature of SFI, value of SFI in ranges
Prior to expending funds on a PHS award, UK must post to a public website certain information about any SFI held by senior/key personnel related to the PHS award that is determined to be an FCOI; website is updated annually and with each new FCOI.

Elements posted:
- Investigator name, title, and role on project
- Name of entity, nature of SFI, approximate value in ranges
*Applicable to PHS Only*

**Subrecipients**

- PHS policy is applicable to Subrecipients.

- Subrecipient may have and be subject to a policy that complies with PHS, OR subrecipient Investigators will be subject to UK’s policy.

- In either case, Subrecipient Investigators must:
  - Prior to proposal submission, disclose SFI
  - Prior to expenditure of funds, report any FCOI to UK and UK must report to PHS

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*Applicable to PHS Only*  
Non-compliance

- If an Investigator does not timely disclose an SFI or the Institution does not timely review, the IO must review to determine if it is related to PHS funding and if it is an FCOI.

- If it is determined to be an FCOI, a management plan will be implemented as soon as possible.
Retrospective Review/Mitigation Plan

• If an Investigator does not timely disclose an SFI or the Institution does not timely review or the Investigator does not comply with a management plan, the Institution must conduct a retrospective review of the research to determine if there was bias in the design, conduct, or reporting of the research.

• If bias is found, PHS will be notified and provided a mitigation report outlining actions taken to eliminate or mitigate affect of bias.
*Applicable to PHS Only*

Retrospective Review/Mitigation Plan (Con’t)

• The Institution must monitor the Investigator’s compliance with the management plan and submit annual reports to PHS.

• The Investigator must again complete COI training.

• For certain clinical research the Investigator must disclose FCOI in presentations and request addendum to previous publications.

• PHS may request further information and may impose additional conditions.
Training Conclusion

• You have completed the required training on Financial Disclosure and Conflict of Interest.

• Thank you for your attention to this important requirement!

• If you are unsure about or have any questions pertaining to the material covered in this course, please contact Kelley Davis in the Office of Sponsored Projects Administration at (859) 257-8311 or kelley.king@uky.edu.

• Please continue to the next slide...
• You may now click on the yellow Log off button in the lower corner to close this window.

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Your participation in this course has been completed.

• If this message does not appear, send an e-mail to IRISTraining@email.uky.edu for assistance.

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