School of Pharmacy

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Update on new PHS regulations on financial conflicts of interest and changes to UW policy (GIM-10)

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Federal Research Standard

Conflicts of financial interest occur “whenever financial considerations may have the potential to compromise or have the appearance of compromising an investigator’s professional judgment and independence in the design, conduct, or publication of research.”

- US Public Health Service, 1995

Financial conflicts of interest (FCOI), either actual or potential, occur in all human processes and are not inherently “bad” if they are appropriately managed.
Most frequent examples of FCOI in research

- Outside salary, honoraria, consulting fees
- Compensation for speaking engagements
- Stock, stock options, other ownership interests
- Intellectual property rights (patents, licenses)
- Imputed interests (spouse, etc.)
UW Significant Financial Interest (SFI) Disclosure Policy (GIM-10)

• Applies to all research (sponsored and unsponsored) and tech transfer license transactions

• Addresses conflicts and appearances of conflicts – any SFI that could potentially bias research

• Goal is to prevent –
  ▪ Bias in research
  ▪ Harm to human subjects
  ▪ Misuse of UW and state resources
  ▪ Violations of state ethics act
SFI disclosure is required prior to participating in research or tech transfer activity; anyone having a significant financial interest related to the activity must disclose details.

Disclosures can occur: when research proposal (eGC-1) is submitted to OSP; when IRB application is submitted to HSD; when SFI arises during the course of research; or prior to concluding technology licensing transaction with C4C.
What is a “significant” financial interest?

1. For a Clinical Trial, any Financial Interest.

2. For Human Subjects Research other than a Clinical Trial (i) any Financial Interest exceeding $5,000 in value, (ii) any Equity Interest; or (iii) any Intellectual Property Interest.

3. For all Research other than Human Subjects Research and all Technology Transfer Transactions, (i) any Financial Interest (including a Compensation Interest, an Equity Interest and an Intellectual Property Interest) exceeding $10,000 in value, or (ii) any Equity Interest representing more than a 5% ownership in any single entity. *(PHS / NSF definitions)*

*NOTE: New PHS regulations and definitions of FCOI will apply August 24, 2012*
New PHS Rules on Financial Conflicts of Interest (FCOI)

Institutions receiving federal funding must be in full compliance with all of the requirements by the earlier of:
- August 24, 2012; or
- upon making its revised institutional financial conflict of interest policy publicly accessible.

In the interim, institutions should continue to comply with the 1995 regulations.
Summary of Key PHS Changes

(1) Lowers the minimum 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.

(2) Requires investigators to disclose all significant financial interests related to their institutional responsibilities (rather than only those related to the PHS-funded research).
Summary of Key PHS Changes

(3) Increases the institution’s responsibilities regarding identifying significant financial interests related to PHS-funded research; managing financial conflicts of interests; federal reporting requirements, and verifying assurance that sub-recipients are compliant with the PHS regulations.

(4) Requires public transparency of FCOI management plans by either publicly accessible website or written response to any requestor within 5 business days of request for institution’s financial conflict of interest policies and certain information regarding any key personnel whose significant financial interests are related to PHS-funded research.
Most troublesome PHS Changes

(5) Requires all “investigators” to complete mandatory training prior to engaging in research related to any PHS-funded grant or contract. Re-training required every 4 years.

(6) PHS-funded investigators must disclose the occurrence of any reimbursed travel or sponsored travel related to institutional responsibilities (including purpose of trip, sponsor/organizer, destination, and duration); some exceptions are allowed. The institution must subsequently determine if any travel reimbursement constitutes a FCOI with respect to the investigator’s PHS-funded research project(s).
What will change for all UW investigators with respect to FCOI disclosure process?

a) All UW investigators that have financial interests related to their research will be subject to the lower threshold of FCOI for disclosure requirements, regardless of sponsor (i.e., there will be a single standard to define FCOI)

b) ORIS is developing an electronic disclosure process that will replace the current paper-based procedure, which will reduce the administrative burden for faculty disclosing FCOI related to research projects.
Highest impact changes for PHS-funded investigators at UW (effective 8/24)

a) All PHS-funded investigators will have to complete mandatory online training prior to engaging in PHS-sponsored research.

b) PHS-funded investigators must disclose all SFI related to their institutional duties.

c) All investigators on PHS-funded grants will need to disclose all travel reimbursements paid directly to them by an outside entity (with a few exceptions); the online disclosure system currently in development will allow such disclosures (in addition to other SFI disclosures).
Where will we need help from UW P.I.s and department administrators?

• Many investigators (e.g., postdocs) are not included in Key Personnel at the time the proposal is submitted (i.e., not identified on the eGC-1)

• We currently do not have any means to centrally track new personnel added on to ongoing PHS-funded projects. We thus are dependent on P.I.s and departmental administrators to remind “new” investigators of the mandatory training and disclosure requirements.
Key Definitions

“Investigator” means any University personnel regardless of title or position responsible for the design, conduct, or reporting of University Research.

- This includes, but is not limited to, the Principal Investigator, project director, co-principal investigator, and may also include other Senior/Key Personnel

- The primary factors to be used in determining who is an Investigator are the significance of the tasks assigned to the individual with regard to the design, conduct and reporting of the Research and the degree of independence that individual may have in performing such Research-related tasks; the P.I. is responsible for identifying “investigators” on the eGC-1.
Key Definitions

Institutional Responsibilities – Investigator’s professional responsibilities on behalf of the Institution, including research, teaching and clinical work.

Significant Financial Interest (SFI) – Any financial interest that meets the threshold and is related to an Investigator's research or, for PHS-funded investigators, to their Institutional Responsibilities.

Financial Conflict of Interest (FCOI) – An SFI that may directly and significantly affect the design, conduct or reporting of research or a Technology Transfer transaction.
Thresholds

The SFI Threshold for ALL research will be $5,000

• Reduce the non-Human Subjects research threshold from $10,000 to $5,000

• Human Subjects research threshold remains at $5,000

• Clinical trials threshold is increased to $5,000
Disclosure Requirements

PHS-funded Investigators must disclose ALL SFI that is related to their Institutional Responsibilities

Travel

• All sponsored or reimbursed travel related to a PHS-funded Investigator’s Institutional Responsibilities must be disclosed.

• May also be an SFI when aggregated with compensation from a single entity toward threshold

• Applies to all travel, except when paid by:
  o UW
  o Federal, state or local government
  o Institution of Higher Education
  o Research Institution Affiliated with Institution of Higher Education
  o Academic Medical Center

• Therefore, must disclose travel when paid by a professional association independent of the above
## Investigator SFI Disclosure and Institutional FCOI Reporting Requirements

| Investigator Discloses known SFI(s) to the Institution | Institution Reports identified FCOI(s) to the NIH  
Designated official(s) review the disclosures to make determinations of FCOIs and report any FCOIs to NIH. |
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<td><strong>At time of Application</strong>* (note requirement for 1 year window before and after)</td>
<td><strong>Prior to the Expenditure of Funds</strong></td>
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<tr>
<td><strong>Within 30 days of acquiring or discovering SFI</strong></td>
<td><strong>Within 60 days of identification</strong></td>
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<td><strong>Annually at the time period prescribed by the Institution during the award period</strong></td>
<td><strong>Annually: At the same time as when the grantee is required to submit the annual progress report, including multi-year progress report, or at time of extension. Annual FCOI report is submitted through eRA Commons</strong></td>
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Mandatory Training

a) Each Investigator must complete training prior to engaging in research related to any PHS-funded grant or contract and at least every four years.

b) OR has published an online training program for Investigators to complete.
   - Training must be complete before expenditure of PHS funds after Aug 24, 2012.
   - Working with affiliated institutions (FHCRC and SCRI) to have reciprocal training agreements.
   - Only Investigators doing PHS funded research must complete the training.

www.washington.edu/research/topics/fcoi
Recommendations

- Although the mandatory training is required for new monies (i.e., existing awards are “grandfathered”), all PHS-funded investigators (including those who expect to acquire first-time grants after Aug. 24) should complete the mandatory training requirement as soon as possible.

- Due to the “twelve months prior” disclosure requirement for travel reimbursement at the time of application, PHS-funded investigators should begin disclosing travel reimbursements received on or after Aug. 24.
Timeline for changes

- SFI disclosures will convert to an web-based / electronic process (all SFI including travel reimbursements).
- Phase 1 of the electronic disclosure process will go live with the new policy effective Aug. 24.
- Eventually, this electronic disclosure process will also be used for SFI associated with unsponsored research and tech transfer transactions.
- An updated set of FAQs to be posted by Aug. 16 at www.washington.edu/research/topics/fcoi; questions may be submitted to research@uw.edu.