Investigator Procedures Summary
for Financial Conflict of Interest in Research
in Public Health Service-Funded Projects

For complete information, see resource page at:
http://unh.edu/research/financial-conflicts-interest-research-projects-funded-public-health-service-phs

Policy (including definitions): http://www.usnh.edu/olpm/UNH/VIII.Res/T.htm

I. Disclosure Process

A. Initial Disclosure Process for New Projects Funded by the Public Health Service (PHS): No later than the time of proposal submission, each investigator responsible for the design, conduct, or reporting of research activities funded or proposed for funding by PHS must disclose to UNH all his/her significant financial interests (SFI) related to his/her institutional responsibilities. (See attached Appendix for examples.) In addition, any SFIs held by the investigator’s spouse or domestic partner and dependent children that are related to the investigator’s institutional responsibilities must also be disclosed.

Therefore, each investigator who has (or whose spouse/partner/dependent child has) an SFI that is related to his/her institutional responsibilities must complete a UNH Financial Conflict of Interest in Research for PHS-Funded Projects Disclosure Statement. The form and any supporting documentation must be submitted by email or in a sealed envelope marked “Confidential” to the Office of the Senior Vice Provost for Research (OSVPR). If the Disclosure Statement indicates involvement of human subjects in the research, the OSVPR will notify the chairperson of the UNH Institutional Review Board for the Protection of Human Subjects in Research (IRB) so the situation may be addressed by the IRB.

B. Investigators who join an ongoing PHS-funded project must comply with this policy before commencing work on the project.

C. Updates of Disclosures to Reflect Changes in Financial Circumstances: An investigator must submit an updated Disclosure Statement within thirty (30) business days of discovering or acquiring a new SFI related to his/her institutional responsibilities.

D. Annual Updates of Disclosures: For the duration of the award period, each investigator research must submit an updated disclosure of significant financial interests related to their institutional responsibilities at least annually (July 1 – June 30). The disclosure will include any information not previously disclosed and will update information on SFIs previously disclosed.

II. Management Plans

The UNH Disclosure Review Committee (DRC) will review all Disclosure Statements and accompanying documentation and determine whether an investigator’s SFI is related to the PHS-funded research, and if so, whether the SFI represents a financial conflict of interest (FCOI). A financial conflict of interest exists when the significant financial interest could reasonably be seen as DIRECTLY and SIGNIFICANTLY affecting the design, conduct, or reporting of the PHS-funded research.
If the DRC determines that an actual or potential FCOI exists, the DRC will request that the investigator submit a proposed conflict management plan that details steps that could be taken to manage, reduce, or eliminate the FCOI. The DRC will review the proposed conflict management plan and approve it or add conditions or restrictions to ensure that any conflict is managed, reduced, or eliminated. In all cases, resolution of the actual or potential conflict or establishment of an acceptable conflict management plan must be achieved before expenditure of any funds under a PHS award.

III. Training: Investigators must complete training prior to engaging in research related to any PHS-funded grant, and at least every four (4) years thereafter. UNH provides a brief online training at https://rit.sr.unh.edu/training/rcr-training/conflict-of-interest.html.

**Summary of Investigator SFI Disclosure Timing**

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<th>Type of Disclosure to UNH and Project</th>
<th>Timing of Disclosure of SFI to UNH</th>
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<tr>
<td>Initial Disclosure Related to New PHS Project</td>
<td>No later than time of submission of application by UNH to a PHS agency</td>
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<td>Addition of Investigator to Ongoing PHS Project</td>
<td>Before commencing activities on project</td>
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<tr>
<td>Update to an Existing Disclosure</td>
<td>Within 30 days of acquiring or discovering SFI</td>
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<td>Annual Update</td>
<td>Once annually (July 1 – June 30) during award period</td>
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## Investigator Procedures Summary for PHS FCOIR
### Appendix: Summary of Types of Financial Interests and Significant Financial Interests (SFI)

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<tr>
<th>Type of Financial Interest</th>
<th>Included in SFI Definition</th>
<th>Not Included in SFI Definition</th>
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| Salary, and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship) | Publicly traded entities: If value of any remuneration received from entity by investigator (or investigator’s spouse/domestic partner and dependent children) in 12 months preceding disclosure when aggregated with the value of any equity interest in the entity as of the date of disclosure exceeds $5,000.  
Non-publicly traded entities: If value of any remuneration received by investigator (and/or investigator’s spouse/domestic partner and dependent children) in 12 months preceding disclosure, when aggregated, exceeds $5,000. | Salary or other remuneration paid by UNH to the investigator if the investigator is currently employed or otherwise appointed by UNH.  
Publicly traded entities: If value of any remuneration received from entity by investigator (or investigator’s spouse/domestic partner and dependent children) in 12 months preceding disclosure when aggregated with the value of any equity interest in the entity as of the date of disclosure is less than $5,000.  
Non-publicly traded entities: If value of any remuneration received by investigator (and/or investigator’s spouse/domestic partner and dependent children) in 12 months preceding disclosure, when aggregated, is less than $5,000. |
| Equity interest (i.e., stock, stock option, or other ownership interest) | Publicly traded entities: If value of any equity interest held in the entity by investigator (or investigator’s spouse/domestic partner and dependent children) as of the date of the disclosure when aggregated with any remuneration received from entity in 12 months preceding disclosure exceeds $5,000.  
Non-publicly traded entities: When investigator (or investigator’s spouse/domestic partner and dependent children) holds any equity interest. | Publicly traded entities: If value of any equity interest in the entity by investigator (or investigator’s spouse/domestic partner and dependent children) as of the date of the disclosure when aggregated with any remuneration received from entity in 12 months preceding disclosure is less than $5,000.  
Non-publicly traded entities: When investigator (or investigator’s spouse/domestic partner and dependent children) holds any equity interest. |
| Income from intellectual property rights and/or interests (e.g., patents, copyrights, royalties) | Income related to such intellectual property rights and interests when rights and/or interests are not assigned to UNH. | Income related to intellectual property rights and/or interests when rights and/or interests are assigned to UNH.  
Royalty income received from UNH. |
| Sponsored Travel | Travel in 12 months preceding disclosure by investigator (and/or investigator’s spouse/domestic partner and dependent children) related to the investigator’s institutional responsibilities that is paid for on behalf of the investigator (and not reimbursed to the investigator so that the exact monetary value may not be readily known), and when sponsoring/reimbursing entity is not a/an:  
- Federal, state, or local government agency,  
- Institution of higher education as defined at 20 U.S.C. 1001(a),  
- Academic teaching hospital,  
- Medical center, or  
- Research institute that is affiliated with an institution of higher education. | Travel in 12 months preceding disclosure by investigator (and/or investigator’s spouse/domestic partner and dependent children) related to the investigator’s institutional responsibilities paid on behalf of the investigator (and not reimbursed to the investigator so that the exact monetary value may not be readily known,) and when travel is reimbursed or sponsored by a/an:  
- Federal, state, or local government agency,  
- Institution of higher education as defined at 20 U.S.C. 1001(a),  
- Academic teaching hospital,  
- Medical center, or  
- Research institute that is affiliated with an institution of higher education. |
| Income from investment vehicles (such as mutual funds and retirement accounts) | When the investigator has some degree of control in the investment decisions made in these vehicles. | When the investigator does not directly control the investment decisions made in these vehicles. |
| Income from seminars, lectures, or teaching engagements | Income from seminars, lectures, or teaching engagement when entity is not a/an:  
- Federal, state, or local government agency, | Income from seminars, lectures, or teaching engagements sponsored by a/an:  
- Federal, state, or local government agency, |
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