

## MCW Corporate Policy RS.GN.020 Financial Conflicts of Interest in Research: Summary of Revisions

Prepared by the MCW Corporate Compliance Office

### Summary of Revisions (new and/or revised policy language highlighted in yellow)

Revision	Previous	NEW
<b>1) Expand policy scope</b>	PIs, co-Is, other Key Personnel, others who influence or are responsible for the design, conduct or reporting of research (Covered Person) funded by the US Public Health Services (PHS)	PIs, co-Is, other Key Personnel, others who influence or are responsible for the design, conduct or reporting of research (Covered Person) funded by the following sponsors: <ul style="list-style-type: none"> <li>i. the US Public Health Service (PHS),</li> <li>ii. a Non-PHS Sponsor,</li> <li>iii. the National Science Foundation,</li> <li>iv. any other federal funding agency as required per agency policy or award terms and conditions, or</li> <li>v. an Industry Sponsor (for sponsored awards funded by an Industry Sponsor, only the PI is considered a Covered Person).</li> </ul>
<b>2) Revise definition of a Significant Financial Interest (SFI) with regard to the dollar threshold for equity in a publicly-traded entity</b>	Publicly Traded Entity – if the aggregated amount of income or interest exceeds \$5000 in the previous 12 months (prior to the Covered Person’s disclosure) from the entity. <ul style="list-style-type: none"> <li>i. Income includes salary, payment for services (e.g., consulting fees, honoraria, paid authorship)</li> <li>ii. Interest includes equity interests (stocks, stock options and/or other ownership).</li> </ul>	Publicly Traded Entity – if the aggregated amount of income exceeds \$5,000 in the previous 12 months (prior to the Covered Person’s disclosure) from the entity; or any amount of interest (equity). <ul style="list-style-type: none"> <li>i. Income includes salary and payment for services (e.g., consulting fees, honoraria, paid authorship)</li> <li>ii. Equity Interest includes stocks, stock options and/or other ownership.</li> </ul>
<b>3) Establish higher dollar threshold for when an SFI may constitute an FCOI with regard to Industry-sponsored Research</b>	(none)	In the case of industry-funded research, a Significant Financial Interest may be a FCOI when the following financial thresholds are met or exceeded: <ul style="list-style-type: none"> <li>i. Income financial interest – if the aggregated amount of income exceeds \$25,000 in the previous 12 months (prior to the Covered Person’s disclosure) from the entity, whether Publicly Traded or Non-Publicly Traded.</li> <li>ii. Publicly Traded Entity – if the value of equity or stock options exceeds \$50,000 in the previous 12 months (prior to the Covered Person’s disclosure)</li> <li>iii. Non-Publicly Traded Entity – any amount of interest or stock option, regardless of value.</li> </ul>

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### Responsibility of MCW Investigators, by Type of Sponsored Award

Award Type (Covered Award):	To Whom the Policy Applies (Covered Person):		Policy Requirement:			
	PIs, co-Is, other Key Personnel, others who influence or are responsible for the design, conduct or reporting of research	PI only	Complete Training (every 4 years)	Disclose Significant Financial Interest (SFI) (annually and within 30 days of acquiring a new SFI)  <i>The nature and value of SFIs that must be disclosed are described below.</i>	Disclose SFI in scholarly publications (if required by the journal) and presentations (to the audience and meeting organizers)	Comply with prescribed Management Plan for any SFI determined to be an FCOI with a sponsored award
US Public Health Service (PHS)	✓	-	✓	✓	✓	✓
Select non-profit funders (non-federal, non-PHS) <sup>1</sup>	✓	-	✓	✓	✓	✓
National Science Foundation or other federal funder	✓	-	✓	✓	✓	✓
Industry Sponsor	-	✓	✓	✓	✓	✓ <sup>2</sup>

### Significant Financial Interests that must be disclosed include the following:

Nature of financial interest	Value
<u>Compensation</u> – Any income, consulting fee, or other payment for service from an outside entity	...that is greater than \$5,000 (Aggregate of compensation received over the preceding 12 months)
<u>Equity interest</u> – Any stock, stock option, or other ownership interest in an outside entity	...regardless of dollar value (No threshold - disclose regardless of value of equity interest or amount of income received from IP rights and interests. Equity interest includes stock options that have not been exercised.)
<u>Intellectual Property rights and interests</u> – Income received from IP rights and interests in an entity	

<sup>1</sup> A list of the select non-profit funders can be found here: <https://infoscope.mcw.edu/FileLibrary/Groups/InfoScopeCorporateCompliance/ListofNonprofitSponsors.pdf>. Other non-profit funders that have adopted federal PHS FCOI-R regulation will be identified by inclusion of PHS regulations in award terms and conditions.

<sup>2</sup> Only SFIs that meet or exceed the following financial thresholds may be identified as an FCOI with a research study funded by an industry sponsor:

1. Income financial interest – if the aggregated amount of income exceeds \$25,000 in the previous 12 months (prior to the Covered Person's disclosure) from the entity, whether Publicly Traded or Non-Publicly Traded.
2. Publicly Traded Entity – if the value of equity or stock options exceeds \$50,000 in the previous 12 months (prior to the Covered Person's disclosure)
3. Non-Publicly Traded Entity – any amount of interest or stock option, regardless of value

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### Responsibility of Institution, by Type of Sponsored Award

Investigator, by award type:	Policy requirement						
	Training	Disclosure	Review and Management	Retrospective Review	Subrecipients	Reporting	Public Disclosure
<i>PIs, co-Is, other Key Personnel, others who influence or are responsible for the design, conduct or reporting of research (Covered Person) funded by the following sponsors:</i>	<i>Ensure Covered Persons complete required training by specified times</i>	<i>Ensure Covered Persons disclose SFIs at specified times</i>	<ul style="list-style-type: none"> <li>Review disclosed SFI to determine if a FCOI exists.</li> <li>If FCOI exists, determine if FCOI may be managed and issue Management Plan to mitigate conflict</li> <li>Monitor investigator compliance with Management Plan</li> </ul>	<i>Within 120 days of discovery of a SFI not disclosed by a Covered Person, complete retrospective review to determine if failure to disclose SFI has resulted in bias.</i>	<ul style="list-style-type: none"> <li>Ensure that any subrecipient Covered Persons comply with federal FCOI-R regulatory requirement</li> <li>Report FCOIs of subrecipient Covered Persons to funding agency</li> </ul>	<i>Report FCOIs to funding agency</i>	<i>Make FCOIs publicly available per federal FCOI-R regulatory requirement</i>
US Public Health Service (PHS) <i>Includes but is not limited to: NIH, CDC, FDA</i>	✓	✓	✓*	✓	✓	✓	✓
Select non-profit funders (non-federal, non-PHS)	✓	✓	✓*	✓	✓	-	-
National Science Foundation or other federal funder	✓	✓	✓	-	-	-	-
Industry Sponsor (ONLY the PI is a Covered Person on industry-sponsored awards)	✓	✓	✓	-	-	-	-

\*MCW must complete required actions within 60 days