

General Guidelines* for CoIR Management

SFI related to research	Value of SFI	Elements of Management Plan					FCoI?
		Public Disclosure required?	Restricted role in Data Analysis?	Restricted Roles in Human Subjects Research			
				Eligibility determination	Consenting	UPs	
Compensation/earnings	≤5K	Not an SFI – does not require reporting in eCoI disclosure					No
Compensation/earnings	5-10K	Advised per journal policy	An SFI – requires reporting – but <i>typically</i> not considered a CoIR				No
Non-exclusive license received royalties	≤10K						No
Compensation/earnings (or received royalties)	10-50K	Yes	No	restricted	restricted	restricted	typically not
Exclusively licensed or optioned tech – used as a tool** (no start-up relationship)	potential license income, other unusual circumstances affect mgmt. & FCoI determination	Yes	typically not	restricted	restricted	restricted	typically not
Exclusively licensed or optioned tech – used as a tool** (start-up relationship)		Yes	case specific	restricted or not allowed	restricted or not allowed	restricted or not allowed	case specific
Exclusively licensed or optioned tech evaluated/enhanced (no start-up relationship)		Yes	case specific	not allowed	not allowed	not allowed	case specific
Stock or stock options	public: 10-50K; private: >0	Yes	case specific	not allowed	not allowed	not allowed	case specific
Compensation/earnings (including valued stock/options or received royalties)	>50K	Yes	case specific	not allowed	not allowed	not allowed	case specific
Exclusively licensed or optioned tech evaluated/enhanced (start-up relationship)	any	Yes	Yes	not allowed	not allowed	not allowed	Yes
Start-up relationships: Multiple interests such as founder/fiduciary role and/or stock/options and/or licensed tech	any	Yes	Yes	not allowed	not allowed	not allowed	Yes

*This table provides general guidelines that the Conflict of Interest in Research Committee uses to determine conflict management; each situation is individually considered. For further explanation, please see next page and the CoIR web page <http://www.ohsu.edu/xd/research/about/integrity/coi/>.

**See next page, section “Relatedness of SFI to the research: Use of an invented/licensed technology in research.”

Using the *General Guidelines for CoIR Management Table*

The CoIR Committee reviews potential conflicts on a case-by case basis to determine appropriate management, taking numerous factors into account. Examples of factors considered are:

Human subjects studies:

- Comparison or placebo-controlled trial; randomized group assignments?
- Blinding and/or monitoring procedures to minimize bias?
- Number of study sites/number of subjects enrolled at OHSU versus for the study as a whole
- Sponsorship of trial

Relatedness of SFI to the research:

- SFI arising from consulting: What is the nature of consulting for the entity vis-à-vis the aims of research being funded by the same entity?
- **Use of an invented/licensed technology in research:
 - Is the technology used for its already-commercialized purpose (a licensed technology used as it would be by anyone else buying the tool (e.g., assay) for research that has other aims) or do the aims of the research include improvement, expanded application, enhancement of the technology?
 - Nature of the license or option agreement including “field of use.”
 - If the technology is under option for an exclusive license and there is no other relationship with the company and no human subjects research is involved then typically no CoIR management will be required until a license is issued or pending.

Other factors:

- Degree to which conflicted investigator is involved in the research (e.g., collaborator for basic research vs. full involvement in investigator-initiated human subjects study).
- If technology is the financial interest: other relationships to company to which technology is licensed (e.g., founder, executive position, compensation/employee, stockholder); Is the technology one of the main technologies being developed by the company?

Glossary:

SFI = significant financial interest: <http://www.ohsu.edu/xd/research/about/integrity/coi/glossary.cfm#sfi>

CoIR = Conflict of Interest in Research: A determination official that a significant financial interest (SFI) might affect, or reasonably appear to affect, the design, conduct, or reporting of research. Such situations may require management, but may not be found to constitute an FCoI as defined below.

FCoI = Financial Conflict of Interest: A determination by the designated official that a significant financial interest (SFI) could directly and significantly affect the design, conduct or reporting of the PHS-funded research

UP = unanticipated problem (adverse event)

Compensation/Earnings: refers to prior 12-month period, from one source/entity (e.g., consulting income, royalties). Note that patents for intellectual property are not considered financial interests unless licensed.

Public Disclosure: The inclusion of a statement about the nature of the financial interest/conflict in:

- Publications, presentation materials for all research related to the SFI and/or as explicitly defined by the CoIRC. Note that researchers must follow journal policy for disclosures, whether or not the CoIRC explicitly requires disclosure.
- Consent forms and information sheets, if human subjects work is involved. Note that consent forms typically also require standard commercialization language, per the OHSU IRB consent form templates.

Restricted role in data analysis: This means that a qualified individual who does not have a financial interest in the same entity and who does not report to someone with a financial interest in the same entity is involved in data analysis. For more details about how this requirement can be met, see *[link to data analysis guidance sheet]*

Human subjects Research:

- Restricted (role) = not sole involvement in determining eligibility, consenting/enrolling, unanticipated problems (UP) analysis/reporting. For each subject, a qualified non-conflicted individual must be involved, including presence for informed consent process and signature on consent form. (Non-conflicted means no SFI in same entity. In some cases, the CoIR Committee will also require that the person not report to someone with a financial in the same entity; this is typically the case for UP analysis.)
- Not allowed = no involvement allowed in these roles. A qualified non-conflicted individual must be available to fulfill these roles for all subjects.