

## General Guidelines for CoIR Management

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/>.

SFI related to research	Value of SFI	Elements of Management Plan					FCoI?
		Public Disclosure required?	Additional Requirements for Data Collection & Analysis?	Restricted Roles in Human Subjects Research			
				Eligibility determination	Consenting	UPs	
Compensation/earnings	≤5K	Not an SFI – does not require reporting in eCol disclosure					No
Compensation/earnings	5-10K	Advised per journal policy	An SFI – requires reporting – but typically 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, researcher’s role in research and any unusual circumstances affect mgmt. & FCoI determination	Yes	Typically not but depends on the relatedness of research	restricted	restricted	restricted	typically not
Exclusively licensed or optioned tech – used as a tool (start-up relationship)		Yes		restricted or not allowed	restricted or not allowed	restricted or not allowed	typically not
Exclusively optioned tech evaluated/enhanced (no start-up relationship)		Yes		not allowed	not allowed	not allowed	typically not
Exclusively licensed tech evaluated/enhanced (no start-up relationship)		Yes	Depending on relatedness of research: Data analysis – typically yes; data collection- depends on protocol	not allowed	not allowed	not allowed	Yes
Stock or stock options	public: >10K; private: >0	Yes	Data analysis – typically yes; data collection- depends on protocol	not allowed	not allowed	not allowed	Yes
Compensation/earnings (e.g., consulting, received royalties)	>50K	Yes		not allowed	not allowed	not allowed	Yes
Exclusively licensed or optioned tech evaluated/enhanced (start-up relationship)	any	Yes	Data analysis – yes; Data collection – typically 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	Data analysis – yes; Data collection – typically yes	not allowed	not allowed	not allowed	Yes

**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:**

- Study design: Control group, randomization, blinding procedures, placebo-controlled, etc.
- 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 income or stock:
  - For consulting: What is the nature of consulting for the entity vis-à-vis the aims of research being funded by the same entity?
  - Is the company's product the primary focus of the research?
- 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 agreement including "field of use" and anticipated royalty stream.
  - Additional 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?
- Degree to which conflicted investigator is involved in the research (e.g., collaborator for basic research, PI in an investigator-initiated human subjects study).

**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

**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 [Guidance: Data Analysis](#).

**Restricted role in data collection:** This means that non-conflicted personnel are involved in data collection. Whether this is feasible or required, and to what extent, depends on the study protocol. For example, the inventor of a device would need to be involved in the procedure (expertise) but someone else might be present to collect other aims-driven data. Or, perhaps a conflicted person is the expert at interpreting imaging data, but there is a blinded procedure by which this data is compared to a standard/control so that the potential bias otherwise introduced is controlled.

**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.

**Colored Table designation is “Restricted”** Guidance provided in management plans is:

**Role restrictions – Not sole involvement:**

1. **Eligibility determination:** You may not be solely involved in determining eligibility for subjects; another non-conflicted qualified individual must review eligibility for each subject.
2. **Consenting:** You may not be solely involved in consenting subjects. You may be present for the consenting process – answering questions that arise, etc. – but another, non-conflicted, qualified individual must conduct the process and sign the consent form.
3. **AEs/UPs:** You may be involved in the identification, analysis and reporting of adverse events (AEs) and unanticipated problems (UPs) that occur in this study. However, a non-conflicted qualified study team member must also have input to the analysis and any required reporting of AEs and UPs and in particular for UPs occurring at OHSU. See [Guidance – UP analysis in ColR management plans](#).

**Colored Table designation is “Not Allowed”** Guidance provided in management plans is:

**Role restrictions – Only limited involvement is permitted**

1. **Eligibility determination:** You may not determine subject eligibility. You may, however, refer to your team potential candidates from your clinical practice.
2. **Consenting/enrolling subjects:** You may be available to answer questions about the study. The detailed consent form review process shall be conducted without you in the room, by a qualified, non-conflicted research team member who also signs the consent form as the one conducting the consent process. Note that this same process shall be used for re-consenting purposes.
3. **AE & UP analysis:** You may be involved in identifying AEs and UPs that arise during the study. However, it must be the responsibility of a non-conflicted, qualified study team member to analyze and report the AEs and UPs. See [Guidance – UP analysis in ColR management plans](#)
  - eIRB submissions for UPs as RNIs (Reportable New Information): The qualified non-conflicted individual shall prepare the RNI report. The person who alerts you to submit the RNI using “notify PI” shall clearly note in the comment field which qualified non-conflicted individual analyzed the UP and reviewed the report prior to its submission via the eIRB.