



COI Management Plan (CMP) for Human Subject Research

for Significant Financial Interests (SFIs) Not Requiring PI-Exclusion

Project and Personnel Information

| | |
|-----------------------------------|--|
| Protocol ID | |
| Full Project Title | |
| Principal Investigator | |
| Primary Department Affiliation | |
| Individual with SFI | |
| Primary Department Affiliation | |
| Supervisor of Individual with SFI | |

COI Management Plan

In view of my Significant Financial Interest (SFI) in **[name of company and/or describe intellectual property]**, I agree to the following plan to manage my conflict of interest with research covered by the above protocol:

1. My SFI will be disclosed in the informed consent form using the following language:

[Use if Principal Investigator has a conflict of interest with this study.]

One or more of the investigators conducting this research has a financial interest in **[name of company and/or describe intellectual property]**. This means it is possible that results of this study could lead to personal profit for the individual investigator(s) and/or the University of Pittsburgh. Any questions you might have about this will be answered fully by the Human Subject Protection Advocate of the University of Pittsburgh at (866) 212-2668.

[Use if Principal Investigator does not have a conflict of interest with this study.]

One or more of the investigators conducting this research has a financial interest in **[name of company and/or describe intellectual property]**. This means it is possible that results of this study could lead to personal profit for the individual investigator(s) and/or the University of Pittsburgh. Any questions you might have about this will be answered fully by the Human Subject Protection Advocate of the University of Pittsburgh at (866) 212-2668, or by the Principal Investigator, **[name of Principal Investigator]**, at **[telephone number of Principal Investigator]**, who has no financial conflict of interest with this research.

2. I understand that the COI Office will notify the other investigators involved in research under this protocol of my conflict of interest and that students may only be engaged in the protocol with the approval of their department chair or equivalent supervisor.
3. I will inform the COI Office whenever new investigators are added to the protocol so they can be informed of my conflict of interest.
4. I will disclose my SFI in all abstracts, publications, presentations, and press releases resulting from this study and/or involving research sponsored by the company, research evaluating or further developing the company's products or intellectual property, or research that could reasonably be perceived to have a potential to directly affect the company's finances, marketing, or business interests.

5. If directed by the potential funding source, I will disclose my financial interest in the company in all applications or proposals to fund research evaluating or further developing the company's products or intellectual property or research expected to lead to outcomes that might have a direct effect on the company's finances, marketing, or business interests. If no directions about COI disclosure are available, or if the directions are unclear, I will contact the agency or sponsor to ask for instruction and follow their guidance.
6. **[This element is required if the PI indicates to the COI Office that the research involves multiple participating sites and/or a study steering committee. Delete if not applicable.]** I will disclose my SFI to any other participating sites and to the overarching study steering committee prior to the commencement of the study.
7. **[This element is required if the PI indicates to the COI Office that the research will be under FDA or other regulatory oversight. Delete if not applicable.]** I will disclose my SFI to any regulatory agencies (such as the Food and Drug Administration) with oversight jurisdiction for the study at the time and in a manner that is appropriate to the applicable regulatory agencies.
8. I will inform the COI Office of any changes in the source(s) of support for this protocol.
9. **[This element is required if the study is an FDA Covered Clinical Study and Individual with SFI is PI or if the relevant supervisor has added as a requirement.]** **[Name, Title, and Department affiliation]** will serve as a data steward for this protocol. They will meet with the study team periodically, but not less than annually, to review data collection and interpretation. They will submit annual reports to the COI Office documenting the dates and times of the meetings and providing their opinion about the integrity and interpretation of the data.
10. **[When Individual with SFI is serving as PI, their supervisor will be asked if they require any additional elements for the CMP. Add any such additional CMP terms here.]**

(Signature lines on next page)

The remainder of this page is intentionally blank.

Individual with SFI

[Name]

Date/Time

Supervisor of Individual with SFI

I will ensure compliance with the above COI management plan.

[Name]

Date/Time

Principal Investigator

If Individual with SFI is serving as a co-investigator on the study, the PI's signature is required. Remove if not applicable.

I will ensure compliance with the above COI management plan.

[Name]

Date/Time

Data Steward

If an FDA Covered Clinical Study and the Individual with SFI is PI, or if the supervisor has added a data steward in order for the Individual with SFI to serve as PI, the data steward's signature is required. Remove if not applicable.

I am responsible for arranging meetings with the study team to review the collection and interpretation of data and determine if there is any concern that an investigator's conflict of interest has led to any bias in the research results or conduct of the trial. I will immediately alert the COI Office and the conflicted investigator's supervisor if I have any concerns regarding the conduct of the trial. I will provide annual reports to the COI Office and to the conflicted investigator's supervisor.

I understand and accept the role and responsibilities of a data steward.

[Name]

Date/Time

**Upload the final signed copy of this document to the "Local Supporting Documents" page in PittPRO.
In the legacy OSIRIS system, upload this document to Section 7.3 of the protocol form.**

The COI Office will not issue ancillary approval until this document is uploaded.

The remainder of this document is intentionally blank.