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Considerations Made In the Development of Management Plans

A Significant Financial Interest (SFI) exists when an individual researcher discloses a financial interest over the threshold of \$5,000, as related to federally funded studies, or over \$10,000 as related to non-federally funded studies. Ownership of stock in non-publicly traded companies is always deemed significant. Ownership of stock in publicly traded companies may be significant depending on the number of shares held and whether the ownership is individually directed (i.e., not part of a retirement package controlled by an investment group).

When an SFI is found to constitute a Financial Conflict of Interest (FCOI), the researcher may be subject to a management plan as a way of reducing or mitigating the potential financial conflict with the research. The initial step is to determine whether the potential FCOI can be managed in a way that protects the integrity of the research from the appearance of biases in design, conduct or reporting. The plan will be developed by University Research Administration (URA) in collaboration with leadership on campus.

Non-Clinical Research Studies

If a researcher has a financial interest in an entity, and that entity's interests are directly related to the research, but the entity is *not sponsoring the research*, the following may be used to reduce the potential financial conflict of interest:

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- If the research involves evaluating intellectual property (IP) held by the company the researcher has a commercial interest with, disclosure in publications, presentations and to all collaborators is required. Depending upon how directly the research could affect the value of the IP, additional management may be required to protect the objectivity of the research.
- When using, but not evaluating, licensed IP from a company in which the researcher has a commercial relation, disclosure may be required, depending on the extent of the IP use in the research.

If a researcher has a financial interest from an entity that *is sponsoring the research*, the following may be used to reduce the potential financial conflict of interest:

- The researcher must disclose the financial relationship with the entity in all publications and presentations, as well as disclose to the PI and all collaborators, and to the Institutional Review Board (IRB) if applicable.
- The researcher should recuse him/herself from purchasing decisions that involve an entity with which they have a financial relationship.
- The company cannot act on the findings of the sponsored study until the study is completed and the data appear in a public forum (e.g., paper or presentation).
- When evaluating IP licensed to the entity, recognition that the University's Tech Transfer Office must immediately be notified of changes or enhancements made to the IP.

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If a researcher owns equity in a non-publicly traded entity and the entity is sponsoring the research, and/or the research directly evaluates IP licensed or controlled by the non-publicly traded entity, the follow may be used to manage the potential financial conflict of interest:

- The researcher must disclose the financial relationship with the entity in all publications and presentations, as well as disclose to the PI and all collaborators, and to the Institutional Review Board (IRB) if applicable.
- The researcher should recuse him/herself from purchasing decisions that involve an entity with which they have a financial relationship.
- The company cannot act on the findings of the sponsored study until the study is completed and the data appear in a public forum (e.g., paper or presentation).
- When evaluating IP licensed to the entity, recognition that the University's Tech Transfer Office must immediately be notified of changes or enhancements made to the IP.
- A research monitor may be appointed to oversee all aspects of the research, including reviewing articles for publication.
- For research which is funded through the SBIR or STTR program, the PI for the small business and the PI for the sub-agreement to the University must be different individuals. A faculty member cannot serve as both the company and the University researcher.

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Clinical Studies

Clinical trials require the consideration of additional information, including the degree of risk to human subjects, the role of the investigator in the study, the study's design, and the degree of the investigator's influence on the recruitment/enrollment of subjects, as well as the analysis and published results of the study. If the researcher has responsibility for the design, conduct and/or reporting of research involving human subjects and has a financial relationship with the entity sponsoring the research, or owns or licenses the IP being studied, the following may be used to manage potential financial conflicts:

- The researcher must disclose the financial relationship with the entity in all publications and presentations, as well as disclose to the PI and all collaborators, and to the Institutional Review Board (IRB) and to patients recruited to the study.
- The researcher should recuse him/herself from purchasing decisions that involve an entity with which they have a financial relationship.
- The company cannot act on the findings of the sponsored study until the study is completed and the data appear in a public forum (e.g., paper or presentation).
- When evaluating IP licensed to the entity, recognition that the University's Tech Transfer Office must immediately be notified of changes or enhancements made to the IP.
- A research monitor may be appointed to oversee all aspects of the research, including reviewing articles for publication.

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- For research which is funded through the SBIR or STTR program, the PI for the small business and the PI for the sub-agreement to the University must be different individuals. A faculty member cannot serve as both the company and the University researcher.
- Modification to the role of the PI may be necessary, such as removal from patient recruitment, or data analysis, depending on the level of financial involvement with the sponsoring entity.
- Additional restrictions may be applied by the IRB to ensure patient safety.

National Institute of Health (NIH)

The University of Chicago is required to report to NIH all management plans developed for federally funded studies. The University of Chicago must provide a FCOI report to NIH prior to the expenditure of funds, during the period of award, within 60 days of identifying a new FCOI as well as report any changes to the plan for the duration of the project.