**Introduction**

Consistent with the Northwestern’s mission, our community is entering the entrepreneurial space and engaging with industry in greater numbers. Translating ideas and intellectual property from the University to the marketplace is a critical component of Northwestern’s research program. Likewise, it is understood that our community -- as experts in various fields and disciplines -- may engage with industry to educate and translate knowledge in a way that will benefit the public good. Inherent in these relationships and interactions are potential or actual conflicts of interest with respect to competing interests and obligations. We must balance promoting entrepreneurship and engagement in external relationships with preserving our commitment to Northwestern and safeguarding the integrity of University research.

**General Standards for COI Management Involving Human Research**

There are common management strategies utilized to promote transparency with respect to related financial interests in order to mitigate the potential for any actual or perceived lack of objectivity in research design, conduct, or reporting. Northwestern must ensure that the rights and welfare of human research participants are protected against any actual or perceived lack of objective oversight and decision-making due to an investigator’s personal interests and/or relationships.

COI determinations and management strategies are made on a case-by-case basis taking into account the nature and extent of the interest, the nature of the research, and the role of the investigator in the research. General management strategies commonly implemented in situations where an investigator (and/or the investigator’s immediate family member) has financial interests deemed related to research at Northwestern include those in the table below; strategies such as these should be considered when proposing and designing research related to entities in which you have financial interests:

<table>
<thead>
<tr>
<th>Nature of interest deemed related to research (for investigator and/or investigator’s immediate family member)</th>
<th>Common corresponding COI management strategies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Payment for Services &lt; $5,000</td>
<td>None <em>(although disclosure of any related interests to research participants in informed consent document(s) (if applicable) is not discouraged)</em></td>
</tr>
<tr>
<td>Payment for Services: $5,000 - $10,000</td>
<td>Disclosure of the related financial interests to research participants in informed consent document(s) (if applicable)</td>
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</tbody>
</table>
| Payment for Services: $10,000 - $25,000 | Above + any or all of the following:  
- Disclosure of the related financial interests to research team and collaborators  
- Disclosure of the related financial interests in related manuscripts, presentations, publications, and press releases  
- Restricted/reduced involvement in study activities (if applicable) such as recruitment, enrollment, and/or consent of research participants  
- Independent collection and/or analysis of data |
| Payment for Services > $25,000 | Not permitted to serve as PI absent compelling circumstances (see next page)  
- May be permitted to remain involved in the research, but if so, likely to be subject to any or all of the strategies identified above + an independent data safety monitoring board |
| Any related equity interests in non-public entities; OR Intellectual property interests in product or method under evaluation | Not permitted to serve as PI absent compelling circumstances (see next page)  
- If investigator is permitted to remain involved in research, any or all of the management strategies identified above may apply |
| Equity in publicly-traded entities | Varies depending on value of equity relative to overall entity value |
| Sponsored/reimbursed travel | Varies; rarely does a relationship solely involving sponsored/reimbursed travel rise to the level of requiring management, but sponsored/reimbursed travel, when involving an entity deemed related to research, is considered in the context of the total relationship with that entity. |
Guidelines for COI Review and Management for Investigators Involved in Research Involving Humans

COI Review Considerations

The University reviews disclosed financial interests of each investigator in the context of each specific research project, determining whether or not disclosed interests relate to and could actually – or could be perceived to – impact the design, conduct or reporting of the research. Interests considered include, (but are not limited to, intellectual property interests, equity interests, or financial interests/relationships with a company sponsoring the research or manufacturing products under evaluation in the research.

Considerations of the review and COI determination include:

- **Nature of the financial interest** (e.g., consulting; expert witness testimony; training and education; equity; board member; intellectual property, etc.)
- **Extent of the financial interest** (e.g., significant ongoing relationship, or minimal or ad hoc activities; educational in nature, or more commerical or marketing related activities; stage of intellectual property, stage and relative value of company interests, etc.)
- **Nature of the research** (e.g., chart review; clinical trial; early phase, minimal versus greater than minimal risk; randomized, controlled study design; multi-site; funding source, etc.)
- **Role of investigator** (e.g., PI or co-I; role in recruiting, enrollment, consent, and/or data collection and analysis, etc.)

Demonstration of Compelling Circumstances

The concept of a rebuttable presumption against a conflicted investigator serving as PI (or otherwise) in research, and the compelling circumstances required to overcome that presumption, derives from widely accepted national standards; compelling circumstances include:

- **Special qualifications and/or specialized expertise**, particularly in early-stage research (i.e. the conflicted investigator is best-positioned to best carry out the research soundly and safely); and
- The extent to which *research objectivity and integrity can be adequately assured* through research study structure and design and/or COI management strategies; and
- The degree to which *human research participants can be adequately protected* from potential risk or bias through research study structure and design and/or COI management strategies; and
- The perceived *risk to the reputation of the University and the researcher* should the COI impact the research.

School dean's offices and/or committees make final determinations relative to requests of compelling circumstances.

Questions /Help?

Resources:

- One-page investigator guide for research COI process
- Recommended disclosure language for investigators under COI management

Key School Research COI Contacts:

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