

Facilitating Research Where Institutional Conflicts of Interest Exist

Introduction

Northwestern is committed to facilitating scientific discovery and advancing knowledge through innovative and translatable research. Consistent with the University's mission, faculty are entering the entrepreneurial space and working with industry in greater numbers, as well as developing novel solutions to address questions, problems, and disparities in a variety of fields. Translating ideas and intellectual property from the University to the marketplace is a critical component of Northwestern's research program. The translation of Northwestern's pre-clinical discoveries to new diagnostic and therapeutic approaches supports the mission of the University and involves the conduct of early phase clinical studies at Northwestern. These engagements and efforts allow our University community to connect with and benefit society in innovative and transformative ways.

Inherent in these relationships and interactions are potential or actual conflicts of interest with respect to competing and/or conflicting institutional financial and other interests and University interests and obligations. We must balance promoting innovation and entrepreneurship with preserving our commitment to safeguarding the integrity and objectivity of University research. We must protect against even the perception that our research is less than objective due to institutional financial interests in research outcomes that could be perceived to impact the research design, conduct, reporting, and oversight.

These guidelines have been developed to assist the University community and its research collaborators in proactively navigating the complexities of a variety of requirements when operating in the distinct -- yet at times overlapping -- spheres of University and external roles and relationships.

Conducting Research with University Owned Intellectual Property

Research involving the evaluation or validation of University-owned intellectual property presents the potential for an institutional conflict of interest (ICOI). Particularly when such intellectual property is licensed from the University to an external, for-profit entity that intends to commercialize the intellectual property, and the University has interests in the external entity through equity or other financial means, the University stands to potentially directly benefit financially from research outcomes. Institutional officials with individual financial interests in such external entities also presents the potential for ICOIs.

There are common management strategies utilized to promote transparency with respect to such related relationships and financial interests and to mitigate the potential for any actual or perceived lack of objectivity in institutional research oversight, design, conduct, or reporting. It is critical to ensure that the rights and welfare of human research participants involved in such research studies are protected against any actual or perceived lack of objective oversight and decision-making due to institutional financial interests.

Strategies such as those below should be considered when contemplating, proposing and designing research involving University-owned intellectual property or research in which the University has other related financial interests; some or all of these conditions may apply and be implemented:

- ⚙ Disclosure of the University's related financial interests to research study team members and collaborators
- ⚙ Disclosure of the University's related financial interests to human research participants in the informed consent document(s)
- ⚙ Disclosure of the University's related financial interests in any and all manuscripts, presentations, publications, and press releases arising from/related to the research
- ⚙ Use of an external Institutional Review Board to review the research study protocol
- ⚙ Independent data analysis
- ⚙ External data safety monitoring board

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Approval Process

Northwestern's [Conflict of Interest Oversight Committee \(COIOC\)](#) reviews and approves proposed research that presents potential ICOIs on a case-by-case basis in accordance with Northwestern's [Institutional Conflict of Interest Policy in Research](#). While the nature and extent of the institutional financial interest(s) and the nature of the specific proposed research inform the Committee's decisions, the Committee's key considerations for allowing research when ICOIs exist include:

- ⚙ The extent to which the research will benefit society in accordance with the University's mission
 - ⚙ The extent to which Northwestern (by virtue of qualifications and/or specialized expertise, space, equipment, and/or subject population) is positioned to best carry out the research
 - ⚙ The extent to which a conflicted institutional official's authority is over the research and/or the people involved in the conduct of the research
 - ⚙ The extent to which research objectivity and integrity can be adequately assured through research study structure and design and/or COI management strategies
 - ⚙ 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
 - ⚙ The perceived risk to the reputation of the University and the researchers should the ICOI impact the research
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Initiating the Process for Proposing Research Involving University Owned Intellectual Property and/or Research Involving External Entities in which the University has Financial Interests

Individual researchers may not always be aware of related institutional financial interests in a given piece of intellectual property and/or institutional interests an external entity that wishes to engage the University in research. The Conflict of Interest Office (NUCOI), the Innovation and New Ventures Office (INVO), the Office of Sponsored Research (OSR), and others communicate and collaborate closely with respect to entities and activities in which we are institutionally invested. As NUCOI becomes aware of proposed research involving potential related institutional interests, we initiate contact with investigators; however, the earlier in the study proposal/design process that we become engaged, the better. Northwestern's [Institutional Conflict of Interest Policy in Research](#) outlines what types of interests rise to the level of institutional financial interests.

To best facilitate an efficient ICOI review process, if researchers or administrators are involved in or become aware of proposed research that presents potential ICOI issues, ensure the principal investigator or advocate of the proposed research does the following:

- Notify Northwestern's Conflict of Interest Office (NUCOI)¹ that you have a proposed study that may present an ICOI
- Be prepared to provide (at minimum) the following information:
 - A study abstract or study protocol (preliminary drafts sufficient) including study phase, study aims, study methodology, study team members, anticipated enrollment, anticipated risk level to human research participants and potential adverse events, and information about the drug/device/biologic/therapeutic/method under evaluation in the proposed research
 - An explanation outlining why Northwestern is best positioned to conduct the research

¹ Julia Campbell: Juliacampbell@northwestern.edu / 847.467.3938 or nucoi@northwestern.edu / 847.467.4515