

Current Perspectives Regarding Institutional Conflict of Interest

Commentary on “Institutional Conflicts of Interest in Academic Research”

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Abstract Policies and processes dealing with institutional conflict of interest (iCOI) lag well behind those dealing with individual COI. To remediate this, academic institutions must develop strategies for addressing some of the unique challenges in iCOI, including: clarifying the definition of iCOI that addresses the range of individuals potentially involved; implementing a well-designed electronic database for reporting and managing iCOI across multiple leadership constituencies; and providing ongoing education to appropriate institutional officials that communicates the importance of managing iCOI.

Keywords Institutional conflict of interest · Academic research · Higher education · Competing interests · Managing competing interests

Overview

Institutional conflict of interest (iCOI) has the potential to emerge when leaders or those in positions of authority have personal or financial interests that could result in bias or the perception of bias in the discharge of their institutional duties and responsibilities. The awareness of institutional conflict of interest has been increasing since the beginning of the millennium. Discussions around high profile cases in clinical research (Resnik 2007) and the potential impact of so-called umbrella grants to universities that afford corporate sponsors preferential access to research results and exclusive options to negotiate for rights to potential intellectual property (Bradley 2014), have focused discussion on institutional conflict of interest. The academy has mounted a response to concerns of institutional conflict of

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interest by developing policies that speak to financial interests of the institution as well as the identification of institutional conflicts. Although current data on numbers of academic institutions with iCOI policies are not available, recent surveys found that such policies are not in place at most academic institutions. For example, in a 2006 survey of medical schools only 38 % of respondents reported that they had a policy covering the financial interests of the institution (Ehringhaus et al. 2008), and in a 2008 survey of National Institute of Health (NIH) grantees, 69 of 156 (44 %) responding institutions had written policies and procedures addressing institutional conflicts (Department of Health and Human Services 2011).

Because the public pays for the research with taxpayer and philanthropic dollars, widespread deployment of policies and practices that address institutional conflict of interest are needed to earn and keep public trust in research. This commentary explores further some of the issues raised by David Resnik in his article “Institutional Conflicts of Interest in Academic Research” (Resnik 2015). These issues and the challenges they raise should inform how universities think about institutional conflict of interest and its impact on the academic research enterprise.

Individual Versus Institutional Conflict of Interest

Recognizing, disclosing, and managing individual researcher conflicts of interest are processes that have evolved over the past 25 years (Bradley 2014). Dealing with potential researcher conflicts has been established through definitions and policies that have emanated from federal funding agencies, journal publishers, scientific societies, and academic institutions themselves. These processes and policies have promoted a culture of best practices that have also facilitated the development and delivery of educational programs that provide researchers with a knowledge and understanding of the elements surrounding conflicts. This knowledge, in turn, has enabled the identification of competing interests and suggests the means for dealing with them.

Institutional conflict of interest does not have the clarity of definition seen for individual researcher conflict of interest. Similarly, unified and widespread processes and policies for dealing with potential iCOIs, are not well established. This is likely because there are a number of characteristics of iCOI that differentiate it from individual researcher conflict of interest. In some cases, implementing iCOI policies present challenges that may be difficult to meet and overcome. However, examining these challenges offers a framework for thinking about iCOI and for charting a path towards ethically and effectively dealing with it in the academy.

Disparate Institutional Players

Institutional conflict of interest involves a disparate and diverse group of institutional individuals who have decision-making authority. On the one hand, consider a departmental chair who has a research program in medicinal chemistry

with projects funded from both the NIH and a pharmaceutical company. She has administrative responsibilities for a department of 12 faculty members, she trains predoctoral and postdoctoral fellows, and she teaches a yearly course to graduate and pharmacy students. In the course of training junior researchers, she might (unintentionally) subtly pressure graduate trainees to pursue dissertation research on projects that fall under corporate sponsorship in order to increase the probability of developing intellectual property that will lead to royalty payments to the department. She also might unfairly assign space to faculty who have grants from corporate sponsors for the same reason. Thus, as a departmental chair, her actions create the potential for iCOI.

On the other hand, consider a member of this university's board of trustees who is planning to make a gift to fund an endowed research chair in the medicinal chemistry department. A condition of this gift will be the requirement that the position must be filled by someone who works in the field of cardiovascular drug development. Also, this trustee holds large amounts of common stock in a major pharmaceutical corporation that provides several grants to the university to develop and test new drugs. Potential iCOI issues are implicit here because the board member's stated plans create a gift with specific conditions that arguably interfere with the institution's autonomy in setting its research agenda. Further, the board member's stock holdings might create the perception of institutional bias if companies he invests in are funding clinical trials at the institution.

Arguably, the departmental chair and the institutional trustee define the extremes in a spectrum of leadership officials who could be involved in precipitating an institutional conflict. In between the two extremes of this spectrum is an assortment of university leadership positions including many other departmental chairs, deans, vice presidents, the president, other members of the board of trustees, as well as members of various foundation boards that are loosely attached to the university but raise money to promote university interests. These hypothetical conflicts are distinct from one another in terms of the individual who is responsible for the action, the nature of the conflict that emerges, and the impact it could have on the institution. They illustrate the importance of appreciating the breadth of various situations that may contribute to creating conflicts, the diversity of the individuals who may be involved, and the disparate nature of the conflicts themselves.

Finally, one can even extend the cast of characters beyond the level of the departmental chair. A faculty researcher who is a member of an Institutional Review Board (IRB) is placed in a decision making loop that determines whether a human subject protocol is approved. This is a decision that has an impact on the institution by allowing or preventing the research from going forward. Suppose she is asked to review and make a recommendation on a protocol designed to study an experimental antidepressant made by a US drug company. But she also happens to hold a large amount of stock in a foreign company that makes a competing antidepressant which is already on the market. Even if she does not personally make the connection, a negative recommendation on the protocol could be scrutinized on the grounds of bias, thus giving rise to a potential iCOI.

Defining Institutional Conflicts

While a general definition of institutional conflicts of interest can be made, the complexities imposed by the wide array of individuals who may be involved, and the nature of the elements that may come into play to create the conflict, frequently complicate the interpretation of the definition. The individuals whose decisions and actions most commonly create the potential for giving rise to an iCOI fall into three general categories: (1) administrative leadership personnel [e.g., chairs (department heads), deans, senior leadership]; (2) oversight and governance officials (board members, foundation members); and (3) individuals in positions with decision-making responsibilities that may have an institution-wide impact [Examples of such individuals include members of regulatory and oversight committees (e.g., IRB or safety committee members), technology transfer officials, and procurement officers]. A definition of iCOI must take individuals in all these categories into account. Academic institutions have approached defining iCOI in various ways. Some present concise definitions accompanied by examples of actions that might create iCOI. Other institutions create their definition of iCOI through the use of lists of representative iCOI scenarios. Given the complexity of iCOI situations and players, one can reasonably expect that both the form and substance of definitions of iCOI will evolve over time.

Conflict Recognition, Monitoring, and Oversight

The difficulties involved in consistently applying a definition of institutional conflict of interest are linked to another challenge: namely, recognizing such situations as conflicts so that they can be disclosed, evaluated, and, if needed, managed. If the definition of iCOI fails to effectively convey the relevant issues that can lead to the identification of a possible conflict, then the system will, at best, work imperfectly and, at worst, fail.

Even with an effective definition of iCOI, a database for collecting information is critical to the overall process. Just as specific data are now collected for individual researchers—typically on an annual or semiannual basis—a similar process is needed to create the data platform that will inform the implementation of an institutional conflict of interest policy. It is important to recognize that the establishment of such collection methods is resource intensive, and the process may be viewed as overly intrusive, especially by non-university employees who must comply (e.g., trustees and board members). However, the potential risks to the integrity of the institution, its research, and other mission activities, makes it imperative that institutional leaders move forward in implementing robust data collection platforms that facilitate identifying activities, transactions, or personal interests that may create potential iCOIs.

Some Thoughts on a Path Forward

There are a number of elements that should be contemplated by universities and others in advancing iCOI policies and processes.

Clarifying the Definition of iCOI

Ongoing experiences with iCOI will provide new knowledge on both the characteristics and the impacts of potential institutional conflicts of interest. These experiences can inform further refinement of the definition as well as the processes related to disclosure and management of iCOI. While this could be done independently by each academic institution, collecting these experiences across institutions could quickly allow for the creation of a reasonable inventory of the major elements that are potentially associated with iCOI. A working collection of potential cases, possibly housed by a federal agency such as the US Public Health Service Office of Research Integrity (Office of Research Integrity website 2015), would provide a foundation for institutions to construct or refine their definitions and to further develop their policies. This inventory would also provide information that can be used by institutions in surveying appropriate university or university-associated personnel to build an institutional database to facilitate recognizing and pursuing potential iCOI.

Refining the Process for Reporting and Managing iCOI

Because of federal regulations, most institutions must already have a researcher COI policy in place (NIH Conflict of Interest Webpage 2015). An operative and effective program in researcher COI can provide valuable experience in establishing an institutional process for reporting and managing COIs, and creating an expectation among faculty researchers for reporting financial interests. A strong individual COI policy—and lessons learned from its implementation—can help guide the development of an institutional COI policy. From the process of monitoring and oversight of researcher COI the authors have learned that a well-designed electronic database for reporting financial interests is critical. As a starting point, the process for collecting data from faculty, chairs and deans as researchers may serve as one source of information for an iCOI database, but such collection methods usually do not address university senior leadership, trustees or institutional foundation members. Thus, not only is it necessary to develop a data collection strategy for these individuals, but this strategy must be set up in a way such that it can communicate with the individual researcher database for purposes of identifying potential conflicts that may involve various individuals in both cohorts.

Education

Just as with the implementation of individual researcher COI processes and policies, education becomes essential for providing knowledge and understanding about iCOI. Training directed at institutional conflict needs to be delivered to appropriate institutional members on a regular basis, most likely yearly, with successful completion of education certified and recorded at the institutional level. Educational programming in this area will not only provide necessary knowledge for identifying and reporting institutional conflicts, but will establish a culture that communicates the importance of managing these issues at the institution. The inventory of

Table 1 Conflict of interest policy examples

Duke University:	http://duke.edu/services/ethicscompliance/coi/icoi_policy.php
Northwestern University:	http://www.northwestern.edu/coi/policy/institutional_policy.pdf
Penn State University:	http://www.research.psu.edu/orp/coi/institutional-coi
University of Chicago:	http://researchadmin.uchicago.edu/policies_compliance/conflict_interest/ICOI%20532010.pdf
University of Minnesota:	http://policy.umn.edu/Policies/Operations/Compliance/INSTITUTIONALCONFLICT.html
University of North Carolina at Chapel Hill:	http://policy.sites.unc.edu/files/2013/04/Institutional-COI-Policy.pdf
University of Texas at Austin:	http://www.policies.utexas.edu/policies/institutional-conflict-interest-human-subject-research
Washington University:	http://universitycompliance.wustl.edu/conflictinterest/Documents/ICOI%20Policy.pdf

(All of the above sites accessed 4 August 2015)

potential iCOI cases mentioned earlier would be an asset in providing a scope of knowledge that could be valuable in training appropriate personnel on this subject.

Final Thoughts

An appreciation of the importance of identifying and dealing with institutional conflicts has grown significantly in the past decade. This awareness has resulted in the genesis of iCOI policies that aim to ensure institutional integrity in the research and other missions of universities (see Table 1 for examples). Opportunities exist to develop and refine the identification, monitoring, and management of institutional conflicts of interest. Pursuing these will lead to improvements in process that will inspire the confidence of stakeholders whose investments drive the missions of the academy. With respect to their research missions, universities need to seize these opportunities, building on the well-developed models that have been used to deal with individual researcher conflict of interest.

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References

- Bradley, S. G. (2014). Competing interests in research. In Francis L. Macrina (Ed.), *Scientific integrity—text and cases in responsible conduct of research* (pp. 209–241). Washington, DC: ASM Press.
- Department of Health and Human Services, Office of the Inspector General. (2011). Institutional conflicts of interest at NIH grantees (OEI-03-09-00480). <http://oig.hhs.gov/oei/reports/oei-03-09-00480.pdf>. Accessed August 4, 2015.
- Ehringhaus, S., Weissman, J. S., Sears, J. L., Goold, S. D., Beibelmann, S., & Campbell, E. G. (2008). Responses of medical schools to institutional conflicts of interest. *JAMA*, *29*, 665–671.

- NIH Financial Conflicts of Interest Webpage. <http://grants.nih.gov/grants/policy/coi/>. Accessed August 4, 2015.
- Office of Research Integrity, US Dept. of Health and Human Services. <http://ori.hhs.gov/>. Accessed August 4, 2015.
- Resnik, D. B. (2007). *The price of truth: How money affects the norms of science*. New York: Oxford University Press.
- Resnik, D. B. (2015). Institutional conflicts of interest in academic research. *Science and Engineering Ethics*, 20(6). doi:[10.1007/s11948-015-9702-9](https://doi.org/10.1007/s11948-015-9702-9).