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ORIGINAL PAPER

Institutional Conflicts of Interest in Academic Research

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Abstract Financial relationships in academic research can create institutional conflicts of interest (COIs) because the financial interests of the institution or institutional officials may inappropriately influence decision-making. Strategies for dealing with institutional COIs include establishing institutional COI committees that involve the board of trustees in conflict review and management, developing policies that shield institutional decisions from inappropriate influences, and establishing private foundations that are independent of the institution to own stock and intellectual property and to provide capital to start-up companies.

Keywords Conflict of interest · Research · Academic institutions · Ethics · Trustees · Bias · Public trust

Introduction

Academic institutions often have financial interests related to research conducted on campus, such as stock or equity in private research sponsors, intellectual property rights, or relationships with commercial donors (Association of American Medical Colleges 2002; Association of American Medical Colleges and Association of American Universities 2008; Institute of Medicine 2009; Resnik and Shamoo 2002). A conflict of interest (COI) for an academic institution can be defined as a situation in which the institution or its leaders (such as presidents, chancellors, vice presidents, deans, or department heads) have interests that may compromise judgment or decision-making concerning its primary professional, ethical, or legal obligations or academic aims (Institute of Medicine 2009; Resnik and Shamoo

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2002). Institutional COIs can create ethical problems by threatening the objectivity and integrity of research and public trust in the institution, investigators, or the research enterprise (Resnik 2007, 2011).

In one of the most well-known cases involving questions about the impact of financial interests on research (the death of Jesse Gelsinger, a research subject/participant in a Phase I gene therapy trial at the University of Pennsylvania in 1999) the principal investigator, James Wilson, and the university had significant financial interests at stake. Wilson and the University of Pennsylvania both held a substantial amount of stock in Genovo, a company that sponsored gene therapy research on campus, and they both owned patents on gene therapy methods (Resnik 2007). Much of public scrutiny following Gelsinger's death focused on the financial interests related to the trial and how they may have affected the conduct of the study or its oversight (Association of American Medical Colleges 2002). Gelsinger's family sued Wilson and the university, alleging that Gelsinger was not adequately informed of the risks of the research as well as the financial interests of the investigator and institution (Resnik 2007). Some other hypothetical (though realistic) examples of institutional COIs include the following:

- In the clinical trial of a medical device sponsored by a private company, the vice president for research and dean of the medical school write a letter endorsing the study to the committee that oversees human subjects research and ask to attend the meeting in which the study is reviewed. The university and several investigators own stock in the company. Members of the human subjects committee fear that their careers could be harmed if they do not approve the study, or if they require changes that could affect the conduct of the research.
- A university accepts a $300 million gift from a wealthy alumnus who is the chief executive officer of a contract research organization he formed 15 years previously. According to conditions set forth in the gift, the university's school of public health will be renamed after the donor, and the curriculum in the school of public health will include several courses on clinical trial design, management, and regulation. There will also be an endowed professorship in clinical trial design, management, and regulation. Faculty members at the school of public health are concerned because they feel that the donor is inappropriately influencing the curriculum.
- A university enters into a research and development partnership with a robotics company. The company will sponsor research through a new robotics center on campus named after the company. The company will provide funding for a new building to house its robotics research, equipment, and several faculty positions. Under the terms of the arrangement, faculty whose research is sponsored by the company cannot publish results or share data without the company's permission. Research taking place in the new building will be kept strictly confidential, and access to the building will be restricted. University faculty members are concerned that this collaboration undermines academic norms by interfering with open communication and publication.
- A prominent biomedical researcher at a university medical center who holds several patents and brings in millions of dollars per year in grants is accused of

data fabrication and falsification by a junior faculty colleague. The dean of the medical school and an institutional official in charge of reviewing the allegation decide not to pursue it in order to protect the researcher and the institution's financial interests. When the junior faculty member accuses the dean and institutional official of covering up the problem, her employment is terminated.

This paper will examine institutional financial interests related to research in greater depth and provide guidance for academic institutions.

Institutional Conflicts of Interest

Most of the scholarship, research, and policy analysis on COIs in research has focused on individual financial interests. There is a sizeable body of evidence demonstrating that sources of funding and investigator's financial interests can influence research outcomes (Friedberg et al. 1999; Krimsky 2003; Lexchin et al. 2003; Resnik 2007; Ridker and Torres 2006; Sismondo 2008; Stelfox et al. 1998). A leading explanation of the relationship between financial interests and research outcomes is that investigators or companies with financial interests at stake may make decisions that tend to bias research in favor of those interests (Lexchin 2012; Resnik 2007). For example, companies can affect research outcomes by funding studies they expect will produce results favorable to their interests, and not funding or de-funding those they do not expect to yield favorable results. If the company is the dominant funder of research related to a particular topic, the published literature will tend to reflect the company's research agenda (Michaels 2008). Investigators can bias research by using a study design that is more likely to support their hypothesis than other designs or by analyzing or interpreting data in a way that favors their interests or the interests of the sponsor (Michaels 2008). Companies may decide not to publish data that are unfavorable to their products (Lexchin 2012). In extreme cases, investigators or companies may fabricate or falsify data in order to produce results favorable to their interests (Krimsky 2007). While the potential effects of financial interests on science demand careful scrutiny, it is important to realize that financial interests are only a risk factor for bias; they do not automatically invalidate research (Shamoo and Resnik 2015). Even so, it is important to acknowledge and address financial interests in research to reduce their impact (Resnik 2007).

One of the main ways that institutional financial interests can affect research is by compromising independent review and oversight of research conducted at the institution. Independent review and oversight is import for ensuring that research meets scientific, ethical, and legal standards. For example, if an institution or its leaders have a significant financial stake in a clinical study conducted on campus (such as the Gelsinger study mentioned above) then committees that oversee the research may feel some pressure to approve the research or refrain from criticizing it (Resnik and Shamoo 2002). If a well-funded investigator is accused of research misconduct, institutional leaders may be reluctant to conduct a thorough investigation of the allegation because they do not want to jeopardize millions of dollars of

research support or face adverse publicity (Resnik 2008; Rivlin 2004; Shamoo and Resnik 2015; Smith 2006). Because institutional COIs can compromise review and oversight, institutional COIs may affect more people than individual ones. For example, dozens of people could be affected by a research and development partnership with a private company, a corporate gift with strings attached, or lax oversight of a privately-funded clinical trial (Resnik and Shamoo 2002).

Dealing with Institutional Conflicts of Interest in Academic Research

While there are some well-recognized best practices for dealing with individual COIs, such as disclosure to independent parties, conflict management, or prohibition in some cases, there is no consensus regarding how best to deal with institutional COIs (Shamoo and Resnik 2015). Indeed, a recent study by the author and colleagues (Resnik et al. 2015) found that only 28 % of 100 of the top U.S. academic research institutions, ranked by total research funding, had an institutional COI policy. The study also found that having an institutional COI policy was positively associated with total research funding and that there was considerable variation in the content of the policies with regard to committee structure and reporting.

The main reason why there has been a lack of policy development in this area is that federal granting agencies and journals have not adopted regulations or guidelines for dealing with institutional COIs in research. U.S. research institutions have developed COI policies for investigators because this is a requirement for receiving funding from the National Institutes of Health (NIH) or National Science Foundation (NSF) (Resnik 2007). The NIH and NSF rules require investigators who receive grants or contracts to disclose significant financial interests to the institution and the agency (National Institutes of Health 2013; National Science Foundation 2005; Public Health Service 2011). Although a report by the Department of Health and Human Services' Office of Inspector General and the Institute of Medicine (2009) urged the NIH to require institutional grant or contract recipients to develop policies pertaining to institutional COIs, so far the agency has not acted on this recommendation (National Institutes of Health 2013; Wadman 2011). At the same time, the NSF COI policy does require grant or contract recipients to address institutional COIs (National Science Foundation 2005). Most scientific journal policies require authors to disclose their own COIs and sources of funding, but most do not address institutional COIs (Cooper et al. 2006).

Dealing with institutional COIs effectively can be more difficult than dealing with individual ones for at least two reasons. First, since the institution may have many different interests and departments, schools, or committees that deal with those interests, it may be difficult to recognize institutional COIs (Institute of Medicine 2009). No single person, office, or department may be aware of all of the institution's conflicting interests. Second, to manage COIs effectively, it is essential to make use of an independent party who does not have a conflicting interest but who has authority to take actions to deal with the COI. However, it may be difficult to identify independent parties at an institution who can manage its COIs, since

people in leadership positions will often have interests that are directly related to the institution's interests or they may not have the authority to take actions to deal with its COIs (Institute of Medicine 2009). A dean, vice president, or president may not want to raise concerns about a grant, contract, or industry collaboration that brings considerable money or prestige to the institution. The close connection between the interests of the institution and its leaders may even create a climate of corruption in which leaders interfere with institutional oversight and decision-making or turn a blind eye toward ethical, legal, or other problems (Shamoo and Resnik 2015). Although some of the most egregious cases of corruption have involved lax oversight of athletic programs at universities (such as a cover up of sexual misconduct involving a football coach at Pennsylvania State University), corruption involving academic research also occurs (Institute of Medicine 2009; Wolverton 2012).

The most important resource that academic institutions have for dealing with institutional COIs is a board of trustees or similar body. The board of trustees consists of members of the larger community, such as business leaders or alumni, who are not employed by the institution. Many boards also include the student body president and other ex-officio members from the university community. Members of the board are responsible for protecting the institution's integrity, reputation, and financial solvency and promoting excellence in education and research. Boards are supposed to exercise independent judgment in managing the institution. Though the board of trustees delegates decision-making responsibilities to different officials and organizations, it has final authority over all institutional decisions and there are numerous recent legal cases where trustees have been found liable for failing to adequately undertake their fiduciary responsibilities (Institute of Medicine 2009).

The board of trustees could appoint a committee composed of board members as well as other independent parties with expertise to deal with institutional COIs. Alternatively, the board could appoint a committee that reports directly to the board (Duke University 2009). The trustee committee could receive reports of institutional COIs and decide whether they should be disclosed to appropriate parties (such as funding agencies, journals, or research subjects), prohibited, or managed through additional oversight (Institute of Medicine 2009). The trustee committee could also receive reports from different parts of the institution that may have information about COIs (Resnik et al. 2015). For example, most universities have formed committees to review faculty COI disclosures (Institute of Medicine 2009). These same committees could determine whether institutional interests are also affected by the situations that create faculty COIs and whether they should be reported to the trustee committee. Administrators working in various offices and departments could also report institutional COIs to the trustee committee.

Some universities use the committee that oversees faculty COIs to deal with institutional COIs (Resnik et al. 2015; University of North Carolina at Chapel Hill 2009). Others appoint a special institutional COI committee (Resnik et al. 2015; Washington University 2009). While these COI committees may have the expertise to deal with institutional COIs, they may not have sufficient independence or authority to affect decisions made by the academic institution. For example, such committees might not be able to prevent the institution from entering into

questionable relationships. A committee at the level of the board of trustees would have the requisite independence and authority to deal with institutional COIs (Institute of Medicine 2009).

Lack of awareness may be a significant obstacle to forming an institutional COI committee. Trustees may not be familiar with the potential impact of institutional COIs on research and education, or the need to manage these situations objectively. This problem can be overcome if institutional leaders educate trustees about institutional COIs and how they may impact the university. However, some of the trustees may have financial interests of their own that are related to the institutional COIs. For example, a trustee could own stock in a company that sponsors research on campus. One study found that one-fourth of private colleges or universities have financial ties with trustee-affiliated companies (Fain et al. 2010). While this is an important concern, it can be addressed if trustees are aware of COI issues, as well as their own COIs. Thus, institutional COI policies should extend to trustees. In some cases, it may be necessary for trustees to divest themselves of the interests that create COIs. Fortunately, many academic institutions have begun to address the problem of trustee COIs. The Association of Governing Boards of Colleges and Universities has adopted a COI policy that provides useful guidance for board members (Association of Governing Boards of Colleges and Universities 2009). The policy states that board members should disclose all COIs related to institutional business and should recuse themselves from decisions pertaining to business matters in which they have a COI, unless the board determines that their participation in such decisions offers compelling benefits to the institution.

Academic institutions can also develop policies which prevent communication and influence between different administrative offices and functions, such as grants and contracts, compliance and oversight, human resources, legal counsel, and fundraising. This separation can help to protect the integrity and independence of university decisions by preventing inappropriate interference in decision-making. Many of the concerns about institutional COIs pertain to concerns about inappropriate influences on decisions, such as the possibility that fundraising needs may shape curriculum development, or that contracts with companies may affect publication of results. Though many universities and colleges already have such policies in place, those that do not can minimize the impact of institutional COIs by ensuring that different functions remain separate (Resnik and Shamoo 2002).

Academic institutions can also develop policies to ensure that committees and offices that deal with different functions, such as human subjects research, animal research, biosafety, regulatory compliance, equal employment opportunity, and curriculum development, are able to make independent decisions without outside pressure or fear of reprisal. For example, committee meetings can be kept confidential, with only committee members or those invited by the committee in attendance. Meeting minutes should summarize the discussion without identifying individuals. Committee members should have no financial or other interests related to business conducted by the committee (Resnik 2008).

Academic institutions can also establish private research foundations to own stock and intellectual property, engage in fundraising activities, and provide venture capital for start-up companies. Locating these activities in a private foundation can

soften the impact of institutional financial interests even though it does not eliminate them. That is, COIs would remain because the private foundation would be closely aligned with the university and may have an interlocking board of trustees, and leaders in both organizations would probably know and influence each other (Resnik and Shamoo 2002). However, establishing research foundations can help protect university or college decisions from the direct influence of institutional financial interests and promote public trust (Moses and Martin 2001).

Finally, academic institutions can support educational activities, such as seminars, lectures, and online learning modules, concerning institutional COIs. These educational activities could supplement education that already occurs on individual COIs, and would help to raise awareness of the issues among faculty, administrators, staff, and students. Educational activities should provide learners with information about institutional policies on COI disclosure and management.

Conclusion

Financial relationships in academic research can create institutional COIs because the financial interests of the institution as well as those of institutional officials may inappropriately influence oversight and decision-making. Though institutional COIs can be difficult to deal with, universities and colleges have some resources and policy options at their disposal, such as establishing COI committees that involve the board of trustees in conflict review and management, developing policies that shield institutional decisions from inappropriate influences, and establishing private foundations to own stock and intellectual property, and to provide capital to start-up companies. Although funding agencies do not currently require institutional grant or contract recipients to address their own COIs, universities and colleges should develop institutional COI policies themselves without such prodding, in order to protect the objectivity and integrity of academic research and promote public trust.

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