Published in final edited form as:

Account Res. 2010 July ; 17(4): 211–222. doi:10.1080/08989621.2010.493096.

Key Personnel and “Long Distance” Settings: Determining Who Must Report Financial Conflict of Interest

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Abstract

Conflicts of interest can impact the integrity of scientific research. While public imagination has focused on scientists, regulatory discourse recognizes a broader range of individuals who might have financial COIs. This essay asks, for personnel who enroll subjects at a physical and organizational remove from the primary research team, whether reporting COI to an institutional review board or COI committee protects research integrity. After examining definitions of COI, regulations on COI, and rubrics for evaluating COI policies, we argue that requiring recruitment personnel working at a distance from the primary research team to report potential COI protects neither research integrity nor human subjects.

Keywords

conflict of interest; key personnel; scientific integrity; subject recruitment

Introduction

Financial conflict of interest (COI) has great potential to impact the integrity of scientific research. Newspapers report major conflicts of financial interest for biomedical researchers (Harris, Carey, and Roberts 2007; Goldberg 2008; Loyd 2008; Kowalczyk 2009), and scholarly reports show correlations between financial support by industry and the reporting of positive results in clinical trials (IOM 2009; Bekelman, Li, and Gross 2003; Lexchin et al. 2003). While public imagination has focused on the potential for “scientists” to have COI, regulatory discourse recognizes a broader range of individuals. Overlapping regulations from different federal institutions create a complex framework for enforcing the disclosure of conflicts to COI committees and Institutional Review Boards (IRB). Central to this framework is identifying to whom the regulations apply.

This essay considers the issue of key research personnel in relation to financial COI. The National Institutes of Health defines key personnel as “all individuals responsible for the design and conduct of the study” (NIH 2000). However, regulatory requirements for federal-wide assurance, human subjects training, and reporting COI apply to different, yet overlapping, groups. Institutions must therefore cobble together a definition of “key personnel” that meets the needs of all regulatory bodies. Here, we look at scenarios where personnel directly enrolling subjects are physically and organizationally separated from the researchers designing the study and analyzing the results such as occurs in community-engaged scholarship and emergency medicine research in the pre-hospital setting.

This essay examines three “long-distance” scenarios: a research project with minimal community-engagement in the research process, a community-based participatory research project that maximizes community engagement in the research process, and an emergency medicine study where paramedics enroll patients and administer the research intervention outside of a hospital setting. With each case, this essay asks whether personnel removed from the primary research team commonly need to report COI or potential COI to regulatory compliance bodies—COI committees, IRBs, research integrity officers, etc.—who monitor COI at the primary research teams’ home institution. After examining definitions of COI and regulations on reporting financial COI, we argue that despite the clarity over *what* must be reported, regulations are unclear about *who* needs to report COI and that, ethically, recruitment personnel removed from the primary research team do not need to report COI. We then describe standards that regulatory compliance bodies can use when making determinations of which recruitment personnel might forego reporting financial COI.

Conflict of Interest

Situations in which professional judgment about primary interests are unduly influenced, or perceived to be unduly influenced, by secondary interests, like financial gain constitute COI (Thompson 1993). COI can bias research, harm patients, and damage the public’s trust in the research enterprise (Blumenthal 2003; Bodenheimer 2000; Campbell et al. 2006; DeAngelis 2000; Kass et al. 1996; Nabel 2006). COI can take various forms. For example, individuals might feel pressure to produce results and publish data. This seems to have been the motive for some prominent cases of research fabrication, such as that perpetrated by Mark Spector and Hwang Woo-Suk (Ethics and Fraud 2006; List 1985). While personal and professional interests can cause conflicts, regulations have focused on financial COI (Resnik 2004; Sollitto et al. 2003).

The primary means of addressing financial COI has been disclosure to institutional officials and research participants (DHHS 2004; Resnik 2004; Sollitto et al. 2003; Thompson 1993; Weinfurt et al. 2008). Institutional officials must then decide what action to take to protect research participants and the integrity of the research, such as disclosure of the financial interest, having researchers divest themselves of the financial interest, or even prohibiting the research (DHHS 2004; Resnik 2004; Thompson 1993). PHS and NSF regulations mandate disclosure of equity interests exceeding 5% or \$10,000 (42CFR50), and the FDA mandates disclosure of interests exceeding \$25,000 (21CFR54), but managing COI rests with the institutions who define what potential COI must be reported, who should report, and to whom and when that information should be disclosed (DHHS 2004). Policies vary substantially between institutions (Boyd, Lipton, and Bero 2004; Lo, Wolf, and Berkeley 2000; McCrary et al. 2000) and there is often a gap between an institution’s policies and how institutional stakeholders interpret them. One study found less than half the active clinical investigators at two institutions could accurately describe their institutional COI policies (Boyd, Cho, and Bero 2003).

Research on COI has focused on physicians and scientists in a primary investigator or co-investigator role (Thompson 1993; Blumenthal 2003; Resnik 2004; Sollitto et al. 2003; Weinfurt et al. 2008). Most extant research identifies compromised research design as the primary way that research integrity and human subjects are harmed. Some studies have identified recruitment fees as a potential source of financial conflict (Christensen and Orłowski 2005; LaPuma et al. 1995; Rao and Cassia 2002; Wolf 2009). Sharon Unger and colleagues reported that a recruitment team approached more potential participants for a study involving incentives per individual enrolled than for one without such incentive, but they stopped short of concluding that the fees themselves resulted in the difference (Unger et al. 2010). Of note, the potential for COI arising from recruitment fees is inherently different

from the financial COI typically reported by researchers, and it is generally considered in an ethics or IRB review focused on protecting individual participants.

Regulations Regarding COI and Key Personnel

The regulatory framework emphasizes that financial COI can affect multiple areas of scientific judgment, especially decisions related to study design and data analysis and interpretation. DHHS guidance on COI suggests IRBs evaluating potential conflicts should consider how the research is financed, who designed the study, who will analyze the data, and whether researchers and institutions receive compensation that may be effected by the study outcome (DHHS 2004). The guidance reflects the concern that the research tasks most threatened by financial COI are those associated with PIs and the primary research team gathering and interpreting data.

Decisions for managing financial COI are left to individual institutions, which must consider a range of overlapping requirements. The Office of Human Research Protections (OHRP) requires institutions who receive a Federal-wide Assurance (FWA) ensure compliance with relevant regulations (OHRP 2009). The NIH requires that all “key personnel” receive training in responsible conduct of research (NIH 2000). These directives leave unspecified the exact range of personnel placed under institutional oversight. While protecting human subjects and research integrity drives regulation, the application of regulations by local IRBs can range in scope with both overly broad and overly narrow applications of regulations. Given the latter is less likely while institutions protect themselves from legal or regulatory sanction, the situation can arise where everyone even tangentially involved in research might be required to submit information about financial COI.

Evaluating COI Policies

COI policies aim to protect human subjects and research integrity by codifying an institution’s approach to identifying and managing conflicts between a researcher’s primary and secondary interests, but these policies themselves must be evaluated to ensure they are well-formulated and administered. The Institute of Medicine report Conflict of Interest in Medical Research, Education and Practice identifies four standards for evaluating COI policies: proportionality, transparency, accountability and fairness (IOM 2009). Proportionality should answer “calls for policies to be efficient and effective in addressing serious conflicts of interest in a preventive or a corrective way” (IOM 2009, 57). When considering proportionality, an evaluator would ask whether a policy addresses the most important conflicts and does so at an acceptable cost. An evaluator would also consider the likely biases produced by secondary interests, and what harms might arise from those biases.

Transparency requires the expression of policies “in clear and simple language, together with explanations and essential information about their application” (IOM 2009, 58). Transparency is necessary to determine accountability and fairness. Accountability refers to an institution’s willingness to explain policies and their implementation, to answer questions about policies, to respond to suggestions to improve them, and to commit to tracking the outcomes of financial COI policies.

Finally, the principle of fairness requires “similar treatment for those in relevantly similar situations and different treatment for those in relevantly different situations” (IOM 2009, 60). Fairness has implications for policies within and across institutions. Within an institution, policies should hold all individuals involved in research to account for COI, while recognizing that different policies might apply to people in different roles. Across institutions, individuals in the same roles should be treated the same, and different policies and modes of applying them should arise only when situations differ substantially.

The role of persons engaged in recruiting participants for research is a case where applying the principles of proportionality, transparency, accountability and fairness highlights a need to reconsider broad mandates for reporting financial COI. Next, we consider three situations involving enrollment of participants in research in settings that are removed from the primary research team.

The “Long-Distance” Settings: Communities and Paramedics in Medical Research

Research involving individuals not directly connected to an academic center has increased as a result of numerous factors. Some outside collaborations will occur in “long-distance” settings. Two of those settings are lay communities, which we define as a geographically bounded group of non-experts with an interest in the outcomes of the research, and paramedics, who play a role in enrolling patients in emergency medicine research occurring outside of the ED setting.

Community-Engaged Research

Research with non-expert communities takes a number of different forms that can be organized on a continuum of participation and engagement. Community engagement refers to the creation of mutually beneficial partnerships between researchers and communities that involves mutual respect between all parties and some degree of inclusive participation (Calleson, Jordan, and Seifer 2005; Jones and Wells 2007). Minimally, community-engaged scholarship involves a partnership of academic researchers and a community for “addressing a community-identified need, studying community problems and issues, and engaging in the development of programs that improve health” (Maurana et al. 2001, 215). In a minimal engagement scenario, communities identify the needs and might help identify, refer, or recruit subjects for a study. Academic researchers then frame the community’s need as a research question and answer that question using accepted research methods and standards. While researchers might keep in contact with the community during the research process to share interim results and to identify additional research participants, the community would not have a role in formulating research questions, gathering data or interpreting results.

Participatory research, including community-based participatory research (CBPR) and action research, exists at the other end of engagement continuum. Participatory research involves “all potential users of the research and other stakeholders in the formulation as well as the application of research” (Green and Mercer 2001, 1927). Communities participate in formulating research questions and interpreting results, and as far as possible, academic and community participants share power equally (Green and Mercer 2001; Jones and Wells 2007; Ospina et al. 2004). When it takes the form of action research, participatory research involves collaboration in defining research problems and methods, recruiting participants when necessary, gathering and interpreting data, crafting community and policy actions guided by the results, and giving all participants the chance to contribute to any publication or representation of the research (Brydon-Miller and Greenwood 2006; Ospina et al. 2004).

Paramedics and Emergency Medicine Research

Among the issues addressed by emergency medicine research are outside-the-hospital treatments for cardiac arrest, major trauma and stroke. Since only 5% of individuals suffering an out-of-hospital cardiac arrest survive (Weaver and Peberdy 2002), early intervention treatments are needed. The evidence of clinical effectiveness for these early treatments has been scarce, and further research on out-of-hospital treatment interventions for conditions like cardiac arrest is needed (IOM 2006). In order for this research to go forward, paramedics must play a role in the research process. Paramedics interact with

victims of out-of-hospital cardiac arrest, major trauma, etc., and in the study of pre-hospital treatment interventions, they may be administering the clinical treatment under a research protocol using exemption from informed consent (EFIC).

Evaluating COI Policies for “Long-Distance” Settings

The first step in evaluating COI is determining whether the individuals in question are “key personnel” responsible for the design and conduct of the study. A broad definition of key personnel covers any person who plays even a small role in the research process. In all settings described above, those individuals removed from the academic setting play a role in conducting the study by helping identify and enroll individuals into the research study. In the CBPR/action research setting, the community is also actively engaged in designing and conducting all aspects of the study. In other words, community members and paramedics in each of the settings interact with human subjects for research purposes, and in the case of paramedics and CBPR participants, they will be administering research instruments, whether they are clinical interventions or a survey, focus group or interview.

While this means these individuals should be educated about human subjects protections and comply with them, federal regulations do not mandate that these groups disclose potential COIs. The roles identified in COI regulations are those involving study design, research funding and data analysis (DHHS 2004). The scope of COI policies is ultimately determined by individual institutions, and those policies that will best protect the integrity of the research are also those that meet the standards of proportionality, transparency, accountability, and fairness. Proportionality and fairness are the primary concerns in these cases. While transparency and accountability are important, they apply to policies regardless of whether they mandate that recruiters in “long-distance” settings disclose potential COI to institutional officials.

The standard of proportionality evaluates whether a policy addresses the most important conflicts, and fairness considers whether it applies to all relevant groups equally. Different types of conflicts are associated with different roles in the research process. While all members of a research team have an interest in the success of the study and maintaining funding for the research, many of the COI, financial and otherwise, that arise for those in the roles of study designer or data analyst will differ from those providing technical support and recruitment. Considerations of proportionality and fairness require identifying the role or roles individuals have in the research and identifying the roles where conflict of interest is most likely to arise.

Proportionality

Considerations of proportionality lead to the conclusion that paramedics and community members involved in minimally-engaged research should not be required to disclose potential COIs, but lay individuals involved in CBPR will need to report them. The roles of paramedics and laypeople in minimally community engaged research are not central to the research process. The central tasks in research involve acquiring funding, identifying research questions, methods to answer those questions (which include criteria for recruitment), and the analysis and interpretation of the data generated. In the scenarios above, these two groups only play a role in recruitment and, with paramedics, in administering a research intervention. Individual IRBs would need to confirm that these groups do not fulfill more central roles, but once they have done that, the IRB could waive reporting requirements for individuals in these groups. Ultimately, we should find a large percentage of community-engaged research and emergency medicine research only involves a minor role for communities or paramedics: Scholarship on collaborative research has

shown that researchers rarely allow non-researchers to fill roles central to the research process (Jones and Wells 2007).

Community members engaged in CBPR, on the other hand, need to disclose potential COIs. CBPR involves establishing relationships between academic researchers and communities where all individuals perform all the roles in research, especially those roles central to the research process. Community members would help acquire research funding, if funding was thought necessary for the project. They will play an equal role in establishing research questions, identifying research methods, and interpreting data. Because they perform so many roles in research, including the most important roles, they should report financial information to allow institutional officials to determine whether a COI or the appearance of a COI exists.

Fairness

The standard of fairness asks us to consider whether situations differ in significant ways that justify different regulatory requirements about financial disclosure. First, we need to reaffirm the differences between the three cases, especially the two community settings: CBPR involves a greater role in the key areas of the research process for laypeople, whereas the other two cases do not. Second, we should compare the “long-distance” recruitment settings described above and recruitment that occurs in close proximity to the research team (i.e. recruiters working *within* an academic institution) and note the potential differences in roles performed as well as the issue of physical and institutional distance. Recruiters in the “long-distance” settings likely perform a role in recruitment only and, with paramedics, a role in administering the intervention. In contrast, those in close proximity to the research team, such as a research coordinator, are more likely to fill multiple roles. The research coordinator might play a role in recruitment, study management, data collection, etc. The larger number of roles multiplies the situations and ways in which a potential COI can exert a negative influence on research integrity and subject protections.

The distance also plays an important role in distinguishing recruitment in these different settings. The institutional and physical distance is important: Greater distance reduces the ability of research teams to coerce or entice recruiters to enroll ineligible subjects. Specifically, increased institutional distance reduces the means by which coercion or enticement can occur, since research team members will have a diminished ability to threaten job security, promotion, etc., or provide tangible benefits associated with promotion, etc. Increased physical distance also reduces the opportunity to make face-to-face contact in order to pressure or threaten recruiters. While no condition will eliminate the possibility that a determined individual would engage in bribery or coercion, institutional and physical distance helps protect the individuals in the cases we have described from the most egregious and common means of bribery and coercion.

Conclusion

When considering the case of “long-distance” recruiters—those who enroll patients at a physical and organizational remove from the investigators who have sought funding and developed the study—the standards of proportionality and fairness lead us to conclude that these recruiters do not need to report financial COI to institutional officials as long as they do not fulfill a central role like acquiring funding, designing a study, or interpreting results. For the three cases we described, paramedics and those lay people involved in a minimal community engagement research project should not have to report potential COI, while those involved in community-based participatory research should.

We reach this conclusion by differentiating between the roles of PIs, other key personnel and recruiters, as well as addressing the role of institutional and physical distance in protecting “long-distance” recruiters from coercion. Acquiring research funding, developing research studies, managing research funds, collecting data or coordinating its collection, interpreting data and developing the final publications are all roles and responsibilities central to the research enterprise. These roles are performed by PIs, statisticians, research coordinators, etc. Recruiters working in the same setting as the research team often play some of these roles. “Long-distance” recruiters are unlikely to play these roles. Also, those who exist in proximity to the research team are more likely to experience undue influence to ignore enrollment criteria or falsify data, if such pressures existed. While we have focused on three distinct situations and found two of them do not require COI reporting, we believe that recruiters in similar “long-distance” situations should not have to report potential COI either.

While we believe individuals who meet the criteria of “long-distance” and are not engaged with designing or interpreting research should be exempt from COI reporting requirements, this does not remove requirements that they understand and adhere to regulations for human subject protections. Those involved with enrolling research subjects must understand the dynamics of human subjects protection, informed consent, and (when necessary) requirements for research with exemption from informed consent. Such training will help secure human subjects protections and the integrity of research, but additional mandates requiring disclosure of COI will not.

Two possible objections might be raised to our conclusions. First, one might argue that we have removed a safeguard against research misconduct and that “long-distance” recruiters might falsify data, especially information about a subject they have enrolled in order to benefit the study. Unfortunately, financial COI reporting by “long-distance” recruiters does not address the motives for research misconduct that arise during recruitment. COI regulations address motives for research misconduct associated with roles that are central to the research process, such as choosing inappropriate methods or interpreting results to favor a secondary financial interest.

Second, one might object that recruiters do in fact have a COI if they are paid a fee for each subject recruited: Those recruiters would have a financial interest in recruiting individuals and thus might ignore recruitment criteria. While recruitment fees could entice a person to engage in misconduct and those fees are a monetary inducement, recruitment fees are inherently different from the type of financial COI that the COI regulations address. Concerns about the detrimental effect of recruitment fees are generally the purview of an ethics or Institutional Review Board, who explicitly examine such fees to ascertain if the amounts and structure of their disbursement might contribute to inappropriate enrollment. The reporting of financial COI to institutional officials is unlikely to influence such irresponsibility.

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