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# Conflict of interest in academic research

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**Abstract** The potential for conflict of interest in research can occur whenever a faculty member's financial interest in an industrial sponsor is sufficient to affect his or her impartiality in interpreting the results of the sponsored project. Owing, in large part, to the role of public funding of research, the appearance of a conflict of interest can be as damaging to the reputation of the investigator and/or university as an actual conflict. Therefore, universities and governmental funding agencies have established policies to help ensure that the public welfare is upheld through unbiased research conduct and reporting. Industrial partners who sponsor such research should understand the university's need to identify and appropriately manage these conflicts. Violation of the policies that govern conflict of interest in research can compromise public trust in academic research (jeopardising public funding) and pose undue health risks, as well as damage the reputation of the researcher.

**Keywords:** conflict of interest, biomedical research, institutional review board, US government, federal research agencies, industry-university relationship, disclosure

## Introduction

Universities allow and encourage faculty participation in non-university activities because it can benefit the employee, the university and the public welfare. Such activities include outside work for industry, leading to a financial interest by the faculty researcher in that company. A *conflict of interest* in research occurs when the impartiality of that researcher has the potential to be affected by his or her interest in the sponsor. The loss, or perception of loss, of impartiality in research can have severe consequences. Therefore, it is imperative that the university identify and manage the potential for conflicts of interest in research. Acceptable research conduct in industry may be unethical, or even prohibited, within the university owing to its receipt of public monies.

Policy requires that the university either manage or avoid conflicts of interest, as well as *the appearance* of conflicts of interest in research. The appearance of a conflict of interest may have just as much impact on the public's trust in academic research as a real conflict. If an industry sponsor, such as a pharmaceutical company, is funding the conflicted university researcher, the company's reputation/product is also at stake. Hence the need for companies involved in funding academic research to be aware of their role in creating conflicts of interest. This requires an understanding of the academic culture, its research policies, the interest of federal granting agencies in seeing that conflicts of interest are minimised, and the process of identifying and managing conflicts of interest in research.

Currently, US academic institutions

encourage their faculty to seek industry support of research, thereby increasing the potential for conflict of interest. Public funding for academic research is declining and federal granting agencies are able to fund only a small portion of submitted proposals. As a result, university researchers are increasingly turning to private industry for support of their laboratories. At the Massachusetts Institute of Technology, industry funding for research has now reached US\$80m, 25 per cent of all research funding in the university.<sup>1</sup> This is an increase from less than 6 per cent ten years ago. A similar situation exists at many other US and European universities.<sup>2</sup> For example, industry funded 14 per cent (US\$1.6bn) of academic health centre research in 1997.<sup>3</sup> The proportion of industrial funding will probably increase, particularly as technology transfer partnerships develop. However, public support continues to be the primary source of funding for academic research. These conditions make it imperative that conflict of interest in academic research be properly identified and managed so that the public trust is maintained. Quite simply, most universities are not willing to jeopardise their federal (public) research support by improperly accepting industrial support.

### **The academic environment and conflict of interest in research**

The university is a unique environment, particularly compared with private industry. The university mission is to teach and conduct research. In the case of medical schools, a third mission is to provide clinical care. These three functions are aptly described by the motto at the Oregon Health Sciences University: 'Where teaching, healing, and discovery come together.' Not surprisingly, a devotion to product development and sales is not included within the academic mission statement.

By comparison, the corporate mission is to generate revenues for the company and its shareholders. While companies spend

billions of dollars each year to support research activities, they seldom have the capacity to conduct these activities entirely within the company 'walls'. Basic research is the seed-bed for new and innovative products. Academic research institutions are well suited to conduct this kind of research and academic researchers are motivated (and rewarded) by scholarly publication and obtaining funds to support their laboratories. Conversely, corporate research must focus on the identification and development of new products. For these reasons, academia and industry must cooperate to identify and develop new innovative products for the public good.

In many cases, promising new technologies are a result of the university's receipt of research support from the federal and/or state governments. The governing agencies that administer and provide this research support are mandated, as stewards of the public's money, to require that university recipients of federal funds develop new knowledge for the public good. However, the ongoing development of such innovative research is generally not fundable by those same agencies/dollars. This circumstance, combined with an academic researcher's ability to participate in activities outside the university, opens the door for conflict of interest to occur.

Perhaps the greatest impact of improperly managing conflict of interest for universities is the potential loss of the public trust or, in the case of clinical research, the loss of human life. Most academic institutions in the USA are supported by public dollars (in many cases to a great extent). The tuition payers and taxpayers expect that the quality of education, clinical care and research conducted at the institution should not be compromised by outside interests. Any time these outside interests interfere with faculty time, medical treatment and research objectivity, the public trust is compromised. This need to maintain the public trust is often difficult for those in private industry to understand. Unfortunately, it is often overlooked by academic researchers and clinicians, as well.

Conflict of interest in research occurs

when a researcher has the potential to be motivated to obtain affirmative experimental results. This motivation may come from private industry sponsorship of basic research or clinical trials when the researcher has an outside interest in that sponsor and, therefore, the outcome of the study. In order to safeguard the integrity of such research, it is necessary to ensure that financial interests do not affect research project design, interpretation or reporting. Objectivity also can be compromised by interests of the industry partner and the academic institution, as well. More than one university president has awakened to find a negative story about their university on the front page of the morning paper. Whether the story has merit or not is no longer the issue: the public damage has been done.

### **Factors contributing to conflict of interest**

There are a variety of factors that contribute to conflict of interest in research. The major one is the researcher's outside financial interest in the sponsor. Although this can lead to a conflict of interest for anyone involved the research team, it is particularly critical for those individuals involved in patient recruitment, study design, interpretation of results and publication preparation. The impartial objectivity of the industry sponsor, faculty researcher and university administration are all necessary to ensure the highest standards in research and patient care.

### **The industry sponsor**

Industry has benefited significantly from sponsorship of university research. As many as 90 per cent of surveyed life science companies had some relationship with a university in 1994, resulting in marketable products, patents or sales for 60 per cent of the companies.<sup>4</sup> However, the industry partner sponsoring the research can place limits on proper study controls or fair comparisons with competitors' products (drugs), restrict publication or public

reporting of research findings, mislead investigators about drug effectiveness so that patient subjects are exposed to unnecessary dangers, and threaten to withdraw money if findings do not support their product. Two-thirds of surveyed companies had placed restrictions on prompt faculty publication or reporting of research results in order to protect patent applications.<sup>4</sup> Although a two to three month delay for patenting is probably justifiable, nearly half of surveyed companies admitted restricting publications well beyond a reasonable time for patent filing. Others have reported industrial sponsors asking for 10 year non-disclosure agreements regarding publication of findings.<sup>5</sup> Such restrictions of publishing research results is in direct violation of a researcher's moral obligation to enhance the public welfare by quickly reporting findings that will ease suffering and fight disease.<sup>1,5</sup>

Even if the research is published, industry sponsors may unduly influence the conclusions or withhold negative findings. Published reports of clinical trials have concluded that drugs manufactured by the sponsoring pharmaceutical company are more likely to be judged superior, less toxic or more cost effective (sometimes in the absence of any statistical comparisons) than in studies sponsored by an impartial third party.<sup>6-8</sup> In some cases the sponsoring company's drugs were purported to be used in higher doses than their competitor's drugs; providing an edge in treatment outcome.<sup>7</sup> The detrimental impact of such biased results goes beyond the publication because other clinicians may seek guidance for patient treatment from these published studies.

These reports of misleading studies have led to the plea for national standards to be established for studies of the efficacy and value of drugs, full disclosure in the publication of pharmaceutical sponsor support for the study, and strict peer-review of such reports prior to publishing.<sup>9-11</sup> Both the Council of Science Editors (formerly Council of Biology Journal Editors) and International Committee of Medical Journal Editors encourage editors to require authors to disclose commercial support and

affiliations as potential conflicts of interest (Table 1). However, recent surveys show fewer than half of journals actually required this disclosure and only 7 per cent required disclosure of authors' intellectual property rights.<sup>9,12</sup> The lack of uniform acceptance of disclosures does have some justification. Some argue that publishing such disclosures in the research articles unfairly impugn authors with 'implied wrongdoing' when in fact their research is entirely objective.<sup>9</sup> Furthermore, disclosure standards will not affect industry-sponsored studies that are simply withheld from publication by the sponsor because of negative findings<sup>7</sup> or not even considered by the editors themselves because of the lack of new or significant results.

#### The faculty researcher

It must be noted that the overwhelming percentage of researchers aspire to do good things. If they were motivated by financial interests, they would probably not have chosen a career in academic research in the first place. In addition, the competitiveness for federal research dollars requires peer-reviewed articles and, often, a stellar reputation in the research areas for which they seek support. However, the pressures to accumulate affirmative data can be very strong in certain cases. These pressures increase when a researcher accepts industrial sponsorship in their laboratory, and/or receives a financial interest in the sponsor of that research or clinical trial. Even non-financial interests can create a conflict of interest if they are significant enough to influence one's judgment.

Blumenthal *et al.*<sup>13</sup> reported that 28 per cent of faculty at the 50 largest universities have some financial relationship with industry, resulting in almost 9 per cent of their research funding. Although faculty funded by industry was very productive (publications, teaching time, university service), this productivity declined with increasing industrial support. Perhaps the most disconcerting practice found in this study was that industry-funded faculty was less likely to openly share research findings

or biomaterials with colleagues, which impedes academic freedom and serving the public good.

Industry-supported authors must share in the responsibility for accurate reporting of research findings. Reviews of studies on calcium channel blockers and tobacco-related disease have demonstrated that favourable conclusions for a particular product or industry are highly correlated with research sponsorship by the manufacturers.<sup>14,15</sup> This industrial support is not always made apparent to the unsuspecting reader as the authors do not always disclose their funding source in such studies. Stelfox *et al.*<sup>14</sup> found that only 2 of 70 research articles funded by industry actually identified any potential conflict of interest in the report. Also, Krinsky *et al.*<sup>16</sup> reported that 34 per cent of 789 surveyed research articles had industry financial interests, yet none disclosed it. This deficiency must be corrected if public trust is to be maintained.

A conflict of interest also can have a direct impact on patient care. One study showed a significant number of doctors requesting drugs to be stocked in the hospital formulary had accepted money from the respective drug manufacturer.<sup>17</sup> In many cases these drugs were no more effective, and sometimes even less effective, than drugs already in the hospital inventory. The other clinicians within the hospital then unknowingly run the risk of prescribing these less effective drugs for their in-house patients. This finding supports the need for universities to adopt procedures to minimise the influence of outside interests on patient care.

#### The university administration

Academic institutions themselves are not immune from conflict of interest situations. Such institutional conflict of interest can occur if the university has taken an equity interest in a company through a technology transfer agreement. That equity holding has the potential to influence an academic administrator's judgment when entering into contracts with that company. Other

**Table 1** Conflict of interest websites

<p><b>United States Government</b></p> <p>Public Health Service/National Institutes of Health  NIH Policy: Financial Conflicts of Interest and Research Objectivity: Issues for Investigators and Institutional Review Boards.  <a href="http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-040.html">http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-040.html</a>  NIH Bioethics Resources on the Web.  <a href="http://www.nih.gov/sigs/bioethics">http://www.nih.gov/sigs/bioethics</a>  NIH Guide on Objectivity in Research (NIH Guide, volume 24, number 25, July 14, 1995).  <a href="http://grants.nih.gov/grants/guide/notice-files/not95-179.html">http://grants.nih.gov/grants/guide/notice-files/not95-179.html</a>  NIH Regulatory Burden. III. Financial Conflict of Interest – Workgroup Report.  <a href="http://grants.nih.gov/grants/policy/regulatoryburden/conflictinterest.htm">http://grants.nih.gov/grants/policy/regulatoryburden/conflictinterest.htm</a>  Frequently asked questions about DHHS Objectivity in Research Regulations.  <a href="http://grants.nih.gov/grants/policy/coifaq.htm">http://grants.nih.gov/grants/policy/coifaq.htm</a>  NIH Grants Policy Statement. Part II: Terms and Conditions of NIH Grant Awards, Conflict of Interest.  <a href="http://grants.nih.gov/grants/policy/nihgps/part_ii_2.htm#conflictint">http://grants.nih.gov/grants/policy/nihgps/part_ii_2.htm#conflictint</a>  Federal Code: Responsibility of Applicants for Promoting Objectivity in Research. Code of Federal Regulations: Type 'Title 42, part 50, subpart F.'  <a href="http://www.access.gpo.gov/nara/cfr/cfr-retrieve.html#page1">http://www.access.gpo.gov/nara/cfr/cfr-retrieve.html#page1</a>  Federal Code for Contractors. Code of Federal Regulations, Title 45, Subtitle A, Part 94.  <a href="http://www.access.gpo.gov/nara/cfr/waisidx_99/45cfr94_99.html">http://www.access.gpo.gov/nara/cfr/waisidx_99/45cfr94_99.html</a></p> <p>National Science Foundation  Frequently asked questions about NSF Investigator Financial Disclosure Policy.  <a href="http://grants.nih.gov/grants/policy/coifaq.htm">http://grants.nih.gov/grants/policy/coifaq.htm</a>  NSF Investigator Financial Disclosure Policy. Federal Register: 11th July, 1995 (Vol. 60, No.132).  <a href="http://fr.cos.com/cgi-bin/getRec?id=19950711a105">http://fr.cos.com/cgi-bin/getRec?id=19950711a105</a>  NSF Grantee Standards. Conflict of Interests Policies.  <a href="http://www.nsf.gov/bfa/cpo/gpm95/ch5.htm#ch5-6">http://www.nsf.gov/bfa/cpo/gpm95/ch5.htm#ch5-6</a></p> <p>Food and Drug Administration  FDA Guidance for Institutional Review Boards and Clinical Investigators.  <a href="http://www.fda.gov/oc/oha/IRB/toc.html">http://www.fda.gov/oc/oha/IRB/toc.html</a>  FDA Financial Disclosure by Clinical Investigators; Federal Register Feb. 2, 1998, vol. 63, number 021, 63 FR 5233.  <a href="http://fr.cos.com/cgi-bin/getRec?id=19980202a121">http://fr.cos.com/cgi-bin/getRec?id=19980202a121</a></p> <p>Office of Research Integrity, Department of Health and Human Services  Publications, Guidelines, and Study Reports.  <a href="http://ori.dhhs.gov">http://ori.dhhs.gov</a></p> <p><b>Universities</b></p> <p>University of California System  <a href="http://www.ucop.edu/ucophome/system/swpolicy.html">http://www.ucop.edu/ucophome/system/swpolicy.html</a> (Academic Policies Relating to Research; Conflict of Interest Code)</p> <p>Columbia University  <a href="http://cpmnet.columbia.edu/research/bio.htm">http://cpmnet.columbia.edu/research/bio.htm</a></p> <p>Massachusetts Institute of Technology  <a href="http://www.mit.edu/afs/athena.mit.edu/org/p/policies">http://www.mit.edu/afs/athena.mit.edu/org/p/policies</a></p> <p>University of Michigan  <a href="http://www.research.umich.edu/research/policies/policies.html">http://www.research.umich.edu/research/policies/policies.html</a></p> <p>Harvard University  <a href="http://www.fas.harvard.edu/~research/index.html">http://www.fas.harvard.edu/~research/index.html</a>  <a href="http://www.techtransfer.harvard.edu/HarvardInventors.html">http://www.techtransfer.harvard.edu/HarvardInventors.html</a>  <a href="http://www.hms.harvard.edu/otl/conflict.html">http://www.hms.harvard.edu/otl/conflict.html</a></p> <p><b>Academic affiliated organisations</b></p> <p>Association of American Universities  <a href="http://www.tulane.edu/~aau/AAUPolicy.html">http://www.tulane.edu/~aau/AAUPolicy.html</a> (Research Integrity)</p> <p>Association of American Medical Colleges  <a href="http://www.aamc.org/research/dbr/coi.htm">http://www.aamc.org/research/dbr/coi.htm</a></p> <p>Association of University Technology Managers  <a href="http://www.autm.net">http://www.autm.net</a> (Policies – Conflict of Interest)</p> <p>Council of Science Editors (formerly Council of Biology Journal Editors)  <a href="http://www.councilscienceeditors.org/services_DraftApproved.shtml">http://www.councilscienceeditors.org/services_DraftApproved.shtml</a></p> <p>International Committee of Medical Journal Editors  <a href="http://www.icmje.org">http://www.icmje.org</a></p>
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situations that may create an institutional conflict of interest (not necessarily in research) include: entering into research agreements in order to get valuable overhead costs for the university, placing the prestige of the university for clinical trials over the safety of the patients being treated, pressuring the patient protocol review committee (institutional review board, IRB) to approve questionable treatments or studies, pressuring clinical faculty to get research grants to the detriment of teaching and patient care, or allowing research sponsors' access to university resources in such a way that it violates university policy.

The IRBs within universities must place the protection of human subjects over all other factors when analysing new clinical trial opportunities. Despite this obligation, between October 1993 and March 1994, 18 IRBs were found guilty of violating Food and Drug Administration (FDA) regulations, 13 for conflicts of interest.<sup>18</sup> Of these, five were considered institutional conflict of interest. Two of these institutional cases resulted from the administration preventing their IRBs from disapproving questionable human research protocols. These institutional conflicts of interest significantly increased in the next five years. In 1999–2000, approximately 60 academic institutions were not compliant with federal regulations regarding protection of human subjects.<sup>19</sup> Nine of these universities actually received major sanctions by the Office for Protection from Research Risks, such as suspension of federally sponsored research money. These cases not only resulted in some lawsuits by patients, but many university administrators resigned over the scandals. Thus, institutional conflict of interest can also have a significant impact on the university, its administrators, its reputation and its finances.

It is important for university administrators to disclose their conflicts and avoid making critical decisions over contracts with the very companies in which they have significant financial interest. This area of conflict will probably be given a lot more attention in the future.

## Federal and academic guidelines impacting conflict of interest

### Federal policies

#### Public Health Service

The National Institutes of Health (NIH) within the US Public Health Service is the major grant funding agency within the US government. In 1995, the NIH, along with the National Science Foundation (NSF), implemented new guidelines on conflict of interest based upon the model of institutional disclosure and peer review. The threshold for disclosure of conflicts of interest is US\$10,000 in either annual income or equity in a relevant company or 5 per cent ownership in the company. This less restrictive model came about after an earlier attempt by the NIH, in 1989, to implement guidelines that prohibited researchers from holding any equity interests in a company.

A partial listing of NIH and NSF websites detailing these policies is provided in Table 1. These policies have as their underlying principle the quality of research to ensure safeguard of the public and the maintenance of public trust. Included within these research quality guidelines are conflict of interest policies that require institutions receiving federal research funds to assure the governmental agency (and the public) that researchers are not unduly influenced. Excerpts from this NIH policy provide an overview of this position (NIH-OER Grants,<sup>20</sup> Table 1):

Prudent stewardship of public funds that support research programs requires that appropriate steps be taken to ensure high quality results. Therefore, recipient organizations must establish safeguards to prevent employees, consultants, or members of governing bodies from using their positions for purposes that are, or give the appearance of being, motivated by a desire for private financial gain for themselves or others such as those with whom they have family, business, or other ties. Therefore, each institution receiving PHS funds must have written policy guidelines on conflict of interest and avoidance thereof. These guidelines should

reflect state and local laws and must cover financial interests, gifts, gratuities and favors, nepotism, and other areas such as political participation and bribery. These rules must also indicate how outside activities, relationships, and financial interests are reviewed by the responsible and objective institution official(s).

In addition, the institution has the responsibility for maintaining objectivity in research by ensuring that the design, conduct, or reporting of research will not be biased by any conflicting financial interest of investigators responsible for the research in accord with the provisions of PHS regulations 42 CFR Part 50, Subpart F, and 45 CFR Part 94. . . . Institutions which identify research investigator financial conflicts of interest are required to report the conflicts to the NIH Grants Management Officer (GMO) at the NIH Institute or Center (I/C) which funds or will fund the project.

#### **Food and Drug Administration**

The US FDA is another federal agency that has established guidelines for the identification and management of research conflict of interest (Table 1). The issue here is that the sponsor of the study must disclose any financial interests of clinical investigators in the product or drug being tested. The purpose is to identify any factor that could affect the reliability of the research findings in applications to the agency. The summary of this agency's policy is (Federal Register,<sup>21</sup> Table 1):

The Food and Drug Administration (FDA) is issuing regulations requiring the sponsor of any drug, including a biological product, or device marketing application (applicant), to submit certain information concerning the compensation to, and financial interests of, any clinical investigator conducting certain clinical studies. This requirement will apply to any covered clinical study of a drug or device submitted in a marketing application that the applicant or FDA relies on to establish that the product is effective, including studies that show equivalence to an effective product, or that make a significant contribution to the demonstration of safety. This final rule requires applicants to certify to the absence of

certain financial interests of clinical investigators and/or disclose those financial interests, as required, when covered clinical studies are submitted to FDA in support of product marketing. This regulation is intended to ensure that financial interests and arrangements of clinical investigators that could affect reliability of data submitted to FDA in support of product marketing are identified and disclosed by the sponsor of any drug, biological product, or device marketing application. If the applicant does not include certification or disclosure, or both, if required, or does not certify that it was not possible to obtain the information, the agency may refuse to file the application. FDA intends to propose to extend these requirements to submissions for marketing approval related to human foods, animal foods, and animal drugs in a subsequent issue of the Federal Register.

The FDA also establishes guidelines for university IRBs that are responsible for approving research protocols involving human subjects submitted by faculty investigators.<sup>22</sup> It is the duty of the IRB to thoroughly evaluate all factors related to patient safety, inclusion of information in the consent forms signed by the subjects, and faculty conflict of interest. Conflict of interest by faculty investigators may compromise the treatment human subjects receive, expose patients to less effective (or harmful) treatments and increase the liability of the university. Again, the underlying principle is maximising public trust and assurance that protection is afforded those individuals who agree to be research subjects.

#### **University policies**

As outlined in the various federal policies, each institution is required by the federal granting agencies to provide verification that the investigators conducting the research are doing so without conflict of interest. Or, if potential conflicts of interest are identified, then the university must provide verification that the conflict is being managed and the quality of the research is not compromised. Because these federal policies do not dictate how these conflicts should be managed (only that they should

be), each university must establish its own written policies governing the management of conflict of interest. Otherwise, the granting agencies may withhold funds from the university. Table 1 lists the websites of certain US universities, both private and public, that detail their respective conflict of interest policies. Universities have many policies that guide the preparation and submission of research proposals, as well as the management of research grants once they are funded. The identification and management of research conflict of interest is simply one more aspect of university research administration, albeit a very serious one. Faculty conflict of interest in research, real or not, can have a significant impact on the university's continued financial support from the federal granting agencies.

The university IRB is mandated by federal regulations, but managed through university policy. It is there to ensure patient safety by reviewing and approving all human research protocols. Thus, it satisfies the federal requirement that the well-being of human subjects is not compromised. At the same time, it also must be sensitive to the faculty member's research, support the university's need for research income, and help decide the suitability of the industrial sponsor. A conflict of interest can occur in any of these participants and it is critical that the IRB be satisfied either none exists, or a potential conflict is closely managed. Close adherence to IRB procedures and policies is therefore required for any industry-university research relationship. In spite of this, only 1 per cent of universities have policies in place that required faculty to inform the IRB or research subjects of potential investigator conflict of interest as a management mechanism.<sup>12</sup>

### Management of conflict of interest

The identification and management of potential research conflict of interest is required by the federal agencies and institutional policy. Too often the disclosure of these conflicts is thought to be the last

step in management, ie the researcher is now aware of his or her conflict and is making a conscious effort to remain impartial. However, the university's obligation to manage or eliminate these situations goes beyond simple identification. Conflict management is crucial for the university both to utilise public funds responsibly and partner with industry to develop new products.

There are a number of tools to manage conflict of interest in research, thereby allowing industrial partnerships to continue. The federal code detailing the responsibility of research funding applicants to promote objectivity in research suggests possible management procedures (CFR Title 42, part 50, subpart F). Below are a few examples of the steps that can be taken in the management of potential conflict of interest. Of course, proper management is dependent upon a good system for identifying conflict, which is usually the researcher's obligation.

### Public disclosure

Often simply stating the researcher's personal or financial interests in the outcome or presentation of the research is satisfactory. Many research meetings now have provisions that require the statement of potential conflict of interest by the presenting authors. Also, many journals require authors to disclose financial interests in their research publications<sup>12</sup> (Table 1). It is assumed that if the readers or meeting attendees are aware of such potential conflicts of interest, they can interpret the research findings accordingly.<sup>10,11</sup> However, this step alone is often not sufficient to insure impartiality in research; particularly if the study involves human subjects. Also, only 43 per cent of journals and 7 per cent of academic institutions require this publication disclosure by authors,<sup>12</sup> thus it is not a universal policy.

### Independent review

The personal and financial interests of the researcher/clinician may create a conflict of



interest, resulting in the possibility that objectivity is compromised when interpreting research findings. One way to reduce the researcher's chance of being inadvertently influenced when interpreting data or recruiting patients is to have the research protocol and data evaluated by an impartial third party. Concerns over issues such as patient enrolment or data interpretation can then be shared with the researchers before the improper recruitment or publication of biased data occurs. While not entirely foolproof, this process can provide a check to ensure that integrity in research is not compromised. An additional difficulty associated with this process is finding, and funding, independent researchers with sufficient knowledge and time to review such studies. Another way to facilitate this type of review is to require that results of federally funded research not be shared with an industrial sponsor until after publication or an evaluation by the institution's technology transfer office.

#### **Substitute project manager**

Quite often, as in clinical trials, the financial interest of the project manager is simply too great, and the consequences too severe, to leave the project manager in a position of ensuring patient safety. In these cases, it is possible to have another faculty member with no financial conflict take over the management of the project. As long as all parties involved are satisfied with the qualifications and objectivity of the substitute investigator, a potential conflict is avoided without jeopardising the study. Again, suitable substitute project managers may not be available.

#### **Avoidance**

There is always the option of simply refusing the research support from the industrial sponsor. Several universities have adopted policies that prohibit the acceptance of research funds from a company in which the faculty researcher has a significant financial interest. A significant financial interest has been defined by the

NIH as US\$10,000 in annual income or equity in a relevant company, or 5 per cent ownership in the company. These lower limits have been arbitrarily set, as it is difficult to know how much of an incentive is necessary to compromise an individual researcher's impartiality. Upper limits are being discussed in some settings as a way of differentiating between projects that should be disallowed and those that should be managed. Given the fact that most commercially sponsored grants are below US\$100,000,<sup>4</sup> it seems unlikely that any single grant is worth compromising the public trust. An alternative arrangement in these situations is to have the faculty member serve as a consultant to the company/project, have the project contracted to a private research agency, or hire former students of the faculty member to conduct the research at the industrial site.

Lo *et al.*<sup>23</sup> evaluated the policies governing conflicts of interest at the ten medical schools in the USA that receive the largest amount of research funding from the NIH. Their findings show that these institutional policies vary widely and they concluded that 'university-based investigators and research staff be prohibited from holding stock, stock options, or decision-making positions in a company that may reasonably appear to be affected by the results of their clinical research'. Similar conclusions were not made for basic research, reflecting a greater concern for clinical trials than basic research. This total avoidance of participation, or total divestiture of all financial interests in order to participate, certainly represents the extreme view and would not be practical in many cases.

#### **External IRB**

It is possible that the internal IRB itself can have a conflict of interest. This may occur if faculty members on the IRB are personal friends of the faculty member proposing the research, the university has financial interests in the sponsoring industrial partner, or there is a potential for significant future funds from the sponsor. In this case,

conflicted reviewers need to disclose their conflicts and, possibly, abstain from the review of that study. Alternatively, the review of such protocols could be handled by a committee outside the university, such as the medical staff at another hospital or the IRB of another university. Increasing the number of community laypersons on the IRB and the creation of regional (not university) IRBs are sometimes offered as suggestions on how to protect human subjects while still facilitating local university research support from industrial partners.<sup>18,19</sup> However, because federal regulations currently mandate IRBs within the institution where the research is to be conducted, these options would require significant federal policy revision.

## Conclusions

Better understanding and management of conflict of interest in academic research should lead to better industry–university partnerships. Universities are tightly regulated by federal and internal policies governing these conflicts of interest. If industry sponsors can work within the constraints of these regulations, productive partnerships with universities should continue. In fact, one could argue that these partnerships are required to ensure that new innovation is pursued and developed for the public good. Such relationships will undoubtedly increase in the future as universities look for funding and industry looks for talented researchers to help them develop their products. However, maintaining the public trust and protecting human research subjects are crucial to a healthy academic research environment.

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