

Brown University Faculty Forum
Subject: University Conflict of Interest Policy and
Practices of the Conflict of Interest Review Board
November 15, 2011
4:00-5:30 p.m.

Dietrich Neumann (History of Art and Architecture), Chair of the Faculty Forum

Members of the Conflict of Interest Review Board (**boldface = present at the meeting**):

Regina White, Associate Vice President for Research , OVPR, Chair of COI Review Board; **Christopher Bull**, Engineering; Constantine Gatsonis, Biostatistics; **Mark Johnson**, MCB; Julie Kauer, MPB; **Arthur Landy**, MCB; Tayhas Palmore, Engineering; **Lawrence Price**, Psychiatry, Clinical Director and Director of Research, Butler Hospital; **Eli Upfal**, Computer Science; **Ronald Seifer**, Psychiatry and Human Behavior; Thomas Webster, Engineering; **Roderic Beresford**, Associate Provost (ex officio); Edward Hawrot, Associate Dean of BioMed (ex officio); **Katherine Gordon**, Technology Ventures, OVPR; **Julianne Hanavan**, Research Ethics Education and Policy, OVPR; **Norman Hebert**, International Research Administration, OVPR

The Chair of the Faculty Forum, Dietrich Neumann (History of Art and Architecture), convened the forum at 4:01 p.m. He informed those present that the discussion would focus on the practices of the University Conflict of Interest Review Board (hereafter COIRB), particularly in light of upcoming changes to federal regulations about COI. He noted that the discussion would be organized around the following topics:

1. Research Sponsored by an Entity where Faculty Member or Researcher has Significant Financial Interest
2. CEO Position in a Start-up Company
3. Mandatory Disclosure Requirements
4. Department Chair Access to Conflict of Interest Reporting Forms
5. Faculty Education on Conflict of Interest in Research
6. Sanctions for Failure to Report Outside Financial Interests

Before opening the floor to questions, Prof. Neumann called on Clyde Briant, Vice President for Research, to open the discussion. Briant noted that around a year had passed since the COIRB had first suggested holding a Faculty Forum, thinking it good and useful to have faculty input.

The COI policy itself, he said, is very clear, but when the Committee meets, questions do sometimes arise, and the Committee members want to be sure faculty members both understand the policies as the COIRB applies them, and have an opportunity to give input. He noted that Committee concern about these things has heightened in recent weeks, as in August 2011 the NIH revised their regulations concerning financial conflict of interest. The University must be fully compliant with the new regulations by August 2012. Briant pointed out that the discussion concerns ways to promote transparency, and to ensure adequate protection for students working on projects (i.e., that they should not feel hampered because of any COI that a faculty member may have). He reminded listeners that it is of the utmost importance to protect objectivity in research at Brown—a COI should not affect research outcomes. On the other hand, he noted,

there is also an expectation that sometimes faculty members will have conflicts of interest; there is nothing inherently wrong with a COI, and as commercialization of research product increases COIs will continue to arise. The important thing is not so much the fact of the COI, as how it is managed by the process of disclosure to the University and review. Finally, Briant noted that there were a number of members of COIRB present, who would likely participate in the discussion and respond to questions.

Prof. Neumann asked for a show of hands to indicate relative interest in the six topics suggested; having discovered in this way that the first four on the list seemed to hold the greatest interest for those present, he opened the floor for discussion of the first topic.

1. Research Sponsored by an Entity where Faculty Member or Researcher has Significant Financial Interest

Prof. Neumann recognized James Padbury (BioMed Pediatrics), who inquired about what issues had come up in the past year that were difficult for the COIRB to resolve.

Regina White (Chair of COIRB and Associate Vice President for Research , OVPR) answered that, if research is sponsored by a company where a faculty member has a managing interest, or when there is a spin-off of a faculty-created company involved, the research could wind up being funded by a company in which the faculty member has a significant financial interest. Also difficult would be a situation in which the success of the faculty member's company would depend on the outcome of research funded by that faculty member's lab.

Prof. Padbury asked whether those were considered the most common instances, or the most troubling; White replied that they were more a cause for serious thought, because they raised the issue of how to manage them. She emphasized that it was difficult to make a blanket rule, every case being different, and noted that COIRB looks at the circumstances of individual cases, with the goal being responsive and not restrictive management for COIs.

Padbury noted that his own research had been straightforward in terms of COI reporting, despite what he described as circumstances similar to some of what White had just noted.

Regina White replied that the point is that the conflict, or the appearance of any conflict, needs to be monitored and managed; those would be the key things to ensure.

Roberto Tamassia (Chair, Computer Science) suggested that the specific ways the University defines "financial interest" are important. He referred to the current language of the COI Policy, according to which exceptions can be made for compelling circumstances, as for example "when the reported outside financial interest is less than \$10,000 in monetary value, 5% of total value of company or \$10,000 in a publicly traded company." (Brown COI policy, page 12) For example, he said, when the financial interest is in a large publicly traded company like (for instance) Google, if the faculty member has, say, 10K in shares, then accepting sponsored research is not really going to affect the fortunes of that company. However, if the faculty member had 5% of Google's total shares, that would constitute a significant financial interest. For some in the sciences, he said, 10K would not be considered a large amount, so perhaps it makes sense to take

into consideration factors like dollar amount vs. percent of total shares, and whether the company is publicly traded or not. Prof. Tamassia suggested that it might allow the committee to work more easily if the University changed the dollar value denoting “significant financial interest” from, say, 10K to 100K. He suggested that adjusting how financial interest is computed could also make the committee’s work easier, as easing the disclosure requirements in that way could result in fewer cases.

Rod Beresford (Engineering and Associate Provost, COIRB) responded, noting that when a faculty member starts a company it may be small, but its value as it grows has to be monitored if it is the case that the company wants to fund research directly. He described that as a “very fraught situation” and explained that for that reason the Board was interested to hear what faculty members present thought about that kind of situation. He asked what sort of concerns those present had, and what sort of guidelines should exist.

Prof. Beresford also noted that, in the wake of the new regulations, movement will be toward more disclosure rather than less, and the question is rather how the disclosure is done and to whom (for example, whether department Chairs see disclosure forms).

Christopher Bull (Engineering, COIRB) noted that the mandate of the Committee is precisely to deal with the cases that require extra attention, so “the easy cases” do not come to COIRB in any event.

Regina White and several other COIRB members confirmed this, adding that they look at filed reports and see which ones need the Committee’s attention, depending on circumstances.

James Padbury said that Brown should encourage faculty participation in legitimate interactions with industry and also disclose them, that doing so was a mature aspect of the work of a research university.

Lawrence Price (Psychiatry, COIRB) pointed out that the dollar amounts are not random; they follow federal regulations, and in the new NIH regulations the minimum threshold for significant financial interest will be set at \$5,000, so we don’t have a lot of latitude in setting limits on actual dollar amounts, which will depend on the federal regulations.

Ronald Seifer (Psychiatry, COIRB) said that COIRB is a relatively new committee, and as such is still working on articulating principles and a methodology for treating the cases that come to it. Often when a specific case comes to the Committee, the issue winds up being, not the handling of that one case, but rather how to articulate the principles involved in the decision. Sometimes the actual case is one that should be granted an exception, and the Committee recognizes it, but spends time discussing the principles involved anyway, so that there will be guidance in the event of a similar future case. He noted that there have been one or two cases over the four years of the COIRB’s existence where the members were troubled by the content, and said that we should be prepared as an institution to address conflict when it does arise, because the fact of that conflict creates another one, one occurring between faculty member and University (when a faculty member wants to pursue something and the University is in the position of having to say ‘no’).

Peter Shank (Biomed) said that issue is whether a company can fund research of a faculty member who has interest in that company. To override the presumption that it is not a good idea requires that an exception be made.

Rod Beresford added, for example, when it seems that a given lab has a unique talent and is doing something not being done elsewhere.

Prof. Neumann noted that we seem to be talking about a conflict of commitment in some cases, not just a conflict of financial interest.

Jeff Morgan (Biomed, Center for Biomedical Engineering) noted that he saw an internal conflict reflected in the language of the current COI policy. He referred to the section in the COI policy document on Technology Transfer (page 13), which includes the language “to push the boundaries of knowledge,” provide for the public benefit and promote the transfer of technology. He said those positive aspects of the mission were not reflected in other parts of the document, which tend toward what he described as “presumption of guilt until proven innocent.” The effect, he said, was to make the Committee look very risk-averse, and to lead to a presumption of faculty members’ guilt. He suggested that this might be a case of over-managing the situation in the absence of any true data that a COI was actually occurring.

2. CEO Position in a Start-up Company

Jeff Morgan continued, asking about CEOs and start-ups. If a company is large, he said, there is of course no way its CEO could fulfill time commitments both to the University and to the company, but there are also little seedling companies that get started much more easily: you fill out paperwork, and in less than an afternoon you are CEO. He suggested that the Committee look at the issue from the point of view of time commitment. He also noted that there are many other types of situations where a faculty member could be in breach of the time commitment owed to the University. The label “CEO” does not in itself automatically equate to a conflict of time commitment. Seedling start-ups, he concluded, often grow into larger companies, and by having a risk-adverse philosophy, we are essentially discouraging faculty members from the undertaking.

Mark Suchman (Sociology) commented on the question of CEOs, saying that there is a danger in trying to formulate abstract principles that will cover every set of circumstances. The apparent model under discussion here seems to be something like this: science has created something in the lab, and it is something that can go forth and generate a revenue stream. However, there could be other scenarios for start-ups that do not resemble that model. We should be careful that we do not create and apply a set of rules shaped purely around an image of one type of scientific entrepreneurship; it may not be the only useful model. He suggested looking at US-wide data on start-ups to see what the statistics on them are. He gave the example of a start-up that might work along different lines: a polling business that would occasionally hire people every few years. Prof. Suchman concluded by agreeing that we should not make any sort of blanket ruling that CEOs as such definitely create a COI issue.

Prof. Neumann commented that it would seem to be in order to examine the extent of financial and time commitment.

Prof. Suchman inquired about how long a new company should be regarded as a “start-up”? Perhaps operating at a profit for 12 consecutive months?

Jeff Morgan said that there could be other objective data that could substantiate any suggestion of a problem with a faculty member’s time commitment to the University, and the University could get that information without disclosing a business’s confidential financial information.

Peter Shank asked if this was focusing too narrowly on the issue of conflict of commitment, pointing out that any CEO has a fiduciary responsibility to do something that a faculty member does not have.

Prof. Beresford responded that the COIRB is grappling with the issue, noting that extreme cases are easier to deal with than ones in the middle. The Committee understands, he said, that there is a natural evolution between the two extremes; but at what point do we identify what is going on as wrong? Where is the point of changeover? Are there other ways to measure the conflict?

Prof. Morgan responded that that was actually the point he was trying to make: in trying to assess the state of a company, the COIRB might wind up asking for what might be considered confidential information with regard to the company; this in turn can place the faculty member in further conflict over whether or not to share that information on the COI report, as it would be good business practice to keep it confidential. He suggested that we should keep our oversight within the world of the University.

3. Mandatory Disclosure and 4. Department Chair Access to Conflict of Interest Reporting Forms

Rod Beresford asked if the policy should allow the faculty member’s Department Chair access to the COI disclosures.

Prof. Morgan replied affirmatively, saying that that was how the Chair could say if the faculty member was fulfilling his or her responsibilities.

At this point a number of those present raised their hands, asking whether that meant the faculty member’s Chair would have access to a company’s financial information. Several people pointed out that companies have secrets, and in the business world non-disclosure in certain contexts is standard practice.

Katherine Gordon (Technology Ventures, OVPR, COIRB) suggested that in that instance the COIRB, after reading the COI form, could go to the Department Chair for clarification about the faculty member’s work. She said that the CEO issue is whether the faculty member has a fiduciary responsibility to two masters, and whether that puts the faculty member in conflict to his or her fiduciary responsibility to the University; the University needs to know enough to make that decision.

Gerald Diebold (Chemistry) gave examples of cases not involving CEOs that he suggested could constitute COIs: a faculty member shows up for courses and office hours only; the faculty member comes in only to teach classes and does all research at home; or the faculty member does all research away from campus but is very productive. He asked those present what is the difference between someone like that and a CEO who's a "dropout"?

Profs. Bull and Price responded that the point was moot, as COIRB does not look at cases where there is no financial arrangement; the situations just described do not fall under the purview of the COIRB. Prof. Bull added that the COIRB responds to what it sees in the disclosures by faculty.

Prof. Diebold asked if it were not the case that the University was trying to make new policy.

Prof. Bull answered that we were not yet at that point. The current intent is to discuss issues and let people know where policy might be going in the future, given that we are going to have to change some of the ways we do things to comply with the new federal regulations. Those changes will change what faculty members do, and how they are required to disclose it.

Prof. Diebold said that there are cases where the Chair sometimes is the first person to look at conflict of commitment issues and raise them.

Prof. Morgan noted that the Chair's observations could trigger deeper discussion.

Prof. Tamassia was recognized and said that any world-class university should encourage and create an environment for start-ups to succeed. He compared Brown to MIT or Stanford (mentioning the Stanford connection to Google), and wants whatever policy emerges to include language that expresses that encouragement of start-ups. We discourage faculty, he said, when we tell them "we are not MIT." Prof. Tamassia suggested Brown faculty should be polled every year: "which companies did you start up?" He noted that he said as much to the Presidential Search Committee.

Regina White responded, saying that Stanford and MIT are far stricter about COI than Brown; she asked if it was a matter of the language used in the policy statements, saying that Brown actually has the more flexible rules.

Prof. Tamassia answered that it is the perception created by the existing language and the fact of constant queries about COI, rather than asking just as much about what has been created by faculty. There are frequent reminders about filing the COI form, but there is no comparable reminder about technology transfer, for example.

James Padbury opined that transfer is good, and that the previous remark by Jeff Morgan (to the effect that the language of the COI policy should be cast in positive terms, emphasizing things like pushing the boundaries of knowledge and public benefit) should accompany whatever new policy statement results, and would serve as a good preamble for it.

Picking up again the question of whether or not Chairs should have access to the faculty members' COI forms, Gerald Diebold noted that in his department, where nearly everyone in the department has served as Chair, such a rule would mean eventual disclosure to everyone in the department. He pointed out that we already disclose to the Vice President for Research, and asked why it would be necessary.

Dietrich Neumann noted that many departments rotate Chair responsibilities in similar fashion (so it is not a problem unique to one department).

Rod Beresford said the COIRB recognizes that there could be a situation where it is necessary to ask a PI to disclose facts to people working in the lab. Given that this means that students would know, while the Chair would not, this could be potentially problematic.

Prof. Diebold said that the reasoning behind disclosure to students was because they could otherwise be exploited; why, however, did that mean there was a need to disclose to the Chair? What good, he asked, will that do?

Christopher Bull remarked that it might make sense to think in positive terms rather than to assume the worst possible case. He suggested that Prof. Diebold's formulation expressed the worst case idea of "Chair as a busybody," but noted that the policy could be couched in more positive language – the Chair is responsible for the functioning of the department, and the appearance of a real COI could have an affect on how well the department functions.

James Padbury said he was in favor of the Chair knowing, as the Chair has the best understanding of how the faculty member is fulfilling his/her responsibility to the unit and the University.

Mark Suchman asked if there were middle ground: cases when it would be beneficial to consult. He gave an example: say my wife's family has a limited partnership, owning land in central PA; the company leases land for gas exploration, and we get money from it. Some of my colleagues are ardent anti-environmentalists. If I were prospecting for gas, the Chair (in the know) could say: are you aware that you could have a COI by doing this?

Rod Beresford pointed out in that situation the outside activity has no bearing on the work done at Brown, so it cannot be a COI.

Roberto Tamassia said that, as department Chair, he was not asking for more to do, on other hand the Chair is in the best position to evaluate who might be in COI; he is asked to approve every sponsored research proposal. He should know if a faculty member has a financial connection. He noted that the Committee had consulted with him in the past.

Art Landy suggested an addition to Mark Suchman's story: if for example, you are writing political analyses on drilling in PA, then that would mean a COI. It was important, he said, to have the element of transparency, meaning that if you have a financial interest in something you are doing academically, it should be disclosed.

Prof. Suchman responded by asking what portion of that information should come automatically to the department Chair. He confessed himself worried about the possibility of any blanket decision that anything that comes to the Committee also goes to the Chair.

Jeff Morgan responded that the point was almost moot. If, he said, the information that would go to the Chair is the same information that goes to students currently, then that information would be without dollar amounts. He noted that in his own articles he discloses any such connections already, and concluded that one would be giving the Chair access, essentially, to public information.

Rod Beresford asked that, before moving on from the disclosure issue, those assembled commented about submissions to journals. He asked if journals require disclosures of COIs.

James Panbury asked if all journals don't already require disclosure, and Prof. Beresford replied that it was not required across the board in all disciplines.

Regina White and Chris Bull answered that the policy is evolving in the direction of disclosure.

Roberto Tamassia answered that in Computer Science, for example, that sort of disclosure is not done. He noted that if individuals were required to disclose to the COIRB, they would want assurance that those disclosures would be kept confidential.

Prof. Bull noted again that the move was in fact toward more public disclosure of COIs, not less, including the possibility of having information about existing financial interests be available on a publically accessible website.

Prof. Tamassia asked what type of information that might include.

Prof. Bull responded it could be, for example, stating that you have a financial interest in Microsoft, if that was the case.

Regina White noted that next August, NIH will require that if a faculty member has a significant financial interest that has been determined to be a COI, that fact must be either on a publicly available website, or the nature of the COI must be delivered to anyone requesting that information in writing within five days.

Lawrence Price added for the benefit of those in the room not in the life sciences, that many major pharmaceutical corporations already disclose this sort of information, with actual dollar amounts and the nature of the relationship, on their websites; you can go to the given site and see how much each person is pulling in for these activities.

Ronald Seifer pointed out that the reason that sort of information has become publically available in the life sciences is that in some cases conflicts of interest led to abuses at both the intellectual scientific level and in marketing. He suggested that the fact of this having occurred may constitute a good "lesson learned" for other areas of universities' work.

Jeff Morgan urged the University to say that it is a positive thing to start a company, thus putting language the University uses to talk about COI in a better context.

Christopher Bull noted that on the COIRB Art Landy has been struggling to find a new name for the phenomenon of COI, precisely because of the negative connotation of “conflict of interest”; he said that the Committee would be open to suggestions.

5) Faculty Education on Conflict of Interest in Research

Prof. Neumann pointed out that there will be an online education module related to any changes made to the current policy / language.

Roberto Tamassia asked how specifically faculty members were to be educated about the changes, particularly in terms of the key concept “research related to financial interest.” He asked that whatever materials are used for educating provide us with more examples. For instance, what does “related” mean? It’s clear that not black and white, and answers won’t be that simple, but more specific examples or scenarios would be helpful.

Mark Suchman added that giving examples of situations for faculty in different disciplines would help. He added that if the intent is in fact to create something with a positive effect (rather than a cautionary “don’t”), then it would be important to frame educational materials as describing basically positive activities that have a number of important extra precautions involved. Examples: “the technology transfer process;” or “what to do if you want to commercialize an idea.”

Regina White noted that one thing that will happen for NIH-funded people is a change in the understanding of relatedness: it will no longer be just financial interest related to the given research, but any financial interest related to institutional responsibility, and it will be the University that will have to decide whether the interest is relevant to the faculty member’s NIH funded research.

She added that the University will be working with faculty to decide how to do this, noting that there will be an online educational module rolled out. For those funded by NIH, it will be required starting next year, with training every four years for anyone funded by a Public Health Service agency. There will be information and a link available next month.

6. Sanctions for Failure to Report Outside Financial Interests

Regina White said that currently the language about sanctions (if there is a violation of policy) is similar to language connected with violation of other University policies: non-compliance can lead to a series of steps. Those steps are detailed on page 16 of the current COI policy.

Art Landy suggested that in winding up the session talking about sanctions we were ending on the wrong note. He opined that all concerned should be talking about transparency instead, saying that, more than anything, the Committee feels that is hard to do wrong if you are

transparent in your disclosure. He added that this means not just transparency to the Committee, but also transparency to the public; thinking of COI as something that the public is entitled to know, even if you are not profiting from it.

Mark Suchman suggested that doing so could raise a series of other issues. For example, if you go beyond the financial aspect in the definition of conflict, then there could arise a long list of other possible connections whose doings could wind up under the umbrella of potential COI: friends, family members; etc. He wondered if that was where deliberations were headed.

Jeff Morgan inquired about who would mete out any punishment, asking if that were the responsibility of the Committee.

Regina White said that COIRB would make a recommendation to the Vice President for Research, to the Provost or to the President, depending on the nature of the offence and what sanction the Committee recommends.

Prof. Landy added that it has rarely a matter been a matter of an actual offense; more often it has been a question of recalcitrance in disclosure.

As there were no further questions, Professor Neumann thanked all those in attendance for their participation. He adjourned the forum at 5:15 p.m.

Respectfully submitted,

Lynne deBenedette (Slavic Languages)
Secretary of the Faculty Forum