

November 1, 2005

All UCSD ACADEMICS

SUBJECT: Clarification of Principles Related to Conflict of Interest in Research

Dear Colleagues:

The Independent Review Committee (IRC) on Conflict of Interest wishes to clarify principles related to conflict of interest (COI) in research. This communication serves to:

- (1) Alert researchers who have ongoing COI issues that regulations and conflict of interest management are evolving to the point that we consider a clarification necessary (others may regard it as a change). This applies, in particular, to various "small business grants."
- (2) Inform new researchers who may face COI issues in future dealings with the IRC.
- (3) Reassure researchers, whether or not they have COI in their own research, that the campus treats these matters with integrity and discipline.

The University of California maintains high standards for conduct and all UC Investigators are expected to carry out research consistent with these standards. A sensitive situation arises when there is a convergence of an Investigator's private interests with his or her research interests, such that an independent observer might question whether the Investigator's professional actions or decisions are improperly influenced by considerations of personal financial gain. Such conflicts are common in modern research universities and do not necessarily impugn the character or actions of any individual. Nevertheless, they risk serious consequences for both the campus and the individual researcher. Therefore, consistent with State and Federal regulations, it is the policy of the University of California that any Investigator must disclose significant personal financial interests whenever a proposal for funding is made or funding is received. The Campus has determined that the IRC is the appropriate body to review disclosures and recommend to the Chancellor whether funding should be accepted and, if so, whether any conditions are needed to satisfy conflict of interest requirements.

Management of COI is ultimately an administrative matter in that the campus acts for the Regents to accept funding on behalf of University employees. The Chancellor appointed the IRC to assist with this responsibility, and the IRC attempts to act in the best interest of the campus as a whole. Although the IRC is not primarily an ethics committee, it hopes to be sensitive to universal ethical standards and academic traditions, so that financial interests do not compromise objectivity in the manner in which projects are designed, conducted, or reported. However, in reality, the IRC is concerned with compliance of two laws: one State law and one Federal law. These laws place very explicit requirements on the University. In essence, they state that the campus cannot accept money, services, or goods to support research or other scholarly activity by any individual who might have, or even appear to have, a significant financial interest in the outcome of the research. "Significant" refers to equity in an enterprise (more than 5% ownership per the federal law or an investment of \$2,000 or more according to State law), income (more than \$10,000 per year for the federal law, but only \$500 per year for the state law), or management responsibility (because even if there is no current income or ownership, such could be conferred later).

The role of the IRC is basically judicial. It acts, first, as a jury of peers in determining whether a COI exists. In some cases, there is no relation between research proposed and the financial interests of a researcher, despite initial appearances. It is appropriate that such determinations made by an academic committee both as peers and because some cases require considerable technical insight. Secondly, the IRC acts somewhat as a judge, advisory to the Chancellor, in suggesting appropriate mitigation strategies when COI exists.

Laws and regulations designed to separate academic research from for-profit activities may appear to contradict legislation requiring the dissemination of University technology to stimulate economic activity. The University seeks cooperative research relations with industry, but researchers must not divert their energies from academic

responsibilities to pursue commercial activities. Many of us in academia might argue that researchers who believe in their research are likely to be the most effective in disseminating the resulting technology. How does the University resolve this conundrum? Interpreted strictly, conflict of interest laws and regulations place severe restrictions on the campus and its investigators. Some of our colleagues certainly do feel restricted. Many more benefit from the fact that the laws allow a certain latitude. If the campus has in place policies to eliminate the two risks of COI (unjustified financial profit and debased research integrity), then the campus may accept a grant for the benefit of a researcher who might initially appear to have a COI. The practices that make this possible are called “mitigating” and “managing” a COI. Seen in this light, the IRC exists not to stop research, but to make more research possible by putting management strategies in place.

The website [http://ocga3.ucsd.edu/robo/projects/cgaweb/COI/COI\\_Overview.htm](http://ocga3.ucsd.edu/robo/projects/cgaweb/COI/COI_Overview.htm) explains many of the issues involved in managing COI. See especially “Examples” to learn about the IRC. Any researcher who might even remotely risk COI should consult this site. Note, however, that the IRC and the campus are well aware that every case is different and no one’s research is ever forced into “one-size-fits-all” mitigation.

It is important to distinguish COI, which deals with financial matters and is sensitive also to public perception and appearances, from Conflict of Commitment (COC), which deals with the need to ensure that outside activities do not interfere with doing one’s job for the University. Some activities contravene both COI and COC. There are other activities that are acceptable from the view of COC but forbidden by COI rules, for example, memberships on certain Boards of Directors. There are other activities that might be acceptable from a COI standpoint but be disallowed by COC rules, for example, excessive consulting not related to any specific grant.

The following five matters are of particular current interest, arising in part due to recent events beyond the campus.

1. **Disclosure.** Senior officials at NIH have been castigated over the past two years for failure to disclose that they either held equity in drug companies or were consultants to drug companies. Legislators expressed outrage. This had a trickle down effect. The senior NIH officials decided to enforce rigid new rules not only on themselves but also on all internal NIH researchers. These rules are much more restrictive than the rules for universities. So far, they have not proposed extending those rules to outside grant recipients, but it might take only one embarrassing scandal to make that happen. Of particular note, the NIH policy does not tolerate any narrow interpretation of one’s NIH activity. They define “related business activity” to mean anything in health care. This heavy-handed treatment of thousands came about because a handful failed to disclose. The IRC believes that disclosure is an important defense against charges of COI and must be enforced rigorously. This policy of requiring disclosure has also been enacted by most scientific journals. We should all make it a habit to disclose all business relationships in publications, even if we are not under active management for COI.
2. **Equity ownership.** Ownership of more than 5% in any business is taken to imply that an investigator will want to ensure the welfare of that company, has enough influence to direct company interests, and has a strong temptation to transfer to the company intellectual property that is properly owned by others, as specified by the award. Almost always, when one starts a company, one owns more than 5% of it. Ownership by a spouse, dependent children, or a registered domestic partner is identical to ownership by the researcher. This means that as soon as one starts a company, federal and state laws prohibit receiving more money to work in the same area—unless the IRC can recommend a management strategy. A rationale that might be invoked in some instances for early stage start-up companies is that more than 5% of nothing represents no significant financial interest. The public interest in bringing the results of research to the marketplace might also argue for a temporary exception. However, as soon as companies have real value, the researcher-entrepreneurs face a decision. They must either commit to growing the company and resign from the University or they must return to professorial activities and turn over the business to others. They must reduce equity below 5% and may have to limit consulting activity. (Even before this, they must not be part of the company management as defined below.)

3. **Management.** Management positions in a company impose ethical and legal responsibilities to act in the best financial interest of the company, which could result in a conflict with ethical and legal requirements to the University and to the sponsor of a research grant. The appearance of a separation of responsibilities—and a real separation in fact—must be maintained. Even when an exception to the 5% equity limit is made, it is almost never possible for a grant recipient to hold a management position. This includes not only titles like president, CEO, etc., but also the title of Chief Scientific Advisor or membership on a Board of Directors (BOD). (Mere membership on a scientific advisory board is often deemed permissible.) Scandals involving Enron and other corporations in recent years led to ridicule when Directors tried to claim they did not know what the business was doing. Note that this COI limitation exists despite the fact that COC rules permit (with prior approval by the appropriate Dean) membership on a BOD.
4. **Consulting.** It is generally permissible to consult in one's area of expertise while receiving federal grants. However, there are limits on consulting for one's own company when receiving funding from the company or from federal sources for research that may be beneficial to the company, as well as other specific exceptions. One such exception is the following: It is absolutely forbidden for an investigator with any responsible role in a clinical trial involving human subjects to have at the same time any interaction with the company that produces the product or service being tested. It is difficult to imagine why any company would risk having the public learn that someone conducting a clinical trial of their product was being paid by them during the trial, or was even consulting without pay. There is no question that the public would find such research tainted. The difficulty is that researchers may believe that their work with human subjects is actually some distance away from the final trials of a specific product. There are occasional instances in which the IRC would agree; but the argument is only acceptable for very clear, rather extreme cases. Typically, such a case involves no treatment of patients but only the use for research of human tissue samples or diagnostic assays that are archival in nature and anonymous to the researchers. If there is any risk of public misunderstanding and scandal, possibly due to mistaken or unethical reporting, the University must protect itself by enforcing the rule that there is to be "no consulting during human trials." (In principle, a similar problem could occur outside medical trials, but is very rare elsewhere not only because human medicine is particularly sensitive to bad publicity, but also because there are few other areas in which new products are tested by academic centers before being marketed.)
5. **Small Business Grants.** There are several federal and state programs that require a University researcher to collaborate with a private company (specifically, a "small business") to be eligible for funding. These are designed to speed transfer of academic research into the private sector. These are appealing because money is often more readily available in such programs than elsewhere. Ironically, starting a business may make one ineligible to apply for these grants. Conflict of interest is almost inescapable whenever a campus researcher owns a small business and there is a proposal for one of these types of grants. It is not permissible to use the campus as the locale for company research and development. The cruel fact is that the government did not intend to help professors start businesses. It intended to encourage professors to assist existing companies that have an independent life of their own. The campus has struggled with this, and the result has recently been codified. The lax management and mitigation strategies that were sometimes permitted during a few years while all parties grappled with the implementation of COI are no longer permissible. If a UC employee chooses to start a company, then that individual may not apply for any of these grants as both the small business and the University subcontractor. It is acceptable, of course, to construct a proposal in which the UC side of the grant is under real control by other UC researchers who are not involved with the company. This will be a difficult area in the next few years. A summary of the current requirements for small business grants follows: (1) The Principal Investigator (PI) for the small business and the PI for the UCSD subcontract must be different individuals. (2) The management individuals at the business must not be UCSD employees. (3) The UCSD participants, and their families, must not have significant ownership in the business. (4) The business must propose a scope of work that is a significant portion of the entire proposal (50% or more). (5) The business must have functioning research space independent of UCSD. (6) The entire proposal must be submitted for review, not just the UCSD subcontract. (7) There must be some clear distinction between the work done by the business and that done by UCSD. (8) UCSD employees paid by the grant may not also be paid employees of the company, apart from consulting that is covered by consulting agreements acceptable to the campus.

The IRC encourages all members of the University research community to be sensitive to the potential impacts of conflict of interest on the conduct of research. If there are issues of particular concern, please do not hesitate to contact the Conflict of Interest Office at x46465.

Sincerely,

A handwritten signature in black ink, appearing to read "Douglas Magde".

Douglas Magde, Co-Chair  
Independent Review Committee

A handwritten signature in black ink, appearing to read "Nick Spitzer".

Nick Spitzer, Co-Chair  
Independent Review Committee