



OFFICE OF THE PROVOST AND SENIOR VICE PRESIDENT—
ACADEMIC AFFAIRS

OFFICE OF THE PRESIDENT
1111 Franklin Street
Oakland, California 94607-5200

October 11, 2004

**VICE CHANCELLORS FOR RESEARCH
CAMPUS CONFLICT OF INTEREST COORDINATORS**

Dear Colleagues:

I am writing to follow up on a matter discussed last year at a meeting of the Council of Vice Chancellors for Research (COVCR) regarding the application of California financial interest disclosure regulations to Material Transfer Agreements (MTAs). As you will recall, a number of campus Conflict of Interest coordinators wrote to me on August 21, 2003, asking that the Office of the President rescind the advice to campuses that Principal Investigators may be required to file a Statement of Economic Interest (Form 700-U) in connection with receiving research support through Material Transfer Agreements.

After further consultation with the Office of General Counsel (OGC), we concluded that withdrawing the original advice is not warranted. Although I mentioned this briefly to the COVCR, I wanted to follow up with this letter, which I hope will provide clarification regarding the limited circumstances under which filing a Form 700-U in connection with an MTA is required.

The original advice to campuses was issued through transmission of a February 18, 2003 memorandum from Ross Smith, Coordinator of Information Practices and Conflict of Interest for the Office of General Counsel. Mr. Smith stated that if materials of value from a nongovernmental entity are received by the University and earmarked for a specific research project or investigator, the investigator should complete a financial interest disclosure form in accordance with the Fair Political Practice Commission's Academic Decision Regulation (Cal.Code Regs., Title 2, § 18702.4(c)). The Academic Decision Regulation governs financial interest disclosure in sponsored research conducted in California's public universities.

After hearing from campuses concerned about this issue, the Office of Research asked the Office of General Counsel for clarification regarding the applicability of the Academic Decision Regulation to MTAs. Maria Shanle, University Counsel, prepared a response and her memo to the Office of Research is enclosed.

Ms. Shanle concluded that Mr. Smith's original analysis is correct and that the provision of materials under an MTA is not excluded from the disclosure requirements of the Academic

Decision Regulation. She concurs that the filing of a financial interest disclosure may be required in certain MTA transactions, and clarifies that not every MTA automatically requires a financial interest disclosure. Under the Academic Decision Regulation, disclosure is required only “in connection with a decision made by a person or persons at an institution of higher education with principal responsibility for a research project to undertake such research.” Therefore, MTAs that are not made “in connection with a decision . . . to undertake . . . research” do not trigger the financial interest disclosure requirement.

We must rely on the legal advice rendered by OGC to provide guidance to the campuses on how to apply state financial interest disclosure rules to MTAs. **Based on the legal advice from OGC, an MTA only triggers a requirement to file a Form 700-U financial interest disclosure if all of the following criteria are met:**

1. **The MTA is entered into “in connection with a decision to . . . undertake research.”** This is the most important criterion limiting the applicability of state financial interest disclosure requirements to MTAs. Indeed, the campus Conflict of Interest coordinators noted in their letter their belief that the decision to undertake research is rarely made in connection with the decision to acquire research samples from a particular provider. Presumably, in many cases, the decision to undertake research is made well before the receipt of materials through an MTA is even contemplated. However, where a researcher can reasonably anticipate the use of an MTA to obtain materials from a specific entity at the time of the decision to undertake research, a Form 700-U should be filed.
2. **The MTA is between UC and a non-exempt nongovernmental entity.** OGC specifically noted that financial disclosure via a Form 700-U is not required if the MTA is:
 - a. between UC and an individual, e.g., an individual researcher;
 - b. between UC and a governmental entity, e.g., a state university;
 - c. between UC and a nongovernmental entity that is deemed exempt from researcher disclosure by the Fair Political Practices Commission.
3. **The University does not pay for the material acquired through the MTA.** OGC specifically noted that financial disclosure via a Form 700-U would not be required in cases where the University pays for the material.

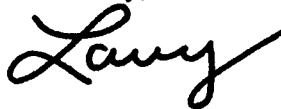
With respect to the first criterion listed above, we acknowledge that it may be difficult to distinguish between an MTA that is entered into “in connection with a decision to . . . undertake research” and an MTA that is not. We invite you to consult the Office of Research and the Office of General Counsel when you need assistance in making such decisions. The Office of Research will track your queries and, if needed, work with OGC to provide more detailed guidance regarding how to handle financial interest disclosure in connection with MTAs.

The Office of Research recommends that campuses, if they have not already done so, establish a process to capture investigator financial interest in non-exempt nongovernmental entities that

support research through MTAs when the MTA is entered into in connection with a decision to undertake research. Some UC campuses employ an MTA checklist or questionnaire to gather information from the investigator before drafting an MTA. If it does not already, the questionnaire should include a question about investigator financial interests in the organization providing the material. The campus could then explore with the investigator the circumstances of that financial interest and whether a 700-U statement is required. Campuses may wish to consider whether there are circumstances giving rise to heightened concern in which filing of a 700-U form should generally be required – such as when an MTA supports human subject research, or research in which the principal investigator has a pattern or history of conflict of interest arising from relationships with nongovernmental research sponsors.

As you well know, academic research institutions are operating in an environment of heightened scrutiny for conflict of interest in sponsored research. The above recommendations attempt to meet that scrutiny with processes that are reasonable and not onerous. Your role in preserving the integrity of research at UC is essential and is much appreciated. We look forward to working with you on this issue.

Sincerely,



Lawrence B. Coleman
Vice Provost for Research

Enclosure

cc: Provost Greenwood
University Counsel Shanle
Coordinator Smith
Executive Director Auriti
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February 17, 2004

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PRINCIPAL ANALYST REBECCA LANDES
Office of Research

Re: Conflict of Interest Issues Related to Material Transfer Agreements (MTA's)

This memo is intended to supplement the advice provided to your office on this subject by Ross Smith in a memo dated February 18, 2003 ("OGC Memo"). The question originally posed to the Office of the General Counsel was whether materials provided to the University through a Material Transfer Agreement (MTA) for a research project would initiate the filing of a Statement of Economic Interests, Form 700-U. The OGC Memo concluded that the provision of materials under an MTA is not excluded from the disclosure requirements of the academic decision regulation, and thus may trigger the filing of a Form 700-U. This analysis has apparently created some concern on the campuses, resulting in a letter dated August 21, 2003, to Vice Provost Coleman.

This memo briefly addresses the arguments raised in the August 21, 2003 letter to Vice Provost Coleman, and concludes that the original analysis in the OGC Memo was correct. However, the letter to Vice Provost Coleman also highlights an apparent misunderstanding at the campus level regarding the implications of the OGC Memo, which this memo is intended to clarify.

1. Materials Provided to the University Through a Material Transfer Agreement are Not Exempt from the Disclosure Requirements of the Academic Decision Regulation

The Fair Political Practices Commission (FPPC) adopted an academic decision regulation (Cal. Code Regs., tit. 2, § 18702.4(c)), which provides in part:

(c)(2) Disclosure shall be required...in connection with a decision made by a person or persons at an institution of higher education with principal responsibility for a research project, to undertake such research, if it is to be funded or supported, in whole or in part, by a contract or grant (or other funds earmarked by the donor for a specific research project or for a specific researcher) from a nongovernmental entity....

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The OGC Memo concluded that the phrase "funded or supported" contemplates all circumstances where assets are provided in support of the research, whether those assets are cash, or other "in-kind" donations such as equipment, materials, etc. This conclusion is based on a straightforward interpretation of the plain meaning of the language of the regulation. Because "in-kind" support of research meets the "funded or supported" criteria of the regulation, materials provided to the University pursuant to a Material Transfer Agreement (MTA) may also meet the "funded or supported" criteria. The provision of materials, such as a cell line, given to the University for research (whether or not provided through a Material Transfer Agreement) meets the "funded or supported" criteria of the regulation.

Therefore, where research is funded or supported by the provision of materials under an MTA, and where the other criteria of the academic decision regulation are met (see discussion below), the person(s) with principal responsibility for the research project must file a Form 700-U.

The August 21, 2003 letter to Vice Provost Coleman argues that the provision of materials for research under an MTA is not subject to the disclosure requirements outlined above in Section 18702.4(c)(2) of the regulations, but rather is exempt from the disclosure requirements by virtue of falling under the exemption of Section 18702.4(c)(1)(B) of the regulations. As the letter points out, Section 18702.4(c)(1)(B) exempts certain academic decisions from the disclosure requirements:

(c)(1)(B) Decisions made by a person who has teaching or research responsibilities at an institution of higher education to pursue personally a course of...research, to allocate financial and material resources for such...research, and all decisions related to the manner or methodology with which such study or research is to be conducted...

This memo does not address whether provision of material under an MTA is subject to Section 18702.4(c)(1)(B), because that is irrelevant to the question of whether the disclosure requirements of Section 18702.4(c)(2) are applicable. The language of Section 18702.4(c) states that: "Except as provided in subsection (c)(2), neither disclosure...nor disqualification is required..., in connection with" subsections (c)(1)(A) and (c)(1)(B). This structure makes it clear that subsection (c)(2) functions as an exception to the provisions of subsections (c)(1)(A) and (c)(1)(B). In other words, if subsection (c)(2) requires disclosure, that trumps an exemption from disclosure under subsection (c)(1)(A) or (c)(1)(B). Therefore, the August 21, 2003 letter to Vice Provost Coleman is not correct in its analysis that subsection (c)(1)(B) trumps subsection (c)(2).

Because provision of material under an MTA is subject to disclosure requirements under Section 18702.4(c)(2), in such a case where the other criteria of the academic decision regulation are met

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(see below), the person(s) with principal responsibility for the research project must file a Form 700-U.

2. Only MTA's Meeting All of the Criteria of the Academic Decision Regulation Require the Filing of a Form 700-U

The August 21, 2003 letter to Vice Provost Coleman appears to interpret the OGC Memo to mean that every MTA would automatically trigger the filing of a Form 700-U. However, the OGC Memo addressed only the "funded or sponsored" criteria of the regulation, and concluded that the provision of materials through an MTA was not excluded from the definition of "funded or supported." The OGC Memo was not intended to imply that an MTA would automatically meet all of the other criteria of the regulation.

A Form 700-U is only required "in connection with a decision made by a person or persons at an institution of higher education with principal responsibility for a research project to undertake such research," where the research is "funded or supported by a contract or grant (or other funds earmarked by the donor for a specific research project or for a specific researcher." (Section 18702.4(c)(2)).

There is little guidance regarding the interpretation of the phrase "in connection with a decision...to undertake such research." This phrase is somewhat vague, and may depend on factors such as timing of the MTA in relation to the decision to undertake research, etc. This memo will not attempt to define those circumstances which would meet this criteria, but rather simply concludes that MTA's which are not made "in connection with a decision...to undertake such research" would not trigger the filing of a Form 700-U. If the campuses need additional assistance in analyzing which MTA's would meet this criteria, the Office of the General Counsel would be happy to provide such additional advice.


There are additional circumstances under which an MTA might not meet the criteria for triggering the filing of a Form 700-U. For example, if the University paid for the materials, the research would not be considered to be "funded or supported" by the MTA. In addition, in order to trigger the filing of a Form 700-U, the materials would have to come from a "nongovernmental entity," and not an individual. Therefore, where the materials are provided by: (1) an individual (such as an individual faculty member at another institution, who is not considered to be an "entity"); (2) by a state public university (which is not considered to be a "nongovernmental" entity); or (3) by an entity specified in the exempt nongovernmental sponsors list, the MTA would not trigger the filing of a Form 700-U. Note that this distinction between individuals and entities relates only to the origin of the materials, and not the recipient of the materials – the University should generally be the recipient of materials under an MTA, not an individual University researcher.

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I hope that this memo is helpful in clarifying the earlier OGC Memo and the apparent misunderstanding which was engendered. Please feel free to contact me with additional questions.


Maria Shanle
University Counsel

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cc: E. Auriti
D. Birnbaum
L. Coleman
M. Simpson
R. Smith