UNIVERSITY OF CALIFORNIA

BERKELEY · DAVIS · IRVINE · LOS ANGELES · MERCED · RIVERSIDE · SAN DIEGO · SAN FRANCISCO

SANTA BARBARA · SANTA CRUZ

OFFICE OF THE PROVOST AND SENIOR VICE PRESIDENT —
ACADEMIC AFFAIRS

OFFICE OF THE PRESIDENT
1111 Franklin Street, 12th Floor
Oakland, California 94607-5200

February 10, 2009

VICE CHANCELLORS FOR RESEARCH

Re: ORGS Guidance on Research Consent Form Disclosures

Dear Colleagues,

The Office of Research & Graduate Studies (ORGS) at the Office of the President has drafted two guidance documents on disclosures to human subjects in research consent forms. The first guidance provides model language to advise subjects concerning property rights to research inventions, based on the California Supreme Court opinion in Moore v. Regents. The second guidance provides model language for disclosure of investigator and institutional financial interests that may be relevant to the study. The guidance documents are enclosed for your review and comment.

I. Guidance on Moore v. Regents

In Moore v. Regents, the California Supreme Court held that research subjects do not have a property right to bodily specimens taken during research or to profits stemming from the development of products based on those specimens, and that subjects must be advised of personal interests of researchers in order for consent to be fully informed. Moore was decided in 1990; in an analysis of the decision, the Office of General Counsel recommended that the campus human research protection programs include language in consent forms that advises subjects of the Court's holding. The campuses have individually crafted disclosure language but there is an absence of clarity and consistency across the campuses in this matter. Accordingly, ORGS has prepared the enclosed guidance document.

The Moore decision concerns the absence of a legal right. The federal regulations on informed consent prohibit exculpatory language in the consent form whereby the subject is made to waive legal rights including property rights. The federal Office for Human Research Protections, however, has accepted such language in those jurisdictions, such as California, where the courts have held that a property right does not exist.

II. Guidance on Disclosure of Investigator Financial Interests

The second enclosed guidance provides model language to disclose both individual and certain institutional financial interests relevant to the study. It addresses the Moore Court's decision that subjects must be advised of personal interests of researchers in order for consent to be fully

informed. It also responds to increasingly vocal calls by legislators, regulators and funding agencies for disclosure to subjects of outside financial interests.

To arrive at the model language, ORGS consulted with campus IRB Directors, COI Coordinators, Licensing Officers and other compliance staff. ORGS also researched disclosure language used by other academic institutions, and reviewed guidance issued by federal agencies such as OHRP and by university associations such as AAMC. There is a broad range of disclosure options; some institutions employ a very brief statement on investigator financial interests in their consent forms and direct the subject to inquire if they want more information, others go so far as to disclose the actual amount of the outside interest. We chose a middle ground, recommending that campuses disclose the type of financial interest held by the investigator. There are myriad types of individual interests that an investigator or research team member may hold; the list in the guidance is not exhaustive.

As to institutional interests, ORGS recommends that the campuses disclose licensing and equity interests where such interests are relevant to the study. Institutional licensing and equity interests are listed in the Operational Tools database maintained by the UCOP Office of Technology Transfer and are accessible to campus licensing officers. We acknowledge that obtaining such information for every human research study may pose a resource issue for the campuses. Nevertheless we believe it is critical that these interests be disclosed, particularly in light of the current focus by Congress and by funding agencies on conflict of interest in research. Enclosed is a memo with proposed processes for collecting institutional financial interests for the consent form.

I solicit your comments on the enclosed and ask that you forward them to Rebecca Landes in my office by February 27, 2009. I also invite you to share the draft guidance documents with your staff and/or counsel for their input. If you have questions, please contact Rebecca at rebecca.landes@ucop.edu or 510-987-9556.

Sincerely,

Steven Beckwith
Vice President for Research & Graduate Studies

Enclosures

cc: Chair Mary Croughan, Academic Senate
University Counsel Joanna Beam
Executive Director Ellen Auriti, ORGS
Coordinator Rebecca Landes, ORGS

University of California Office of the President

Office of Research & Graduate Studies

Guidance Memorandum

January 21, 2009

Use of Specimens (Moore Clause) Disclosure in the Research Consent Form

In **Moore v. Regents of the University of California,** 51 Cal. 3d 120; 271 Cal.Rptr. 146; 793 P.2d 479 (1990), the California Supreme Court held that:

1) An individual undergoing a medical procedure must be advised of any personal interests of the physician/researcher unrelated to the individual's health, such as a research interest, that may affect the physician's medical judgment; and

2) A research subject does not have a property right to bodily specimens taken during research or to profits stemming from the development of products based on those specimens.

The first requirement is addressed in part by disclosing financial interests in the consent form, discussed in Office of Research guidance at *[link]*. The second item, that a subject does not have a property right to profits stemming from products developed from bodily specimens, is a point of information that should be disclosed to the subject in the consent form so that he or she can make an informed decision about participating in the research.

Accordingly, the below paragraph should be included in the consent form for medical research if bodily specimens will be taken from the subject and if they may be used for research and development purposes not related to the subject's treatment or condition. If the research is not medical, or if bodily specimens will not be taken from the subject, the following language need not be included:

> **"If specimens, such as blood or tissue, are taken from you for this study, they will become the property of the University of California. The specimens may be used in this research, may be used in other research, and may be shared with other organizations. The specimens could lead to discoveries or inventions that may be of value to the University of California or to other organizations. Under state law you do not have any right to money or other compensation stemming from products that may be developed from the specimens."**

University of California Office of the President

Office of Research & Graduate Studies

Guidance Memorandum

January 21, 2009

Financial Interest Disclosure in the Research Consent Form

I. Background

The increase in financial relationships between research institutions, investigators and research funders has led to calls for greater disclosure to human subjects of these relationships. Congress,[1] government agencies,[2] courts of law,[3] and professional associations[4] have all taken the position that, in order for a research subject to be able to give a consent that is fully informed, they should be advised of relevant financial interests of investigators and research institutions.

Accordingly, the Office of Research & Graduate Studies offers model language for UC campuses to employ in disclosing to subjects financial interests of members of the research team and of the University. The model language provided below does not attempt to address every type or nuance of outside financial interest that an investigator may have. The campus is encouraged to address the specifics of the situation as completely and clearly as possible in the consent form.

As to University financial Interests, it is recommended that the campus disclose licensing agreements for University inventions and University equity positions in licensees if these are relevant to the study. Information on licensing and equity is available from the Operational Tools database maintained by the UCOP Technology Transfer Office at http://ucop.edu/ott/staff/special.html. While retirement funds and other University investments may be considered an institutional financial interest, they need not be disclosed because of the virtual firewall between research decisions at the campuses and investment decisions by the UC Treasurer.

---

[1] Meier, Barry. (2008, Oct. 17). Senators Question Financial Ties Between Doctors and Stent Manufacturers. *The New York Times.*

[2] OHRP, *Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection,* http://www.hhs.gov/ohrp/humansubjects/finreltn/fguid.pdf

[3] Moore v. UC Regents, *793 P.2d 479 (Cal. 1990)*

[4] AAMC, *Protecting Subjects, Preserving Trust, Promoting Progress I: Policy and Guidelines for the Oversight of Individual Financial Interests in Human Subjects Research*, December 2001; *Protecting Subjects, Preserving Trust, Promoting Progress II: Principles and Recommendations for Oversight of an Institution's Financial Interests in Human Subjects Research*, October 2002, http://www.aamc.org/research/coi/start.htm

II. Model Disclosure Language

A. No Disclosable Financial Interest – Under UC policy, certain members of the research team must report whether or not they have a financial interest in the research. If no one on the study team has a reportable financial interest in the research, no disclosure in the consent form concerning personal financial interests is required.

B. Disclosable Financial Interest – If a member of the research team reports a financial interest in the research, language such as the following should be included in the consent form. Guidance is in *italics*, proposed language is in **bold**.

1. ***Name and role*** *- Provide the name of the person with the financial interest and describe their connection to the study, e.g.,*
   Dr. Jane Doe, a researcher on the study team,
2. ***Interest in an entity or in the product***
   a. *If the interest is in an entity such as the* ***sponsor, manufacturer, licensee,*** *or* ***performer,*** *e.g.,* ***sub-contractor,*** *language such as the following should be included:*
      has a financial interest in _____ *[name of company],*
      the company *paying* for this study; *or*
      the company that will *manufacture* the drug; *or*
      the company that will *sell* the drug; *or*
      a company *conducting* part of this study.
   b. *If the interest is* ***other than a financial interest in an entity****, e.g., in the product being tested, language such as the following should be included:*
      has a financial interest in the *[product, drug, device]* **being studied.**
3. ***Description*** *- Describe the interest; below are examples of language you can use.*
   - *Income -*
     _____ *[name of company and relevance of company to study, e.g., sponsor]*
     is paying Dr. Doe a _____*[describe payment, e.g., consulting fee, salary].*
   - *Scientific Advisor -*
     Dr. Doe is being paid to be a scientific advisor to _____ *[name of company, relevance of company to study, e.g., manufacturer of the drug]*
   - *Member of the Board -*
     Dr. Doe is on the board of _____ *[name of company, relevance of company to study]*
   - *Officer -*
     Dr. Doe is the *[president, chief executive officer, etc.]* **of** _____ *[name of company, relevance of company to study]*
   - *For significant stock ownership in a publicly traded company -*
     Dr. Doe owns stock in _____ *[name of company, relevance of company to study]*
   - *For stock ownership in a non-publicly traded company -*
     Dr. Doe is a [*founder or majority or minority shareholder]* **of** _____ *[name of company, relevance of company to study]*
   - *For stock option -*
     Dr. Doe has a stock option from _____ *[name of company, relevance of company to study]* **and may get income in the future.**
   - *Inventor –*
     Dr. Doe invented the *[drug, device]* **being studied and may benefit financially if it is marketed.**

4. ***Elaborate*** *- If possible, elaborate on the information provided, e.g.,* **The consulting income Dr. Doe receives is in addition to her salary from the University of California.**

C. Licensing or Equity Interests of the University – If UC does not have a relevant licensing or equity interest in the research, no disclosure in the consent form concerning institutional financial interests is required. If UC has a relevant license or equity interest, language such as the following should be included in the consent form. Information concerning licensing agreements and equity interests is available from the Operational Tools database maintained by the UCOP Technology Transfer Office.

1. *Inform the subject that UC has a financial interest:*
   The University of California has a financial interest in this study.
2. *Describe the interest.*
   - *License -*
     The University has granted a license to _____ *[name of company]* **to develop the** *[drug, device]* **being tested in this study. If the** *[drug, device]* **proves to be safe and effective, the University could receive a part of the profits from sales of the** *[drug, device].*
   - *Equity -*
     As part of the licensing arrangement, the University owns stock in _____ *[name of company],* **the manufacturer of the** *[drug, device]* **being tested. This means that the value of the University's stock could go up or down depending on the results of the study.**

D. Opportunity for the Subject to Get More Information – *Provide the following language or a name and contact information for the subject to get more information.*

> **If you have questions, tell the study coordinator and they will put you in touch with someone to talk to.**

E. Sample Disclosure Paragraph – *Based on the above, a scenario in which an investigator on the study has received money for consulting from the study sponsor and the University has licensed development of the drug to the sponsor and has taken equity in lieu of partial payment for the license, would have the following disclosure language:*

> **"Dr. Jane Doe, a researcher on the study team, has a financial interest in XYZ, Inc., the company paying for this study. Dr. Doe is a consultant for XYZ, Inc. The consulting fee Dr. Doe receives is in addition to her salary from the University of California.**
>
> **"The University of California also has a financial interest in this study. The University has granted a license to XYZ, Inc. to develop the drug being studied. As part of the licensing arrangement, the University owns stock in XYZ, Inc. This means that the value of the University's stock could go up or down depending on the results of the study.**
>
> **"If you have questions, tell the study coordinator and they will put you in touch with someone to talk to."**

University of California
Office of the President

Office of Research & Graduate Studies

Memorandum

DATE: January 21, 2009

TO: Vice Chancellors for Research

RE: **Campus Process for Collecting Information on Institutional Financial Interests for Disclosure in the Informed Consent Form**

In a separate guidance memorandum, the Office of Research & Graduate Studies offers the campuses model language for the informed consent form for disclosure of individual financial interests of investigators and equity and licensing interests of the University. Information on UC's equity and licensing interests is available from the UCOP Office of Technology Transfer's Operational Tools database at http://ucop.edu/ott/staff/special.html.

In preparing the guidance, in particular the section on disclosing University equity and licensing interests, the Office of Research & Graduate Studies consulted contracting officers, licensing officers, COI Coordinators, and IRB Directors, and explored with these research administrators the information channels that could be utilized in conveying information on University licensing and equity interests from the Operational Tools database to the research consent form. The suggested processes below stem from those conversations. Of course each campus will have to develop its process individually based on its unique contracting and licensing structures, and its resources and staffing. The Office of Research & Graduate Studies is available to work with the campuses on developing a process that works in the framework of the campus' structure and resources.

The following are suggested alternative processes for obtaining and disclosing licensing and equity information from the Operational Tools database:

- **C&G → Licensing → COI Coordinator → Consent Form Drafter** – Contracting Officer asks Licensing Office to search the Operational Tools database for the name of the sponsor or the manufacturer of the drug or device being studied. Licensing Officer notifies Contracting Officer of results. If the OTT Operational Tools database reveals a licensing arrangement with, or equity interest in, the sponsor or manufacturer of the drug or device being used in the study, the Contracting Officer consults with the COI Coordinator as to relevance. If it is a relevant interest of which the subject should be informed, Contracting Officer notifies the consent form drafter, e.g., investigator, study coordinator.

- **C&G conducts preliminary review → Licensing conducts in-depth review → C&G → COI Coordinator → Consent Form Drafter** – Contracting Officer conducts a preliminary review of the OTT Operational Tools database to see if the sponsor is in the database. If yes, Licensing Officer conducts an in-depth review as above, notifies Contracting Officer who consults with COI Coordinator and who notifies consent form drafter, e.g., investigator, study coordinator.

1111 Franklin Street, 11th Floor
Oakland, CA 94607
Tel: (510) 987-9438

- **C&G → Licensing Consultation → COI Coordinator → Consent Form Drafter** – Contracting Officer has access to Operational Tools database and conducts search, consults with Licensing Officer and COI Coordinator, notifies consent form drafter, e.g., investigator, study coordinator.

- **IRB → Licensing Consultation → COI Coordinator → Consent Form Drafter** – IRB staff has access to Operational Tools database and conducts search, consults with Licensing Officer and COI Coordinator, notifies consent form drafter, e.g., investigator, study coordinator.

End

1111 Franklin Street, 11th Floor
Oakland, CA 94607
Tel: (510) 987-9438