

Subject: Financial Interest Disclosure in the Research Consent Form

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 agencies², courts of law,³ and professional associations⁴ have all taken the position that, in order for research subjects 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, intended as guidance, 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 Innovation Alliances Services 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.

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.

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://w.hhs.gov/ohrp/humansubjects/finreltn/fquid.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 11: Principles and Recommendations for Oversight of an Institution's Financial Interests in Human Subjects Research*, October 2002, <http://w.aamc.org/research/coi/start.htm>

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., subcontractor, 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 the UC campus has identified 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 Innovation Alliances Services office. Guidance is in *italics*, proposed language is in **bold**.

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 a private company to develop the [drug, device] being tested in this study. If the [drug, device] proves to be safe and effective, the University could financially benefit from sales of the [drug, device].

Equity

The University owns stock in a private company, which is 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

Guidance is in *italics*, proposed language is in **bold**.

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

Guidance is in *italics*, proposed language is in **bold**.

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. In addition, 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.”

Contact:

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A handwritten signature in black ink that reads "Wendy D Streit". The signature is written in a cursive style with a large, looped 'W' and 'S'.

Wendy Streit
Executive Director
Research Policy Analysis & Coordination