




MEMORANDUM

OFFICE OF THE CHANCELLOR
140501

20 April, 1999

TO: Investigators and Research Staff

From: Wyatt R. Hume 
Executive Vice Chancellor
Chairperson, Human Research Policy Board (HRPB)

RE: Disclosure of Possible Conflict of Interest to Human Research Subjects

I would like to clarify our institutional obligations regarding disclosure of an investigator's possible conflict of interest in informed consent forms when (A) the researcher is responsible for the healthcare of the subject and/or (B) has a financial interest in the sponsor of the study. The disclosure requirement also extends to a financial interest in the manufacturer of the product being tested in government sponsored research. A brief statement that explains the background of these obligations is on the second page of this memo.

A. HEALTH CARE PROVIDER/INVESTIGATOR DISCLOSURE

Please use the following sub-head and statement on the first page of informed consent forms when the investigator is also the health care provider for the subject:

Disclosure Statement

Your health care provider may be an investigator of this research protocol, and as an investigator, is interested both in your clinical welfare and in the conduct of this study. Before entering this study or at any time during the research, you may ask for a second opinion about your care from another doctor who is in no way associated with this project. You are not under any obligation to participate in any research project offered by your doctor.

B. INVESTIGATOR DISCLOSURE OF FINANCIAL INTEREST

The Human Research Policy Board (HRPB) and the UCLA Institutional Review Boards (IRBs) understand that an investigator's financial relationship with a sponsor may be as simple as a one time honorarium for a presentation or as complex a relationship as officer, director, paid consultant, stockholder, or a close relative of a stockholder.

Due to the possible complex and varying interests investigators may have in sponsors, it is difficult to create a boilerplate informed consent form statement that will universally and adequately inform subjects of the relationship. As a result, the HRPB and the IRBs request that investigators create their own disclosure statements for the informed consent form. The IRB support staff in the Office for Protection of Research Subjects would be happy to help you construct disclosure statements prior to submission of the project for IRB review.

BACKGROUND

It is generally recognized that a researcher has an ethical responsibility to disclose a possible conflict of interest to potential research subjects as part of the informed consent process. Our IRBs are required, per federal regulations and State law, to address an investigator's possible conflict of interest and the manner of disclosure to the potential subject. The above requirements are the result of a 1990, California Supreme Court decision, *Moore v. The Regents of the University of California*, which addressed the concept of full disclosure. The Court stated that, "[A] physician who treats a patient in whom he also has a research interest has potentially conflicting loyalties. This is because medical treatment decisions are made on the basis of proportionality - weighing the benefits to the patient against the risks to the patient.... The possibility that an interest extraneous to the patient's health has affected the physician's judgment is something that a reasonable patient would want to know in deciding whether to consent to a proposed course of treatment." The California Association of Hospitals and Health Systems indicated the Supreme Court ruling meant that, "prior to consenting to treatment, patients have the right to be informed of any potentially conflicting interests (viz., medical research or economic interests) that a physician may have related to such treatment."

Please contact Steven Peckman, Associate Director-Human Subjects Research, at x55344 or <speckman@oprs.ucla.edu> if you have any comments, concerns, or questions regarding the informed consent form disclosure requirements outlined above.