

August 21, 2014

To: IRB Directors

Subject: Use of Specimens (Moore Clause) Disclosure in the Informed Consent Form

Note

This guidance was originally issued by RPAC on May 29, 2009, but was inadvertently omitted in a subsequent revision of the RPAC website. It is being re-issued here to correct that oversight and does not represent new or changed guidance.

Background

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.

Guidance

The first requirement is addressed in part by disclosing financial interests in the consent form, discussed in [Research Administration Office Memo 95-05](#).

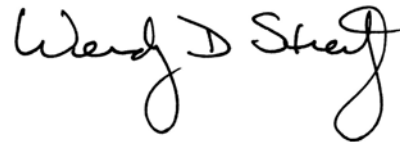
The second item, that a subject does not have a property right to profits stemming from products developed from bodily specimens, is a point of information that should be disclosed to the subject in the consent form so that he or she can make an informed decision about participating in the research.

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 [or, if the specimens belong to the sponsor or another organization, “the property of the [name of organization]”. The specimens may be used in this research, other research, or 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.”

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, looping 'W' and 'S'.

Wendy D. Streit
Executive Director
Research Policy Analysis & Coordination