UNIVERSITY OF CALIFORNIA

Research Policy Analysis & Coordination

Guidance Memo
17-04

August 1, 2017

To: IRB Directors

Subject: Standard language in Research Informed Consent Forms for Research in which biospecimens and/or information derived from biospecimens are obtained from research participants: commercial rights and research interests

Note: This guidance revises and supersedes previously issued RPAC Memo 14-07: Use of Specimens (Moore Clause) Disclosure in the Research Consent Form.

Purpose

This Guidance provides standard language for Research Informed Consent Forms pertaining to research where biospecimens and/or information derived from those specimens are obtained from research participants.

Background

Ownership of a research participant's biospecimens and/or information derived therefrom has been a historically sensitive issue that has been partially addressed by California case law and federal regulation. However, neither source explicitly requires standard consent form language to address this concern. Language in this guidance regarding informing research subjects about rights to profits stemming from the development of products based on those biospecimens is informed by a California State Supreme Court decision, *Moore v. Regents of the University of California*, 51 Cal. 3d 120; 271 Cal.Rptr. 146; 793 P.2d 479 (1990), and Federal Policy for the Protection of Human Subjects (45 CFR 46).

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, whether research or economic, 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.

In addition to the Moore decision, the Federal Policy for the Protection of Human Subjects (45 CFR 46) ("Common Rule") revised in 2017 and effective January 19, 2018, requires, that the informed consent form include, when appropriate, a statement that the research subject's biospecimens (even if identifiers are removed) may be used for commercial profit, and indicate whether the subject will or will not share in this commercial profit.[1]

Guidance

A research participant undergoing a medical procedure (such as one that involves collection of biospecimens) must be advised of any personal interests of the physician/researcher that are unrelated to the individual's health, whether research or economic, that may affect the physician/researcher's professional judgment. This may be accomplished by obtaining informed consent from research participants for their participation in the research, in accordance with applicable human subjects protection regulations, and by disclosing relevant financial interests in the research consent form, as discussed in RPAC Memo 11-04.

In addition, for research that involves collection of biospecimens (and/or information derived from such biospecimens), in the consent form provided to the research participant, a Principal Investigator must disclose that the research participant's biospecimens (even if identifiers are removed) and/or information derived from such biospecimens may be used for commercial profit and that the research participant will not share in any such commercial profit. This information must be shared in order for the research participant to make an informed decision about participating in the research.

Accordingly, the paragraph below should be included in the informed consent form for research if biospecimens and/or information derived therefrom will be collected from a research subject and used for research and/or development purposes:

> "Biospecimens (such as blood, tissue, or saliva) collected from you for this study and/or information obtained from your biospecimens may be used in this research or other research, and shared with other organizations. You will not share in any commercial value or profit derived from the use of your biospecimens and/or information obtained from them."

Please note: the above language does not substitute for a new exempt determination, waiver, or informed consent for that future research.

[1] New additional elements of informed consent included in the revised Common Rule are: (1) A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit (§ ll.116(c)(7); (2) A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions (§ ll.116(c)(8); and (3) For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (§ ll.116(c)(9).

Contact

Agnes Balla
Agnes.Balla@ucop.edu
(510) 987-9987

Wendy D. Streitz
Executive Director
Research Policy Analysis & Coordination

Attachments: July 2008 Office of Research Memo
February 2009 Academic Affairs Memo
August 2014 Research Policy Analysis and Coordination Memo 14-07