

Policy Number: 31

Title: Payment for Participation in Research

Date of Last Revision: July 5, 2007

I. Overview

The *Belmont Report - Ethical Principles and Guidelines for the Protection of Human Subjects of Research* and the federal regulations for the protection of human research subjects require the voluntary participation of individuals in research. The federal regulations require the UCLA IRB/OPRS to scrutinize research to ensure that “An investigator shall seek consent only under circumstances that provide the prospective subject or their representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence.”¹

Payment to research subjects is not considered a benefit of participation, but is instead compensation for time and inconvenience, or a recruitment incentive.

Investigators must identify the amount and schedule of all payments to the UCLA IRB/OPRS at the time of initial review. Payments may also include reimbursement for costs of participation (parking fees, travel, lost time from work, baby-sitters, etc.).

The UCLA IRB/OPRS will review proposed research to ensure that both the amount of payment and the proposed method and timing of disbursement neither are coercive nor present undue influence.

II. Investigator Responsibility

- A. UCLA investigators must include the following information in their application for UCLA IRB review and approval or Certification of Exemption from UCLA IRB review:
1. A description of all plans to pay subjects, whether in cash or in kind
 2. The amounts of any financial inducement or payment for participation subjects will receive
 3. Services or other non-cash benefits subjects will receive
 4. Reimbursement for travel and other expenses subjects will receive
 5. The timing of disbursement and the conditions, if any, which must be fulfilled by subjects in order to receive either full or partial payment

¹ OPRR guidebook, Chapter III.

- B. UCLA investigators are encouraged to implement a prorated system of payment whereby subjects who do not finish the protocol are paid in proportion to the part completed.
1. Prorated payment may not be appropriate for all research activities. As 45 CFR 46.116(a) and 21 CFR 50.25(a) requires that subjects' voluntary refusal to participate or discontinue participation involve no penalty, the UCLA IRB/OPRS will require full payment for subjects' partial completion of surveys or questionnaires or for "inadequate" participation in group discussions.
- C. UCLA investigators are encouraged to provide reimbursement for parking and transportation costs for research-related visits.
- D. Consent forms should include a section entitled *Payment for Participation* which explains the information in A-C above. If no payment and/or reimbursement will be provided, the consent forms should clearly state such.
- E. UCLA investigators should not provide subjects with private industry sponsor's advertising materials (i.e., items containing the sponsor's name, logo, commercially identifiable marking or drug name) as a method of payment.
- F. UCLA investigators may not provide or allow payment in the form of a coupon good for a discount on the purchase price of the test article once it has been approved for marketing.
- G. When appropriate, UCLA investigators should follow the "wage payment model"² which requires structuring payment, "on a scale commensurate with that of other unskilled but essential jobs," since participation in research "requires little skill but does require time, effort, and the endurance of undesirable or uncomfortable procedures."
- H. For research involving minors, UCLA investigators should specify whether the payment is provided directly to the subjects or to their parent or legal guardian.
- I. Recruitment materials must not emphasize payment or characterize it as a benefit.

III. UCLA IRB/OPRS Responsibility

- A. During its review, the UCLA IRB/OPRS will ensure that:
1. compensation offered for participation in research, monetary or otherwise, does not constitute undue influence;

² The "wage payment model" is endorsed by the authors, Neal Dickert & Christine Grady, in their article, "What's the Price of a Research Subject? Approaches to Payment for Research Participation" published in the New England Journal of Medicine (NEJM, 1999; 341:198-203).

2. compensation offered is reasonable, given the complexity and the inconvenience of the study and the subject population;
 3. payments are made on a schedule appropriate to the length or intensity of the study;
 4. credit for payment accrues as the study progresses and is not contingent upon completion of the entire study;
 5. any amount paid as a bonus for completion is reasonable and not so large as to unduly induce participants to stay in the study when they would otherwise have withdrawn.
- B. The UCLA IRB/OPRS may request justification for payment amounts from the investigator in order to assess the appropriateness of the proposed payment plan.
- C. The UCLA IRB/OPRS will review all informed consent and recruitment documents to ensure that payment to subjects is described in accordance with the protocol.

IV. Collection of Social Security Numbers [SSN's] for Payment Purposes

- A. Large amounts of sensitive personal information, including tax information, credit information, school records, and medical records, are keyed to Social Security Numbers ("SSNs"). Because these data are sensitive, SSNs should generally be collected for research purposes **only when necessary to comply with IRS reporting requirements**. For further information about such requirements, please contact UCLA Corporate Accounting.
- B. If payment will involve collection of SSNs, this should be explained in the application for IRB review and the following safeguards should be implemented:
1. Records containing SSNs should be stored securely and separately from research records, should not be copied unnecessarily and should be destroyed as soon as is feasible.
 2. Subjects should be informed of this limitation to the confidentiality of their information. The consent form should indicate that subjects will be asked for their SSNs, why SSNs will be collected, and how this information will be protected.
 3. When completing check requests or other paperwork using SSNs, staff should take care not to include extraneous but potentially damaging information such as the study title, the nature of the research or the names of procedures undergone.
- C. It is not clear that a Certificate of Confidentiality will protect from discovery of study information through an IRS audit of accounting records. For research into sensitive matters requiring a Certificate of Confidentiality, the study team is strongly encouraged to contact UCLA Corporate Accounting regarding methods of payment and recordkeeping that may serve the University's interests while also protecting subjects.

References:

U.S. Office for Human Research Protections' (OHRP, formerly OPRR) *Protecting Human Research Subjects Guidebook* (1993), Chapter 3. http://hhs.gov/ohrp/irb/irb_chapter3.htm#e7

The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *The Belmont Report - Ethical Principles and Guidelines for the Protection of Human Subjects of Research*, April 18, 1979. <http://hhs.gov/ohrp/humansubjects/guidance/belmont.htm>

Dickert, Neal & Grady, Christine. *What's the Price of a Research Subject? Approaches to Payment for Research Participation*. NEJM, July 15, 1999; 341 (3): <http://content.nejm.org/cgi/content/full/341/3/198>

FDA, *IRB Information Sheets: Payment to Subjects*, September 1998. <http://www.fda.gov/oc/ohrt/irbs/toc4.html#payment>