Chapter 12
Subject Compensation and Recruitment

Subject compensation and recruitment issues are significant concerns of the IRB. Compensation must not be excessive or coercive. Recruitment materials must reflect the true nature of the research and not mislead potential participants. This chapter explores these issues and discusses criteria for recruitment and subject compensation including industry sponsored studies.

12.1 Compensation

Compensation for participation in research remains a contentious issue with no regulatory guidelines. However, many papers have been written about subject compensation and guidelines have been suggested. Compensation takes many forms such as school supplies, gift certificates, parking reimbursements, meal coupons, nominal gifts, lotteries or cash.

The plan for compensating subjects must be submitted to the IRB in the study application. In addition, the form of compensation must be described in the informed consent document (such as cash, gift card, or chance to win a gift) as well as a description of the conditions under which a subject would receive partial or no payment.

For participation in an FDA regulated, sponsored trial, compensation may not be offered in the form of a discount coupon on the purchase price of the product after it has been approved for marketing.

Guidelines for Compensating Research Participants:

- Payment for participation in research should not be offered as a means of coercion. Rather, it should be a form of recognition for the investment of the subject's time, loss of wages, or other inconvenience incurred. Compensation may not be withheld contingent on the subject's completion of the study.
- In cases involving ongoing participation, compensation should be given on a reasonable, prompt, and prorated basis to avoid possible coercion. The payment should be made throughout the course of the study, contingent on participation as described in the protocol.

- The Principal Investigator and IRB should consider the risk, duration of participation, effort required, and local economy when determining appropriate compensation for a study population. Additional caution should be exercised when establishing compensation for greater than minimal risk studies. Economically disadvantaged subjects are especially vulnerable to undue influence from excessively high levels of compensation.
- It is acceptable to provide a chance to receive a gift as a form of compensation in lieu of providing cash or other remuneration. The "thank you" gift is commonly used by student investigators with limited funds. Examples of gifts include a chance to win a "thank you" item such as an MP3 player, cellular phone, or gift-card.

Compensation for U.S. Military Personnel for Department of Defense (DOD) Sponsored Research

When Department of Defense-sponsored research is conducted on US military personnel, the following limitations on dual compensation for US military personnel apply:

- Prohibits an individual from receiving pay from more than one position for more than 40 hours of work in one calendar week.
- Includes temporary, part-time and intermittent appointments.

Being a research subject is generally not a part-time job nor is it an intermittent appointment. There are some situations where active duty can be compensated. The Army allows this when military personnel are 'off-duty' or on 'official leave'. If the research is greater than minimal risk the Commanding Officer must give permission for the military personnel to enroll. DOD allows compensation for military personnel up to $50 per blood draws whether on or off duty.

12.2 Recruitment

Recruitment of subjects is considered to be the beginning of the informed consent process. Recruitment is one of the most challenging aspects of research involving human subjects. Recruitment is often conducted through newspapers, email, posters, brochures,

by internet, radio or television announcements, or by soliciting volunteers in public spaces, hospitals, clinics and laboratories.

The pressure to enroll subjects raises ethical challenges for investigators and research staff. Recruitment of subjects must be equitable and include racial, ethnic, educational, socioeconomic, and gender diversity appropriate to the condition being studied. All recruitment efforts must respect personal rights to privacy and confidentiality and be compliant with FDA, OHRP, and HIPAA regulations, as applicable.

For additional information, refer to FDA Information Sheet "Recruiting Study Subjects".

Recruitment Materials

When a project requires IRB review, all recruitment materials under local control including advertising and marketing materials must be reviewed as part of the study. Any recruitment materials generated by USC investigators or research personnel must be submitted to the IRB for review and approval before they can be used.

The following information should be included in recruitment materials:

- Accurate description of the research purpose
- Name and address of the investigator or facility (including university affiliation and/or department)
- Condition under study or purpose of the research
- Eligibility criteria
- Time commitments required
- Location of the research
- Person to contact for further information

The following information should NOT be used in recruitment materials:

- Coercive language
- Claims that a device or drug is safe and effective

- The words “new treatment,” “new medication,” or “new drug” if the test article is investigational
- Promises of “free medical treatment”
- Amount of payment, dollar signs, or the words “free” in large or bold face type
- Compensation should not be excessive relative to the nature of the project
- Statements or implications assuring favorable outcome or other benefits beyond what is outlined in the consent document and protocol
- Claims, either explicitly or implicitly, that the test article is known to be equivalent or superior to any other drug, biologic, or device
- Exculpatory language

Note: content allowed in recruitment materials may differ between the University Park and Health Sciences Campuses. If you have questions, contact your local IRB for more information.

National Recruitment Materials Not Reviewed by the IRB

Industry sponsors often produce recruitment materials that are used on a national basis and that cannot be modified by local sites. Examples include websites, radio or television advertisements, and call center scripts. Recruitment materials that cannot be modified by USC investigators will not be reviewed, approved, or acknowledged by the USC IRB. These materials should not be attached in the iStar application.

Recruitment Materials Used in Exempt Research

Recruitment plans, materials and advertisements should be submitted with the initial study submission to the IRB. However, when a study receives an exempt determination by the University Park IRB, if the researcher subsequently wants to use advertisement materials that were not included in the original IRB submission, or alters the recruitment plan, the investigator does not need to submit these changes for IRB review (note: only for exempt research reviewed by the UPIRB) unless the materials change the level of risk or IRB determination. Exempt study advertising and recruitment materials should follow the guidelines suggested.

12.3 Payment for Referrals (Finder's Fees) Are Not Permitted

USC policy does not allow any finder's fees. Investigators, or any other member of the research team, may not offer payment to subjects (prospective, previously enrolled, or currently enrolled) for referring their friends, family member, or other individuals. Finder's fees may not be offered to other investigators, clinicians, researchers, or any other individual or group for referring potential subjects.

Chapter 13:

Investigator's Role and Responsibilities

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