IRB TIP: PAYMENTS AND INCENTIVES FOR THOSE REFERRING RESEARCH PARTICIPANTS

GUIDANCE FOR IMPLEMENTING FEDERAL AND INSTITUTIONAL IRB POLICIES

The responsible conduct of clinical trials requires that the trials be conducted in a manner that does not create inappropriate risk for study subjects. One area of risk that must be assessed relates to the financial arrangements of the clinical trials themselves. Any financial arrangements that could influence, or reasonably be perceived as influencing, the way that study investigators recruit and otherwise interact with study subjects are not acceptable.

1. Payments to an LLUH-entity for a clinical trial should be directly based upon the cost of the study, including the total costs for the infrastructure, personnel, and equipment necessary to recruit, screen, and enroll subjects in the trial.

2. Any extra payment or increase in payment that is not attributable to an increase in actual costs to implement the study is considered to be a "bonus payment" and is not acceptable.

While payment structures for clinical trials vary, typically a sponsor pays the hospital or other entity on a per-subject basis in order to reimburse costs proportionally. The IRB may develop further guidelines and make decisions in individual cases that do not clearly fall into "acceptable" guidelines.

Generally Acceptable Payment Schedules

1. Payment schedules that provide for unvarying per-subject payments, or payments which are to be made at fixed times, with no contingencies, and that are based upon the actual cost of the study including recruitment, screening, and enrollment, will be presumed acceptable.

2. Payment schedules which provide for increasing per patient payments over the course of a trial may be acceptable. For example:

- The increased payments are based on increased costs associated with the additional patients, which costs do not accrue unless and until those additional patients are enrolled (for example costs of additional staff that will not be needed unless a certain number of patients are enrolled);

Unacceptable Payment Schedules

Payment structures which create an incentive to hasten or complete enrollment of subjects are unacceptable. For example:

- A per-subject payment schedule that increases after the enrollment of a specified number of subjects (e.g. $100 per subject for the first 10 subjects and $150 per subject for the next 10 subjects, etc.), unless such increase is based on a clear increase in costs.

- Additional "bonus" payments upon the completion of a specified number of patients.

- Payments that are made only if a specified number of subjects are recruited, i.e. no payments for 48 subjects, but full payment for 50, or payments made only if 50 subjects are enrolled by a certain date. These payment schemes could influence, or reasonably be perceived as influencing, the way the last few subjects may be recruited.

Incentives and Rewards for Recruitment of Patients and Referral to Clinical Investigators

Timely enrollment of patients into approved trials is desirable, but care must be taken to ensure that the interests of patients are not jeopardized during the recruitment process.

- Finder's Fees: Cash payments or other financial or non-monetary incentives to physicians for referral of patients, otherwise known as "finder's fees," pose a conflict of interest and are not permissible.

- Financial Incentives: Financial incentives to physician-investigators to accelerate enrollment of their own patients in their own clinical trials pose a similar conflict of interest and are not acceptable.

- Payments with Disclosure: Full disclosure of any financial arrangements that may encourage physicians to recruit patients for research participation that may not be in the patient's best interest is required. In some special circumstances, physicians who are not formally listed on the protocol may be performing specific research-related activities (such as conducting screening examinations or tests, or participating in the consent process), but solely in the role of service providers. These physicians may be reasonably compensated for their time and effort. Such arrangements should be clearly detailed and justified in the research protocol.

Additional Requirements for Department of Defense (DoD) Research

When research involves U.S. military personnel, additional requirements must be considered. See guidance on "Additional Requirements for Department of Defense Research."

NOTE

For guidance on Medicare Coverage for compensation of physicians in clinical research, see related Policy and Procedures.