

March 8, 2005

## Policy on Payments In Clinical Trial Agreements

*[to be included with Partners Human Research Committee Policies and Procedures]*

### Introduction

Conducting clinical trials is an important part of the charitable mission of Partners and its affiliated hospitals. Clinical trials are the proven and effective mechanism for validating new drugs, devices, and other patient-care diagnostics and therapies, and thereby facilitating advancement and improvement in medical care.

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. It is for this reason that Partners and Harvard Medical School, as well as other institutions across the country, have rigorous policies regulating the direct financial interests of investigators pertaining to clinical studies. However, the financial arrangements between the study sponsor and the institution itself can likewise give rise to conflicts that could affect, or reasonably be perceived as affecting, the safety of subjects. The purpose of this Policy is to address clinical trial payment structures between the study sponsor and the Partners-affiliated institution conducting the trial that may create inappropriate conflicts of interest. Of particular concern are payment structures that may provide an inappropriate incentive for the recruitment of patients.

### Policy

Accordingly, the following Policy on Payments In Clinical Trial Agreements has been adopted by Partners Human Research Administration for clinical trials conducted at Partners-affiliated entities.

1. Payments to a Partners-affiliated 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.

## Examples of Acceptable and Unacceptable Payment Structures

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. Examples of acceptable and unacceptable structures include the following. The IRB may develop further guidelines and make decisions in individual cases that do not clearly fall into “acceptable” guidelines.

### Generally acceptable payment schedules.

- 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 under this policy, absent unusual circumstances (e.g. unusually high per patient payments).
- Payment schedules which provide for increasing per patient payments over the course of a trial may be acceptable if both of the following conditions are met:
  - 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);
  - Corporate Sponsored Research and Licensing, in consultation with the IRB, reviews and approves the payment schedule.
- In the foregoing examples, reasonable mark-ups from actual costs will generally be acceptable when tied to fair market value of the work performed.
- Increased payments which are not provided for, or anticipated in, the initial budget may be acceptable during the course of a study if the increased payment is based on past expenses having been higher than anticipated, or on unanticipated increases in future costs.

Unacceptable payment schedules. Payment structures which create an incentive to hasten or complete enrollment of subjects are unacceptable. Examples of payment schemes which will be presumed unacceptable include the following:

- 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 (see above).
- 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

## Incentive Payments to Individuals Involved in Clinical Studies

The purpose of this Policy is to address payment structures to the *institution*, and is not to address payments structures that may be offered to *investigators and other individuals* involved in clinical studies. Such payments are already addressed by other institutional policies including the policies on conflicts of interest and the Human Research Administration Policy on Recruitment of Research Subjects (<http://healthcare.partners.org/phsirb/recruit.htm>). This existing Policy prohibits, among other things, incentive payments to physicians for referrals of patients to studies, and prohibits any incentive payments to investigators to accelerate enrollment of study subjects.