

Negotiating Clinical Trial Agreements: The Hospital's Perspective

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Presentation Overview

- Sponsorship Agreement Overview
 - Parties and Relationship of Parties
 - Compensation Structure
 - Insurance and Indemnity
 - Compensation to Subjects if Injured
 - Budget
 - Arrangements with Co/Sub Investigators
 - Best Practices and Observations



- Best Practice: Three party agreements between Sponsor, PI, Hospital (assuming PI is not Hospital employee)
 - Language should recognize independent contractor relationship
 - Allows all payments to be made to Hospital and passed through to PI

- Independent Contractor Status of PI
 - Important in states with corporate practice of medicine prohibitions (such as CA)
 - Most sponsorship agreements assume employment relationship
 - Affects indemnity and insurance provisions

Parties and Relation of Parties

- Model language:

“Sponsor acknowledges and agrees that Investigator is an independent contractor, and not an employee, of Hospital. Hospital shall not exert any control over or bear any responsibility or liability for the professional judgment, acts, or omissions of Investigator.”

Compensation Structure

- Three possible structures:

- Sponsor makes separate payments to Hospital and PI
- Sponsor makes all payments to Hospital and Hospital passes PI payments through
- Sponsor makes all payments to PI and PI passes payments through (or buys services from Hospital)

Compensation Structure

- Sponsor makes separate payments to Hospital and PI
 - Possibly the cleanest from a compliance perspective
 - Sponsors do not usually want to separate out payments

Compensation Structure

- Sponsor makes all payments to Hospital and Hospital passes PI payments through
 - Most common structure
 - Creates a financial relationship between the Hospital and PI that needs to comply with Stark and the Anti-Kickback Statute

- **Stark Compliance: Personal Services Exception** requires (among other things):
 - Agreement set forth in writing, signed by the parties, and specifies services covered
 - Compensation set in advance and does not exceed fair market value
 - How to determine fair market value . . . ?
 - Burden is on Hospital

- **Sponsor makes all payments to PI and PI passes payments through to Hospital (or buys services from Hospital)**
 - May work where Hospital provides very limited services (i.e., trial is physician office-based)
 - **Stark compliance**
 - Payments by physician exception
 - Ensure payment amount is consistent with fair market value

- Three party agreements require separate insurance provisions
- Many professional liability carriers exclude coverage for clinical research
 - Must obtain a special rider
 - Usually no cost
 - Request must be submitted in writing by physician

- Professional liability carrier policy language may:
 - Exclude coverage for use of “non-approved” drugs and devices
 - Limit coverage to use of “approved” drugs and devices
 - Expressly exclude coverage for experimental treatments/procedures

- Sample PI insurance language:
 - Short Version:

“Investigator shall be solely responsible for obtaining and maintaining professional liability insurance covering Investigator’s performance under this Agreement. Hospital shall not provide or obtain any professional liability insurance coverage for Investigator.”

- (Very) Long Version:

“PI’s Insurance. PI, at PI’s sole expense, shall maintain Continuous Coverage (as defined below) of policies of professional liability and general liability insurance. The insurance policies shall: (i) in the case of the professional liability insurance policy, provide coverage for negligent acts or omissions of PI and each Investigator in the performance of professional services, including, without limitation, services required as the part of any clinical trial; (ii) in the case of the general liability insurance policy, provide coverage for bodily injury and property damages resulting from negligent acts or omissions of PI or any Investigator (other than those matters covered by the professional liability insurance policy); (iii) name PI and each Investigator as named insureds and Hospital as an additional insured party (if permitted by the insurance carrier); (iv) be issued by an insurance company or trust licensed or otherwise qualified to issue professional liability and general liability insurance policies or coverage in the State; and (v) provide for minimum coverage limits consistent with the requirements of the Medical Staff Bylaws, but in no event less than One Million Dollars (\$1,000,000) per claim and Three Million Dollars (\$3,000,000) annual aggregate.

Continuous Coverage. For purposes of this Agreement, the term “Continuous Coverage” means the maintenance of required insurance from the Effective Date, continuing during the entire term of this Agreement and expiring not less than three (3) years following the expiration or earlier termination of this Agreement (the “Insurance Period”). If for any reason any insurance policy maintained by PI pursuant to this Section is terminated, reduced below the minimum coverage requirements set forth in this Section, not renewed or cancelled prior to the expiration of the Insurance Period, PI shall: (i) cause a replacement insurance policy meeting the requirements of this Section to be in effect as of the effective date of the termination, reduction, non-renewal or cancellation of the prior insurance policy; and (ii) purchase either extended reporting coverage (i.e., “tail” coverage) or prior acts coverage (i.e., “nose” coverage) as necessary to meet the requirements of this Section. “Tail” coverage must provide for either an unlimited discovery/reporting period or a discovery/reporting period that would extend through the end of the Insurance Period, and “nose” coverage must provide for a retroactive discovery/reporting period at least as of the start of the Insurance Period.

Certificate of Insurance. “PI shall provide Hospital with certificates of insurance or other written evidence of the insurance policies required by this Section, in a form satisfactory to Hospital, prior to the Effective Date, on each annual renewal of such insurance policies during the Insurance Period, and as requested by Hospital.”

- Indemnity
 - Preference for unilateral indemnity by Sponsor
 - Fall back is separate indemnity provisions (Three for three party agreements)

- Sample Sponsor Indemnity Language:

“Sponsor shall indemnify, defend and hold harmless Institution and Institution’s officers, directors, trustees, employees and Principal Investigator (for purposes of this paragraph “Institution Indemnitees”) from and against any and all liabilities, damages, losses, claims or expenses (“Claim”) incurred by or imposed upon the Institution Indemnitees, or any one of them, relating to or arising out of Sponsor’s breach of this Agreement, drafting the Protocol, designing the Device, manufacturing the Device, or Sponsor’s failure to comply with applicable laws or regulations. Such Indemnity shall not apply to any Claim to the extent that such Claim arises out of: (a) the negligence or reckless or willful misconduct of one or more of the Institution Indemnitees, (b) any failure of one or more of the Institution Indemnitees to adhere to the terms of the Protocol or to follow GCP, or (c) a breach of any Applicable Laws by one or more of the Institution Indemnitees.”

Insurance and Indemnity

- More Sponsor Indemnity Language (unilateral):

“Sponsor shall defend, indemnify, and hold harmless Principal Investigator and his employees (“Principal Investigator Indemnitees”) and Institution and its trustees, officers, agents, and employees (“Institution Indemnitees”) from and against any claims, suits of judgment, losses, or liabilities (each an “Indemnification Event”), including reasonable attorneys’ fees, made or instituted to the extent that such Indemnification Events are caused by or arise from the performance of clinical studies or research programs under this Agreement, except to the extent that any such Indemnification Event is the result of the gross negligence or willful malfeasance of a Principal Investigator Indemnitee (in which case Sponsor’s indemnification obligation shall be invalidated with regard to such Principal Investigator Indemnitee) or an Institution Indemnity (in which case Sponsor’s indemnification obligation shall be invalidated with regard to such Institution Indemnitee).”

Insurance and Indemnity

- Sample PI indemnity language:

“By Principal Investigator. Principal Investigator shall indemnify, defend and hold harmless Sponsor and Sponsor’s officers, directors, trustees and employees (“Sponsor Indemnitees”) and Institution and Institution’s officers, directors, trustees, and employees (for purposes of this paragraph “Institution Indemnitees”) from and against any and all Claims incurred by or imposed upon the Sponsor Indemnitees or Institution Indemnitees, or any one of them, that result from (a) the negligence or reckless or willful misconduct of Principal Investigator, or any of Principal Investigator’s employees, (b) any failure of Principal Investigator or his employees to adhere to the terms of the Protocol or to follow GCP, or (c) a breach of any Applicable Laws by Principal Investigator or any of his employees. Such Indemnity shall not apply to any Claim to the extent that such Claim arises out of the negligence of Sponsor or Institution for which indemnification would be available to Principal Investigator under the terms of this Agreement.”

- Best practice to include specific language or leave silent?
- Consistency between agreements and consent forms

- Sample language:

“Sponsor agrees that if a subject enrolled in the study suffers an injury as a result of: (a) [receiving the study Drug] [use of the Study Device] [undergoing the Study Procedure] or (b) any procedure required by [and conducted in accordance with the Protocol], [and provided that such injury is not caused by the gross negligence of Hospital or Investigator], then [without any admission of wrongdoing on the part of Sponsor], Sponsor shall pay any and all reasonable medical expenses incurred for treatment of such injury, at Hospital’s usual and customary charges.”

Compensation to Subjects if Injured

- Some sponsors may insist upon language that limits their financial responsibility to instances in which the services will not be covered by a third party payor
- Potential problem under Medicare Secondary Payor rules

Budget

- Always include the detailed budget as an exhibit incorporated into the sponsorship agreement
- Specify payments by Sponsor but also payments from Hospital to PI and other Investigators
- Differentiate between standard of care and experimental study procedures/drugs/devices

Budget

- Specify IRB Fees – Whether internal or commercial IRB

“Sponsor shall pay all Study IRB fees to the Hospital IRB at then current rates set forth in the IRB Fee Schedule. The IRB Fee Schedule in effect as of the date of this Agreement is attached as Exhibit X hereto.”

Arrangements with Co/Sub Investigators

- Co/Sub Investigators Likely Not a Party to the Sponsorship Agreement
 - May be added after Sponsorship Agreement signed
 - Ensure compliance with terms of Sponsorship Agreement
 - Selection and approval of co/sub investigators
 - Supervision
 - Payment
 - Agreements must be Stark compliant

Arrangements with Co/Sub Investigators

- Money paid by Hospital to Co/Subs likely creates a “compensation arrangement” for Stark purposes
- Personal Services Exception requires written agreement
- Use of letter agreement or MOU may satisfy Stark requirements

CROs and Middle Men

- Beware of:
 - Physician-owned CROs/Middle Men
 - Budgets that are not transparent
 - Lack of contractual privity
 - Percentage compensation and arrangements that generate business (trials) that may be paid in whole or part by a government payor
 - Undue payments to physicians
 - Unethical recruitment techniques

- Contract language should be precise
 - Never use “patient”
- Ensure consistency between agreements and consents
- Watch for absolute waivers (e.g., indemnification being waived by *any* breach of contract or protocol)
- Revenue Procedure 97-13 compliance for tax-exempt entities

Questions?